Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Annex to the Background document

to the Opinion on the Annex XV dossier proposing restrictions on medium chain chlorinated paraffins ('MCCP') and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17

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Appendix A: Manufacture and uses

A.1. Manufacture, import and export

A.1.1. Manufacturing of chloroalkanes and trends in manufacturing

A.1.1.1. Trends in the manufacture of chloroalkanes

The manufacture of chloroalkanes started in 1930's initially in the United States.

According to Gluge et al. (2016), the manufacture of chloroalkanes can be divided into three time periods: (i) 1935–1974: the manufacture volumes were below 35 000 tonnes/year; (ii) 1975–2005: the sum of worldwide chloroalkanes manufacture increased from 60 000 to 350 000 tonnes/year; (iii) 2006–2012: the sum of worldwide chloroalkanes manufacture increased much more rapidly than before and went up to 1 100 000 tonnes/year. It should be noted that these numbers may still be an underestimate, as not all countries have reported they manufacture and reported data may be incomplete, even after data interpolation (Gluge et al., 2016).

In recent years, manufacture of chloroalkanes has decreased in Europe and North America, but has increased significantly in Asia (e.g. India, China, Taiwan and Japan) (EFSA, 2020). According to van Mourik et al. (2016), India manufactured 226 400 tonnes of chloroalkanes in 2010, although according to WCC[1] (World Chlorine Council), the manufactured chloroalkanes were mainly short chain ones.

Information on global manufacture of chloroalkanes on a carbon chain length level (short, medium, long) is limited and difficult to determine, because for example in China the distinction between chloroalkanes is made based on chlorination degrees rather than on carbon chain lengths (van Mourik et al., 2016). The main chloroalkanes manufactured are CP-42, CP-52 and CP-70, of which CP-52 accounts nearly 90 % of the chloroalkanes manufactured in China in 2012 according to WCC[2].

According to the REACH MCCP registrants' consortium[3], in 2021, China remained the largest global manufacturer of chloroalkanes. It is also the main consumers of the manufactured chloroalkanes. In 2020, ~ 900 000 tonnes of chloroalkanes were produced in China, and it is estimated that most of its production is used for the local down-stream industry and therefore consumed locally in China.

The second, third and fourth largest producers are India, Europe and the United States with respectively 500 000 – 700 000 tonnes, 50 000 - 100 000 tonnes and 20 000 –

[1] World Chlorine Council. International Chlorinated Alkanes Industry Association (ICAIA) newsletter No. 1. April 2012

[2] World Chlorine Council. International Chlorinated Alkanes Industry Association (ICAIA) newsletter No. 2.

[3] Webex meeting between ECHA and the Consortium in January 2022

25 000 tonnes manufactured in 2020. Russia is also manufacturing chloroalkanes but there is no data available on their manufacturing capacity.

The chloroalkanes produced in different areas of the world have different carbon chain length that reflects the different sources of alkane/alkene used as feedstock (cf. section B.1.1).

A.1.1.2. Trends in the uses of EC 287-477-0 in Europe

Table 1: Shares of EC 287-477-0 uses in the past 20 years in the EU

Reference year	**2003[1]**	**2006[2]**	**2013[3]**	**2019[4]**
Use#00 - PVC	60 %	54 %	64 %	26 %
Use#01 - adhesives and sealants	15 %	18 %	28 %	61 %
Use#02 - rubber	7 %	11 %	Counted in Use#01	6 %
Use#03 – metalworking fluids	15 %	16 %	8 %	3 %
Use#04 - paints and coatings	Counted in Use#01	Counted in Use#01	6 %	< 1 %
Use#05 - leather	4 %	1 %	-	-
Use#06 – paper	< 1 %	-	-	-
Use#07 – other uses	-	-	-	2 %

Source: [1] ENTEC (2004) referred to in (KEMI, 2018) assumed EU-15
[2] (Danish EPA, 2014) referred to in (KEMI, 2018) assumed EU-25
[3] INEOS Vinyl comments in Öko-institut, 2014 referred to in (ECHA, 2021b)
[4] (ECHA, 2021b)

A.1.2. Value of sold production, exports and imports by PRODCOM list (NACE Rev. 2)

Table 2 provides an overview of the sold production, exports and imports in quantity for some selected types of mixtures and articles that are within the scope of the Dossier Submitter's investigations.

In the following table:

- Export value: this field gives the value of exports in unit, derived from the External Trade statistics.
- Import value: this field gives the value of imports in unit, derived from the External Trade statistics.
- Production value: this field gives the value of production in unit, derived from the External Trade statistics.
- The data is for the period January-December 2019.

- The data is presented for European countries[4] only, as data for Iceland, Lichtenstein, and Norway are usually not available in Eurostat for the selected codes.

Table 2: Production, exports and imports of mixtures/articles (Jan-Dec 2019)

PRCCODE	Unit	Export quantity	Import quantity	Production quantity	Estimated consumption
17127600 - Carbon paper, self-copy paper and other copying or transfer paper, in rolls or sheets	[t/y]	63 210	17 751	155 025	109 566
20301230 - Paints and varnishes, based on acrylic or vinyl polymers	[t/y]	37 245	13 937	138 140	114 832
20521080 - Prepared glues and other prepared adhesives, n.e.c.	[t/y]	456 606	177 885	4 307 279	4 028 558
20594158 - Lubricating preparations obtained from petroleum or bituminous minerals	[t/y]	276 186	46 841	517 704	288 359
20601140 - Acrylic tow and staple, not carded, combed or otherwise processed for spinning	[t/y]	35 013	25 001	180 000	169 988
22194050 - Rubber conveyor belts	[t/y]	71 846	62 749	166 576	157 479
23121330 - Multiple-walled insulating units of glass	m²	3 893 813	1 852 664	104 460 511	102 419 362
23991930 - Mixtures and articles of heat/sound-insulating materials n.e.c.	[t/y]	126 716	35 761	1 308 107	1 217 152
24201310 - Tubes and pipes, of circular cross-section, seamless, of stainless steel	[t/y]	65 409	52 139	210 395	197 126
24201330 - Precision tubes and pipes, of circular cross-section, cold-drawn or cold-rolled,	[t/y]	120 594	17 195	538 201	434 802

[4] European countries: 27 countries part of the European Union in 2022 (i.e. AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK)

PRCCODE	Unit	Export quantity	Import quantity	Production quantity	Estimated consumption
seamless, of steel other than stainless steel					
24201350 - Tubes and pipes, of circular cross-section, cold-drawn or cold-rolled, seamless, of steel other than stainless steel	[t/y]	23 468	27 029	120 000	123 560
25121050 - Aluminium doors, thresholds for doors, windows and their frames	p/st[1]	3 160 263	4 774 514	41 373 889	42 988 140
29102230 - Motor vehicles with only petrol engine > 1 500 cm³ (including motor caravans of a capacity > 3 000 cm³)	p/st	2 315 693	592 788	3 755 899	2 032 994
30112130 - Cruise vessels	CGT[2]	not available	not available	2 400 000	not available
30112150 - Ferries	CGT	not available	not available	100 864	not available
30121100 - Sailboats (except inflatable) for pleasure or sports, with or without auxiliary motor	p/st	5 053	4 851	17 656	17 454
30301100 - Aircraft spark-ignition internal combustion piston engines, for civil use	p/st	11 288	2 388	8 000	-900
20163025 - Plasticised polyvinyl chloride mixed with any other substance, in primary forms	[t/y]	147 760	47 445	749 221	648 907
27311100 - Optical fibre cables made up of individually sheathed fibres whether or not assembled with electric conductors or fitted with connectors	[t/y]	65 089	64 269	101 319	100 499
27311200 - Optical fibres and optical fibre bundles; optical fibre cables (except those made up of individually sheathed fibres)	[t/y]	1 335	7 016	67 057	72 738
22212920 - Flexible tubes, pipes and hoses of plastics, with a burst pressure >= 27,6 MPa	[t/y]	14 315	12 435	7 083 691	7 081 810

PRCCODE	Unit	Export quantity	Import quantity	Production quantity	Estimated consumption
22212935 - Flexible tubes, pipes and hoses of plastics, not reinforced or otherwise combined with other materials, without fittings	[t/y]	96 072	35 680	668 255	607 863
22212937 - Flexible tubes, pipes and hoses of plastics, not reinforced or otherwise combined with other materials, with fittings, seals or connectors	[t/y]	12 517	16 225	53 273	56 980
22212950 - Plastic tubes, pipes and hoses (excluding artificial guts, sausage skins, rigid, flexible tubes and pipes having a minimum burst pressure of 27,6 MPa)	[t/y]	84 487	54 603	500 589	470 704
22212970 - Fittings, e.g. joints, elbows, flanges, of plastics, for tubes, pipes and hoses	[t/y]	100 335	61 828	823 982	785 476

Source: Data - codes from 17127600 to 30301100 – were extracted on 09/12/2021 from Eurostat PRODCOM database (last data updated on 15/07/2021). Data for codes 20163025 to 22212970 were extracted from Eurostat PRODCOM database on 22/06/2022. Last update on 18.03.22.

Note: [1] p/st means Number of items

[2] CGT= compensated gross tonnage

Based on the data available in Table 2, Table 3 gives an indication of the share of the imported mixtures/articles compared to the one manufactured in Europe, as well as an indication of share of the manufactured mixtures/articles that are exported.

Table 3: Share of imports and exports compared to the EU production (Jan-Dec 2019)

PRCCODE	Ratio export/production	Ratio Import/production
17127600 - Carbon paper, self-copy paper and other copying or transfer paper, in rolls or sheets	41 %	11 %
20301230 - Paints and varnishes, based on acrylic or vinyl polymers	27 %	10 %
20521080 - Prepared glues and other prepared adhesives, n.e.c.	11 %	4 %
20594158 - Lubricating preparations obtained from petroleum or bituminous minerals	53 %	9 %
20601140 - Acrylic tow and staple, not carded, combed or otherwise processed for spinning	19 %	14 %
22194050 - Rubber conveyor belts	43 %	38 %
23121330 - Multiple-walled insulating units of glass	4 %	2 %
23991930 - Mixtures and articles of heat/sound-insulating materials n.e.c.	10 %	3 %
24201310 - Tubes and pipes, of circular cross-section, seamless, of stainless steel	31 %	25 %
24201330 - Precision tubes and pipes, of circular cross-section, cold-drawn or cold-rolled, seamless, of steel other than stainless steel	22 %	3 %
24201350 - Tubes and pipes, of circular cross-section, cold-drawn or cold-rolled, seamless, of steel other than stainless steel	20 %	23 %
25121050 - Aluminium doors, thresholds for doors, windows and their frames	8 %	12 %
29102230 - Motor vehicles with only petrol engine > 1 500 cm³	62 %	16 %

PRCCODE	**Ratio export/production**	**Ratio Import/production**
30112130 - Cruise vessels	not available	not available
30112150 - Ferries	not available	not available
30121100 - Sailboats (except inflatable) for pleasure or sports, with or without auxiliary motor	29 %	27 %
30301100 - Aircraft spark-ignition internal combustion piston engines, for civil use	141 %	30 %
20163025 - Plasticised polyvinyl chloride mixed with any other substance, in primary forms	20 %	6 %
27311100 - Optical fibre cables made up of individually sheathed fibres whether or not assembled with electric conductors or fitted with connectors	64 %	63 %
27311200 - Optical fibres and optical fibre bundles; optical fibre cables (except those made up of individually sheathed fibres)	2 %	10 %
22212920 - Flexible tubes, pipes and hoses of plastics, with a burst pressure >= 27,6 MPa	0.2 %	0.2 %
22212935 - Flexible tubes, pipes and hoses of plastics, not reinforced or otherwise combined with other materials, without fittings	14 %	5 %
22212937 - Flexible tubes, pipes and hoses of plastics, not reinforced or otherwise combined with other materials, with fittings, seals or connectors	23 %	30 %
22212950 - Plastic tubes, pipes and hoses (excluding artificial guts, sausage skins, rigid, flexible tubes and pipes having a minimum burst pressure of 27,6 MPa)	17 %	11 %
22212970 - Fittings, e.g. joints, elbows, flanges, of plastics, for tubes, pipes and hoses	12 %	8 %

A.2. Uses information

A.2.1. REACH data

A.2.1.1. Uses reported in registrations

The following uses are reported in registrations[5].

Table 4: Registered uses of substance EC 287-477-0 (Alkanes, C14-17, chloro)

Life cycle stage	Use names
Manufacture	Manufacture of MCCP
Formulation	Various industrial manufacturing Manufacture of preparations Formulation into mixture PVC Plastisols and Compounds PVC resin Masterbatches and/or Compounds Textile Flame Retardant and Waterproofing Formulation* Adhesives and sealants Flame retardant in conveyor belts Rubber MetalWorking Fluids Paints and coatings Lubricants Flame retardants Furniture manufacture* Construction chemicals
Uses at industrial sites	PVC compounding Production of cables Production of plastic articles PVC and Rubber Processing Manufacture of adhesives and sealants Use of adhesives and sealants at industrial sites Rubber compounding and article manufacturing Use of metalworking fluids at industrial sites Metalworking Fluid Use - Emulsion Metalworking Fluid Use – Neat Oil Use of paints and coatings at industrial sites Textile treatment* Textile Flame Retardant and Waterproofing Use* Textile binders* Manufacture of adsorbent formulations* Furniture manufacture* Fuels* Denaturing of fuels*

[5] ECHA Dissemination website accessed on 19/05/2022.

Life cycle stage	Use names
	Manufacture of preparations for mining applications
	Building and construction
	Various industrial manufacturing
	Manufacture of preparations
	Paper products and recycling*
Uses by professional workers	Professional use of adhesives and sealants
	Metalworking Fluid Use
	Professional use of paints and coating
Consumer uses	Adsorbents*
Article service life	PVC Article Service Life (Consumers)
	PVC Article Service Life
	PVC and Rubber Indoor Service Life
	Cables
	Adhesive/Sealant Outdoor Service Life
	Adhesives and Sealants Service Life (Professional)
	Adhesive/Sealant Indoor Service Life
	Adhesives and Sealants Service Life (Site)
	Rubber Article Service Life
	Rubber Article Service Life (Consumer)
	Flame retardant in conveyor belts
	Painted Article Service Life (Professionals)
	Painted Article Service Life (Site)
	Paint Indoor Service Life
	Paint Outdoor Service Life
	Textile Service Life (Consumers)*
	Textiles Indoor Service Life*
	Textile Outdoor Service Life*
	Paper products service life*
	Paper products Service Life (Consumers)*

*Note: * these uses have been reported as obsolete/not relevant in the Registrants' survey.*

Table 5: Registered uses of substance 'Di-, tri- and tetrachlorotetradecane'

Life cycle stage	Use names
Manufacture	-
Formulation	-
Uses at industrial sites	-
Uses by professional workers	Automotive fluids
Consumer uses	Automotive fluids
Article service life	-

Table 6: Registered uses of substance EC 264-150-0 (Paraffin waxes and Hydrocarbon waxes, chloro)

Life cycle stage	Use names
Manufacture	LCCP manufacture
Formulation	Polymer / Rubber Compounding Flame Retardant (including mining belts) Metalworking Fluids Paints and Coatings Paper Products* Lubricants Furniture* Building and Construction Chemicals
Uses at industrial sites	Production of cables PVC Polymer / Rubber Compounding Use of Metalworking Fluids Painting Textile Binders* Building and Construction Chemicals Furniture*
Uses by professional workers	Building and construction business
Consumer uses	Uses in PU foam
Article service life	Polymer / Rubber Compounding Production of Cables Flame Retardant (including mining belts) Textile Binders* Paper Products*

*Note: * these uses have been reported as obsolete/not relevant in the Registrants' survey.*

Table 7: Registered uses of substance 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified'

Life cycle stage	Use names
Manufacture	Manufacture of the substance
Formulation	Formulation of preparation
Uses at industrial sites	Leather making Leather manufacturing process Industrial treatment of textile
Uses by professional workers	-
Consumer uses	-
Article service life	Service life (consumers) handling of leather articles

Table 8: Registered uses of substance 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified'

Life cycle stage	Use names
Manufacture	Manufacture of the substance
Formulation	Formulation of preparation
Uses at industrial sites	Leather manufacturing process
Uses by professional workers	-
Consumer uses	-
Article service life	Service life (consumers) handling of leather articles

Table 9: Registered uses of substance EC 269-145-7 (Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated)

Life cycle stage	Use names
Manufacture	Manufacture of products for leather and fur industries
Formulation	-
Uses at industrial sites	Substance registered under REACH Article 17/18 only Manufacture of products for leather and fur industries Neutralisation
Uses by professional workers	-
Consumer uses	-
Article service life	-

Substance EC 269-145-7 is registered as an intermediate used under strictly controlled conditions under REACH Article 17/18. This use is in scope of restriction. No information is available in the registration dossier and no information has been provided by the registrants in response to the Dossier Submitter's questions to describe the risk management measures applied and recommended to the user in accordance with paragraph 4 of Article 18 of REACH.

A.2.1.2. Information from Downstream Users reports

One downstream user report (REACH Article 38) has been submitted for substance EC 287-477-0, but the report does not contain any information.

A.2.1.3. Information from Substances in Articles (SiA) notifications

Six notifications have been made for the SVHC entry 'MCCP' (defined as UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17) that covers substances (di-, tri- and tetrachlorotetradecane, Alkanes, C14-17, chloro (EC 287-477-0, CAS 85535-85-9), Tetradecane, chloro derivs. (CAS 198840-65-2) and Alkanes, C14-16, chloro (CAS 1372804-76-6).

The notifications all refer to uses in electrical cables.

A.2.1.4. Uses advised against by the registrants

The following uses are advised against for substance EC 287-477-0[6]:

- no discharge during formulation (ERC 2, 3), industrial uses (ERC 4, 5, 7) and professional uses (ERC 8c, 8f).
- All uses where emissions are not minimized are considered "uses advised against". In order to minimise release, do not discharge EC 287-477-0 to waterways or sewers during use.

There are no uses advised against for the registered substances (EC 264-150-0; EC 269-145-7; 'Di-, tri- and tetrachlorotetradecane'; 'Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated, saponified'; and 'Paraffin waxes and hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified')[7].

A.2.2. Information on uses from other sources

A.2.2.1. SCIP data

The addition of the 'MCCP' (defined as UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17) to the Candidate list, triggers notification obligations (aka SCIP notifications) under the Waste Framework Directive 2008/98/EC. Articles containing substances of very high concern (SVHCs) on the Candidate List at a concentration above 0.1 % weight by weight (w/w) placed on the EU market (after 1 January 2021) have to be notified by the supplier of the article according to Article 9(1)(i) of the Waste Framework Directive 2008/98/EC.

SCIP notifications can cover discrete articles (a screw or cog) or complex objects (a car). Notified complex objects can contain information on other complex objects (e.g. an engine, a gearbox) and articles that can be connected in a hierarchy e.g. car > power train > engine > cog.

Table 10 gives an overview of the SCIP notifications received. It should be noted that the number of unique articles covered by the SCIP database entries is much lower than the numbers of disseminated entries on ECHA dissemination website as the disseminated data includes the referencing[8].

The vast majority (~90 %) of the SCIP notifications[9] were made using the generic

[6] Joint CSR submitted by the lead registrant of EC 287-477-0 on 13 January 2022.

[7] ECHA Dissemination website consulted on 10 January 2022 and 27 April 2022.

[8] SCIP notification using 'referencing' for one or more components of that complex object, includes the information contained in the dossiers already submitted to the SCIP Database for those components that the dossier is referring to. More information available on https://echa.europa.eu/scip-support

[9] ECHA dissemination website consulted on 20 April 2022

Candidate List definition 'UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17' rather than specifying the exact substances. It is therefore not possible to know exactly which substance is used in articles or complex objects.

Table 10: Summary of SCIP data overview

Substance name	EC	CAS	Number of SCIP database entries [1]	Number of SCIP notified articles [2]
'MCCP' (defined as UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17)	-	-	195 227	
Alkanes, C14-17, chloro	287-477-0	85535-85-9	8 466	
Tetradecane, chloro derivs.	-	198840-65-2	6	
Alkanes, C14-16, chloro	-	1372804-76-6	8	
di-, tri- and tetrachlorotetradecane	-	-	6	
Total			**203 713**	**Estimated between 10 000 and 15 000**

Source: ECHA dissemination website consulted on 20 April 2022

Note: [1] total number of SCIP database entries (or factsheets), including dossiers with "referencing". This corresponds to the number or entries disseminated on ECHA website.
[2] total number of SCIP notified articles (does not include any dossier with "referencing"). This means unique article.

Table 11 and Table 12 provide an overview of the types of article categories, and mixtures incorporated in articles where the 'MCCP' substances in the Candidate List have been reported in a concentration above 0.1 % w/w.

Table 11: Article category reported as containing the Candidate List substances in concentration > 0.1 %

Article category
Motor vehicles, including motorcycles, and their components and accessories, including brakes, bumpers, ignition **wiring sets and other wiring sets for vehicles (insulated wires and cables)**, lighting or visual signalling equipment, rear-view mirrors (CN chapters and headings: 7009, 8703, 8708, 8714, 8512, 8544, 9401)
Machinery and mechanical appliances and components thereof, namely cranes, bulldozers, graders, levellers, scrapers, excavators, loaders, extractors, engines and their components, filtering or purifying machinery and apparatus and their components, centrifuges and their components, pumps and their components (CN chapter and heading: 8407, 8409, 8413, 8421, 8431, 8473, 8481)
Rubber articles including reinforced vulcanised rubber articles, such as plates, sheets, strip, rods, tubes, pipes, hoses and other profile shapes (CN chapters and headings: 4007, 4008, 4009, 4016)
Electrical machinery and equipment and components thereof, namely aerials and aerial reflectors

Article category
and their components, motors and generators and their components, televisions and reproducing apparatus with a screen of the liquid crystal display (LCD) technology, components of electromechanical domestic appliances, printed circuits consisting only of conductor elements and contacts, coaxial cables and insulated conductors (**e.g. cables, wires**), switches, and static converters (CN chapter and headings: 8501, 8503, 8504, 8509, 8528, 8529, 8534, 8536, 8543, 8544)
Components and accessories of optical, photographic, cinematographic, medical, surgical or veterinary's instruments and apparatus, as well as measuring instruments and apparatus, including those for measuring or checking semiconductor wafers or devices, and the flow or level of liquids (Combined Nomenclature (CN) chapter and heading: 9026, 9030, 9033)
Plastic articles, such as plates, sheets, film, foil and strip of **polymers of vinyl chloride**, tubes, pipes and hoses, fittings for e.g. joints, elbows, flanges, (CN chapter and headings: 3917, 3920, 3921, 3926)
Ferrous-metal articles and copper articles, such as threaded and non-threaded screws, bolts, nuts, washers and alike, and tubes, pipes and other hollow profiles (CN chapter and heading: 7304, 7318, 7326, 7415)
Textile fabrics impregnated, coated, covered or laminated with plastics, in particular with **poly(vinyl chloride) or polyurethane, or rubberised textile fabrics** (CN chapters and headings: 5806, 5903, 5906)
Metal beds, mattresses and similar furnishing (CN chapters and headings: 9403, 9404)
Other articles

Source: ECHA dissemination website consulted on 22 April 2022

Table 12: Mixture category incorporated in articles and reported as containing the Candidate List substances in concentration > 0.1 %

Mixture category
PC-ADH-7 Adhesives and sealants - assembly line processes
PC-TEC-11 Lubricants, greases, release agents
PC-PNT-3 Paints/coatings - Protective and functional
PC-TEC-16 Polymer preparations and compounds
PC-ADH-OTH Other adhesives and sealants
PC-TEC-13 Metalworking fluids
PC-CON-OTH Other construction products

Source: ECHA dissemination website consulted on 22 April 2022

The information from the SCIP database confirms the presence of 'MCCP' (defined as UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17) in the following types of use:

- Use#00 – PVC
- Use#01 – Adhesives and sealants
- Use#02 – Use in rubber
- Use#04 – Use in paints and coating
- Use#07 – Other uses (lubricants)

The SCIP database provides also an overview of the concentration ranges of the Candidate List substance in the articles. The concentration ranges are provided in % weight by weight (w/w) as submitted by the supplier of the article from a list of pre-defined ranges.

After analysing the information available on the SCIP dissemination website, it should be noted that a majority of notifiers for EC 287-477-0 is reporting a concentration range between 1 and 10 % in articles. Concentrations above 20 % are reported as well for this substance. This information is consistent with the information on concentration gathered by the Dossier Submitter from other sources.

No conclusion can be made for the generic entry 'MCCP' as a majority of the concentrations is reported to be > 0.1 % w/w.

A.2.2.2. BfR product database

Companies placing on the market mixtures classified as hazardous for human health or physical effects have to submit this information to Member States, to be used by their poison centres for emergency health response.

Seven chloroalkanes in the scope of the investigations are classified as hazardous for human health and may therefore trigger the hazardous classification of mixture if present in mixture in concentrations above the generic concentration or specific concentration limit.

Anonymised data were provided by BfR (Bundesinstitut für Risikobewertung) regarding the presence of six chloroalkanes in hazardous mixtures for consumer and professional uses (BfR, 2022).

The information extracted from the database includes information from Product notifications registered at BfR from 1 January 2017 to February 2022, in all notification formats (i.e. national format or PCN). In case of updated notifications, only the information from the latest version is reported.

Uses information

The summary of the information on hazardous mixture is presented in Table 13 to Table 18.

Even though limited to six substances with human health hazard, the information from the BfR products database confirms the presence of substances containing CA:C14-17 in the following types of use:

- Use#00 – PVC
- Use#01 – Adhesives and sealants
- Use#03 – Use in metalworking fluids
- Use#04 – Use in paints and coating
- Use#05 – Use in leather
- Use#07 – Other uses (lubricants)

It also indicates that for the same category of mixtures plenty of alternative formulations are available on the market.

Table 13: Hazardous mixtures reported as containing EC 287-477-0

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category [3]	Technical functions
-	Mixtures for further formulation	1.0 - >30.0 %	√	√	√	10 - 50	>100 000	active substance adhesive (sticker) diluting agent drying agent filler Fire Retardant lubricant oil plasticiser
00	Polymer preparations and compounds	1 - >30.0 %	√	√		50 - 100	10 000 - 50 000	
01	Adhesives and sealants - household, office or school use	1.0 - >30.0 %		√	√	<10	1 000 – 5 000	
01	Adhesives and sealants - building and construction works (except cement-based adhesives)	<0.1 - >30.0 %	√	√	√	100 - 500	10 000 - 50 000	
01	Adhesives and sealants - transportation industry	1.0 - 20.0 %	√	√		<10	5 000 - 10 000	
01	Adhesives and sealants - woodworking and joinery (includes putty)	1.0 - 10.0 %	√	√	√	10 - 50	10 000 - 50 000	
01	Multi-component adhesives and sealants	1.0 - >30.0 %	√	√	√	10 - 50	10 000 - 50 000	
01	Other adhesives and sealants	0.1 - >30.0 %	√	√	√	50 - 100	10 000 - 50 000	
01	Foams	0.1 - >30.0 %		√	√	50 - 100	500 - 1 000	
01	Construction materials, auxiliary materials and sealants - not classified	10.0 - 20.0 %		√		<10	1 000 – 5 000	
01	Adhesives for the construction sector	1.0 - 20.0 %		√	√	<10	1 000 – 5 000	
01	Rubber glue	1.0 - 10.0 %		√	√	<10	<100	
01	Wood glue, wood glue	1.0 - 10.0 %		√		<10	100 - 500	
01	Adhesives - unclassified	1.0 - 10.0 %		√	√	<10	5 000 - 10 000	
01	Building materials, sealants and adhesives - unclassified	0.1 - >30.0 %		√	√	10 - 50	1 000 – 5 000	
03	Metalworking fluids	0.1 - >30.0 %	√	√	√	150 - 200	1 000 – 5 000	

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category [3]	Technical functions
04	Aerosol paints and coatings	0.1 - 10.0 %	√	√	√	10 - 50	10 000 - 50 000	
04	Paints/coatings - Decorative	0.1 - 20.0 %	√	√	√	100 - 150	>100 000	
04	Paints/coatings - Protective and functional	0.1 - 20.0 %	√	√	√	1 000 – 2 000	>100 000	
04	Marine vessel coatings (excludes anti-fouling products)	0.1 - 10.0 %	√	√	√	10 - 50	10 000 - 50 000	
04	Automotive and aerospace coatings	0.1 - 10.0 %	√	√	√	<10	10 000 - 50 000	
04	Other paints and coating materials	0.1 - 20.0 %	√	√	√	10 - 50	>100 000	
04	Antifouling products (Biocides)	0.1 - 10.0 %	√	√	√	50 - 100	500 - 1 000	
04	Primers	1.0 - 10.0 %		√	√	10 - 50	1 000 – 5 000	
04	Universal paints including primers	1.0 - 10.0 %		√		<10	10 000 - 50 000	
04	Alkyd paint	1.0 - 10.0 %		√		<10	1 000 – 5 000	
04	Hardener and other paint additives	1.0 - 10.0 %		√		<10	500 - 1 000	
04	Interior wall paint	0.1 - 1.0 %		√	√	<10	500 - 1 000	
04	Paints and primers - unclassified	0.1 - 10.0 %		√	√	<10	5 000 - 10 000	
04	Underbody preserver for vehicles	1.0 - 10.0 %		√		<10	<100	
04	Metal surface treatment agent - non-galvanic	1.0 - 10.0 %		√		<10	500 - 1 000	
04	Anti-corrosive preparations for vehicles	>30.0 %		√	√	<10	100 - 500	
04	Antifouling products for underwater devices (Biocides)	0.1 - 10.0 %		√	√	10 - 50	100 - 500	
05	Auxiliaries for the leather and fur industry	20.0 - 30.0 %		√		<10	500 - 1 000	

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category [3]	Technical functions
07	Commercial printing inks, toners and related finishing products	1.0 - 10.0 %		√		<10	5 000 - 10 000	
07	Pressroom chemicals	>30.0 %		√		<10	100 - 500	
07	Other air care products	0.1 - 10.0 %	√	√	√	<10	1 000 – 5 000	
07	Abrasive cleaning products	1.0 - 10.0 %		√		<10	1 000 – 5 000	
07	Engine cleaners	1.0 - 10.0 %	√	√	√	<10	500 - 1 000	
07	Other vehicle (all types) cleaning and care products	1.0 - 10.0 %		√	√	<10	5 000 - 10 000	
07	Other cleaning, care and maintenance products (excludes biocidal products)	0.1 - 1.0 %	√	√	√	<10	10 000 - 50 000	
07	Construction chemicals	<0.1 - >30.0 %	√	√	√	100 - 150	50 000 - 100 000	
07	Other construction products	1.0 - 20.0 %	√	√	√	50 - 100	10 000 - 50 000	
07	Fuel additives and fuel components	1.0 - 10.0 %		√	√	10 - 50	1 000 – 5 000	
07	Lubricants, greases, release agents	0.1 - >30.0 %	√	√	√	100 - 150	10 000 - 50 000	
07	Metal surface treatment products	>30.0 %	√	√		<10	10 000 - 50 000	
07	Reagents and laboratory chemicals	0.1 - 1.0 %		√		<10	10 000 - 50 000	
07	Textile treatment products (excludes dyes and pigments)	10.0 - 20.0 %	√			<10	1 000 – 5 000	
07	Other products for chemical or technical processes	1 - >30.0 %	√	√	√	10-50	10 000 - 50 000	
07	Flame retardants	1.0 - 10.0 %		√		<10	100 - 500	
07	Cleaners and care products for vehicle parts	1.0 - 10.0 %		√	√	<10	1 000 – 5 000	

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category [3]	Technical functions
07	Engine cleaner	1.0 - 10.0 %		√	√	<10	100 - 500	
07	Cleaners and care products for vehicles - unclassified	>30.0 %		√		<10	500 - 1 000	
07	Lubricant	<0.1 - >30.0 %		√	√	10 - 50	5 000 - 10 000	
07	Lubricating oil	1.0 - >30.0 %		√	√	10 - 50	1 000 – 5 000	
07	Grease	1.0 - 20.0 %		√	√	<10	500 - 1 000	
07	Additives for heating and fuels	1.0 - >30.0 %		√	√	<10	1 000 – 5 000	
07	Chemical and galvanochemical metal treatment agents	20.0 - >30.0 %		√		<10	1 000 – 5 000	
07	Products for chemical-technical processes/procedures - not classified	>30.0 %		√		<10	5 000 - 10 000	
07	Chemical agents for technical devices, processes and products - not classified	1.0 - >30.0 %		√	√	<10	10 000 - 50 000	
07	Chemical / physicochemical agents - not classified	>30.0 %		√		<10	1 000 – 5 000	

Source: (BfR, 2022)

Note: [1] mixture category either according to the defined EUPcS format or National German format (TKS). Mixture category reported according to the TKS format are reported with a blue font. TKS format reporting does not include industrial uses.
[2] 'I' stands for 'industrial use of the mixture', 'P' for 'professional use of the mixture' and 'C' for 'consumer use'.
[3] only ranges provided.

Table 14: Hazardous mixtures reported as containing EC 264-150-0

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category[3]	Technical functions
-	Mixtures for further formulation	1.0 - >30.0 %	√	√	√	10 - 50	>100 000	active substance

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category[3]	Technical functions
00	Polymer preparations and compounds	1.0 - 10.0 %	√	√		<10	10 000 - 50 000	coating agent denaturant filler flame retardant lubricant plasticiser synergist
01	Adhesives and sealants - household, office or school use	1.0 - 10.0 %	√		√	<10	1 000 – 5 000	
01	Adhesives and sealants - building and construction works (except cement-based adhesives)	1.0 - 30.0 %		√	√	10 - 50	10 000 - 50 000	
01	Adhesives and sealants - paper and board related processes	1.0 - 20.0 %	√			<10	1 000 – 5 000	
01	Adhesives and sealants - woodworking and joinery (includes putty)	1.0 - 10.0 %	√			10 - 50	10 000 - 50 000	
01	Multi-component adhesives and sealants	1.0 - 10.0 %	√	√	√	10 - 50	10 000 - 50 000	
01	Other adhesives and sealants	1.0 - 20.0 %	√	√		<10	10 000 - 50 000	
01	Building protection and sealants	1.0 - 10.0 %		√		<10	500 - 1 000	
01	Foams	1.0 - >30.0 %		√	√	10 - 50	500 - 1 000	
01	Construction materials, auxiliary materials and sealants - not classified	1.0 - 10.0 %		√		<10	1 000 – 5 000	
01	Adhesives for the construction sector	0.1 - 10.0 %		√	√	<10	1 000 – 5 000	
01	Adhesives - unclassified	0.1 - 10.0 %		√	√	10 - 50	5 000 - 10 000	
01	Building materials, sealants and adhesives - unclassified	1.0 - 10.0 %		√		<10	1 000 – 5 000	
03	Metalworking fluids	1.0 - >30.0 %	√	√		10 - 50	1 000 – 5 000	
03	Metalworking coolants	1.0 - 10.0 %		√	√	<10	<100	
04	Aerosol paints and coatings	0.1 - 10.0 %	√	√	√	10 - 50	10 000 - 50 000	
04	Paints/coatings - Decorative	1.0 - 20.0 %	√	√	√	100 - 150	>100 000	

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category[3]	Technical functions
04	Paints/coatings - Protective and functional	0.1 - 30.0 %	√	√	√	500 - 1 000	>100 000	
04	Marine vessel coatings (excludes anti-fouling products)	1.0 - 20.0 %	√	√	√	10 - 50	5 000 - 10 000	
04	Automotive and aerospace coatings	1.0 - 10.0 %	√	√		<10	10 000 - 50 000	
04	Other paints and coating materials	1.0 - 20.0 %	√	√	√	10 - 50	>100 000	
04	Metal surface treatment products	1.0 - 10.0 %	√			<10	10 000 - 50 000	
04	Antifouling products (Biocides)	1.0 - 10.0 %	√	√	√	50-100	1 000 – 5 000	
04	Primers	0.1 - 20.0 %		√	√	10 - 50	1 000 – 5 000	
04	Enamel paints including primers, thinners and additives	0.1 - 10.0 %		√	√	500 - 1 000	10 000 - 50 000	
04	Alkyd paint	0.1 - 1.0 %			√	<10	1 000 – 5 000	
04	Acrylic paint	0.1 - 10.0 %		√	√	10 - 50	1 000 – 5 000	
04	Car paint	0.1 - 1.0 %		√	√	10 - 50	100 - 500	
04	Tinting paste/colour and colour pigments	1.0 - 10.0 %		√	√	<10	1 000 – 5 000	
04	Paints and primers - unclassified	1.0 - 10.0 %		√	√	10 - 50	5 000 - 10 000	
04	Paints, varnishes and dyes - not classified	0.1 - 10.0 %		√	√	10 - 50	5 000 - 10 000	
04	Metal surface treatment agent - non-galvanic	10.0 - 20.0 %		√		<10	500 - 1 000	
04	Anti-corrosion agent	1.0 - 10.0 %		√	√	<10	1 000 – 5 000	
04	Antifouling products for underwater devices (Biocides)	1.0 - 10.0 %		√	√	10 - 50	100 - 500	

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category[3]	Technical functions
05	Other textile and leather cleaning and care products (including footwear)	1.0 - 10.0 %	√	√		<10	1 000 – 5 000	
05	Leather treatment products (excludes dyes and pigments)	1.0 - 20.0 %	√	√		<10	1 000 – 5 000	
07	Other inks, toners and related printing materials	1.0 - 10.0 %	√			<10	1 000 – 5 000	
07	Grout cleaners	1.0 - 10.0 %	√	√	√	<10	100 - 500	
07	Construction chemicals	1.0 - 10.0 %	√	√		<10	50 000 - 100 000	
07	Lubricants, greases, release agents	1.0 - 20.0 %	√	√	√	10 - 50	10 000 - 50 000	
07	Other products for chemical or technical processes	0.1 - 10.0 %	√	√		50 - 100	10 000 - 50 000	
07	Chemical products - uncategorised	1.0 - 10.0 %	√	√		<10	10 000 - 50 000	
07	Flame retardants	1.0 - 20.0 %		√		<10	100 - 500	
07	Metal cleaner for metal industry	1.0 - 10.0 %		√	√	<10	500 - 1 000	
07	Lubricant	10.0 - 20.0 %		√		<10	1 000 – 5 000	
07	Lubricating oil	1.0 - 10.0 %		√		<10	1 000 – 5 000	
07	Chemical and galvanochemical metal treatment agents	1.0 - 10.0 %		√	√	<10	1 000 – 5 000	
07	Auxiliaries for the textile industry	1.0 - >30.0 %		√		<10	1 000 – 5 000	
07	Chemical auxiliaries for other processes	1.0 - 10.0 %		√		<10	<100	
07	Products for chemical-technical processes/procedures - not classified	1.0 - >30.0 %		√		<10	5 000 - 10 000	
07	Chemical agents for technical devices, processes and products - not classified	1.0 - 10.0 %		√		<10	10 000 - 50 000	

Source: (BfR, 2022)
Note: [1] mixture category either according to the defined EUPcS format or National German format (TKS). Mixture category reported according to the TKS format are reported with a blue font. TKS format reporting does not include industrial uses.
[2] 'I' stands for 'industrial use of the mixture', 'P' for 'professional use of the mixture' and 'C' for 'consumer use'.
[3] only ranges provided.

Table 15: Hazardous mixtures reported as containing EC 287-196-3

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category[3]	Technical functions
04	Paints/coatings - Decorative	0.1 – 1.0 %	√	√		<10	>100 000	Not provided

Source: (BfR, 2022)
Note: [1] mixture category according to the defined EUPcS format only.
[2] 'I' stands for 'industrial use of the mixture', 'P' for 'professional use of the mixture' and 'C' for 'consumer use'.
[3] only ranges provided.

Table 16: Hazardous mixtures reported as containing EC 263-004-3

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category[3]	Technical functions
-	Mixtures for further formulation	>30.0 %	√			<10	>100 000	Not reported
04	Acrylic paint	1.0 – 10.0 %		√	√	<10	1 000 – 5 000	
05	Cleaners, care products for textile and leather goods - not classified	1.0 – 10.0 %		√	√	<10	<100	

Source: (BfR, 2022)
Note: [1] mixture category either according to the defined EUPcS format or National German format (TKS). Mixture category reported according to the TKS format are reported with a blue font. TKS format reporting does not include industrial uses.
[2] 'I' stands for 'industrial use of the mixture', 'P' for 'professional use of the mixture' and 'C' for 'consumer use'
[3] only ranges provided.

Table 17: Hazardous mixtures reported as containing EC 287-478-6

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category[3]	Technical functions
01	Building protection and sealants	1.0 – 10.0 %		√		<10	500 - 1 000	Not reported
	Adhesives - unclassified	1.0 – 10.0 %		√		<10	5 000 - 10 000	
	Building materials, sealants and adhesives - unclassified	1.0 – 10.0 %		√		<10	1 000 – 5 000	

Source: (BfR, 2022)

Note: [1] mixture category reported according to the TKS format are reported with a blue font. TKS format reporting does not include industrial uses.
[2] 'I' stands for 'industrial use of the mixture', 'P' for 'professional use of the mixture' and 'C' for 'consumer use'
[3] only ranges provided.

Table 18: Hazardous mixtures reported as containing 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified'

Use#	Mixture category [1]	Reported concentration range	I[2]	P	C	Number of mixtures containing the chloroalkane	Total number of mixtures in the mixture category[3]	Technical functions
-	Mixtures for further formulation	1.0 - >30.0 %	√	√		<10	>100 000	Not reported
05	Leather treatment products (excludes dyes and pigments)	1.0 - >30.0 %	√	√		<10	1 000 – 5 000	

Source: (BfR, 2022)

Note: [1] mixture category according to the defined EUPcS format only.
[2] 'I' stands for 'industrial use of the mixture', 'P' for 'professional use of the mixture' and 'C' for 'consumer use'
[3] only ranges provided.

Substance identification information

Table 19 provides an overview of the different names reported by the companies placing hazardous mixtures on the market to identify the chloroalkanes in the scope of the investigations.

Table 19: Overview of the names reported by companies to describe some chloroalkanes under investigation in the BfR product database

Mixtures containing chloroalkane	Name(s) reported by the company placing the hazardous mixtures on the market
EC 287-477-0	Alcanes, C14-17, chlorés; paraffines polychlorées, C14-17
	Alcanos, C14-17, cloro
	Aliphat. C14-C17 Kohlenwasserstoff, chloriert
	Alkane
	Alkane, C 14-17, Chlor
	Alkane, C14-17, chlor-
	Alkane, C14-17-, Chlor-Chlorierte Paraffine, C14-17
	Alkane, C14-17-, Chlorparaffin
	Alkane, C14-C17, chloro
	Alkane,C14-C17, Chlor-
	Alkanes C14-17 chloro
	Alkanes C14-17, chloro, chlorinated paraffins, C14-17
	Alkanes, C14-17, chloriert
	Alkanes, C14-17, chloro
	Alkanes, C14-17-, Chloro
	Alkanes, C14-17, chloro
	Alkanes, C14-17, chloro (ID2)
	Alkanes, C14-17, chloro (MCCP, Medium chained chlorinated paraffins)
	Alkanes, C14-17, chloro chlorinated paraffins, C14-17
	Alkanes, C14-17, chloro; chlorinated paraffins, C14-17
	Alkanes, C14-17, chloro; chlorinated paraffins, C14-17
	ALKANES, C14-17-,CHLORO
	Alkani, C14-17, klor
	C14-17 chlorierte Paraffine
	C14-17 CHLORINATED PARAFFIN
	C-14-17 CLORINATED PARAFFINS
	C14-17 PARAFFINA CLORURATA
	C14-17 PARAFFINE CLORURATE
	C14-C17 CHLORINATED PARAFFIN
	C14-C17, chloro Alkanes
	Chloor par
	Chloralkane (C14-17)
	Chloralkane, C14-17
	Chloralkane, C14-17,
	Chloralkane, C14-17, chlorierte Paraffine, C14-17
	Chloralkane, C14-17,; chlorierte Paraffine, C14-17
	Chlorierte Paraffine, C14-C17

Mixtures containing chloroalkane	Name(s) reported by the company placing the hazardous mixtures on the market
	Chlorierter aliphatischer Kohlenwasserstoff mit ca. 50 % Chlor (Basis C14-17)
	chlorinated paraffin
	chlorinated paraffin (C14-17)
	Chlorinated paraffins, C14-17
	Chlorinated paraffins, C14-17 (52 %)
	Chlorinated Paraffins, C14-17 (52 %).
	Chlorparaffin
	Chlorparaffin (C14-C17)
	Chlorparaffin C14-17
	Chlorparaffine C14-17
	Chlorparaffine C14-C28
	CLOPARIN 50=MAKCHLOR 5 CLOROPARAF
	Cloroalcani C14-17
	CP 52 FL
	PARAFFINE CLORURATE, C14-17
	Parafinas cloradas C14-C17
	ZZZ0098 Chlorinated paraffins, C14-17 (52 %)
EC 264-150-0	1,2,3,4,6,7,10-heptachlorododecane
	4P436 - Paraffin waxes and Hydrocarbon waxes, chloro
	Additivi anticorrosivi ed untuosanti
	ALKANE, C10-13-, CHLOR-
	Alkanes, C20-28, chloro
	Alkanes,C22-30, chloro
	Bentonit
	C18-30 chloriertes Paraffin
	C22-30 Chlorinated paraffin
	C22-30 chlorinated paraffin (chlorination: 30-48 %) (Long chain chlorinated paraffins (LCCP))
	C22-30 chlorinated parrafin (chlorination: 42-48 %)
	C18-C20-Chlorparaffin (Chlorierung: 20 - 50 %) - Cereclor M 47
	C22-C30 Chlorinated paraffin (chlorination degree: 30-48 %)
	CERA DI PARAFFINA CLORURATA
	Cere paraffiniche e cere idrocarburiche, cloro
	Chlorierte Paraffinwachse und Kohlenwasserstoffwachse
	Chlorierter aliphatischer Kohlenwasserstoff mit 44 % Chlor (Basis > C18)
	Chlorinated hydrocarbons (chlorinated paraffins)
	Chlorinated paraffin
	Chlorinated Paraffin 48
	Chlorinated Paraffin 70
	CHLORINATED PARAFFIN, LONG CHAIN GRADES
	CHLORINATED PARAFFINS
	Chlorinated Paraffins (C22-30)
	chloroparaffin
	Chloro-Paraffin 70

Mixtures containing chloroalkane	Name(s) reported by the company placing the hazardous mixtures on the market
	Chlorparaffin/ca 44 % Chlor,C>18 Chlorparaffine Chlorparaffine C18-C28 CLORINATED PARAFFIN WAX CLOROPARAFFINA CLOROPARAFFINA 42 % Cloroparaffina C18-C20 Cloroparaffine C18-C20 CLOROPARAFINA CP 52 AD Hydrocarbon waxes langkettige Chlorparaffine, Chlorgehalt 42 %-48 % LCCP (long chain chlorinated paraffin) Paraffin waxes and hydrocarbon waxes Paraffin waxes and Hydrocarbon waxes (C18 and longer), chloro Paraffin waxes and hydrocarbon waxes, chlorinated C22-C30 (42-48 % chlorine) PARAFFIN WAXES AND HYDROCARBON WAXES, CHLORINE Paraffin waxes and Hydrocarbon waxes, chloro (C12, 60 % chlorine) Paraffin Waxes, and Hydrocarbon waxes, chloro Long chain chlorinated paraffins (LCCP) Paraffin waxes and Hydrocarbon waxes, chloro Paraffine clorurate C22-30 - clorurazione 42-48 % Paraffinwachse und Kohlenwasserstoffwachse, chloriert
EC 287-196-3	Chlorierter aliphatischer Kohlenwasserstoff mit ca.52 % Chlor (C > 18)
EC 263-004-3	Alkanes, chloro C20-28 chloro alkanes
EC 287-478-6	Alkanes, chloro Long Chain (C18-28) Chlorinated Paraffin
Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified	939-273-4 Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified

Source: (BfR, 2022)

Change of substance identifiers in the formulations

During data processing, BfR spotted product notifications updated according to the notifiers *"after a significant change of composition*[10]" where a chloroalkane was replaced by another chloroalkane in the mixture's formulation. The spotted changes in formulation are reported in Table 20. It is important to note that BfR only looked at the product notifications updated for the specific above-mentioned reason. A systematic comparison

[10] according to Part B of Annex VIII to CLP changes in the formula

of formulation between updated versions could not be performed.

Even though limited to a small number of product notifications, the few examples in Table 20 show the substitution potential from one chloroalkane to another and the versality in identification of chloroalkane on the mixtures labelling.

The examples in formulation update shows also that the concentration of chloroalkane in the formulation was in general not impacted by the change of chloroalkane.

The changes in the formulation from EC 264-150-0 to EC 287-477-0 is difficult to interpret, as a substance not listed on the Candidate List (but under scrutiny for the restriction work) has been replaced by a substance listed on the Candidate List (and under scrutiny for the restriction work).

Table 20: Example of changes in formulation "after a significant change of composition" according to the product notifiers

Formulation content before update	Formulation content after update	Comment
EC 287-477-0	EC 264-150-0	11 products were identified by the notifiers as *"New notifications after a significant change of composition"* that no longer contained EC 287-477-0 (with the preceding version including this component) which was replaced by EC 264-150-0. The changes were notified after the identification of EC 287-477-0 as an SVHC, and its inclusion in the Candidate List. For eight of these products (one company from Germany), EC 264-150-0 is used in the formulation in about twice the concentration of EC 287-477-0. For three products, EC 264-150-0 is used in the same concentration as EC 287-477-0.
EC 264-150-0	EC 287-477-0	78 products were identified (two companies from Italy) as *"New notifications after a significant change of composition"* that no longer contained EC 264-150-0 (with the preceding version including this component) which was replaced by EC 287-477-0 in the same concentration.
EC 263-004-3	EC 287-477-0	Ten products were identified (one company from Netherlands) as "*New notifications after a significant change of composition"* that no longer contained CAS EC 263-004-3 (with the preceding version included this component) which was replaced by EC 287-477-0 in the same concentration.

Source: (BfR, 2022)

Market information

Even though essentially focused on the German market, the BfR products database contains also partial information regarding the placing of the market in other Member States of some of the mixtures containing the chloroalkanes in the scope of the investigations (cf. Table 21).

Table 21: Market overview of the hazardous mixtures reported as containing chloroalkanes under investigation

Mixtures containing chloroalkane	German market	Other MS markets
EC 287-477-0	√	√
EC 264-150-0	√	√
EC 287-196-3	√	√
EC 263-004-3	√	No information
EC 287-478-6	√	No information
Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified	√	√

Source: (BfR, 2022)

A closer analysis of some product categories (e.g. use 04) is also showing that a limited number of companies is placing the mixtures on the market. For example, mixtures containing EC 287-477-0 and used for Use 04 - Paints/coatings - Protective and functional were notified between 1 000 and 2 000 times by less than 20 companies located in Belgium, Germany, Denmark, Spain, Italy, The Netherlands and Portugal.

A.2.2.3. Biocides

During the ECHA market Survey, the following substances were reported as co-formulant in several biocidal products (e.g. anti-fouling paints and coatings):

- EC 287-477-0
- EC 264-150-0 – no information available regarding the presence and concentration of CA:C14-17

The presence of the biocidal products containing the above listed substances was reported on multiple EU markets (e.g. France, The Netherlands, Germany, Italy – the list of country is only indicative and non-exhaustive).

A.2.2.4. Literature searches

A literature search was conducted between December 2021 and March 2022. To avoid reporting obsolete uses of CA:C14-17, the literature searches was focusing on the reports and studies published from 2017 onward.

The results of the literature search are presented in the Table 22 from the most recent to the older one.

Table 22: Detected presence of CA:C14-17 in various types of articles and applications

Use number and name	Geographical area of the study	Year of the study	Specified Applications	Reported range concentration [% (w/w)]	Comments	Reference
#00 – PVC and #01- Adhesives and sealants	Norway	2022	Home equipment	0.08 - 9.85	CA:C14-17 detected in 7 samples (out of 40): -Premium adhesive film -Selfadhesive PVC waterproof wall paper (2) -DC-FIX Self-adhesive Wall tiles -Waterproof PVC wall paper -Shower curtain PVC -Laminate floor -Home carpet underlay PVC	(NILU, 2023)
#00 - PVC	Norway	2021	Electrical and electronic equipment Paper, Upholstery, cables and flooring	<LOQ	10 samples from the following 7 categories of PVC articles: -Extension cords -Sockets -Flooring -Wall paper -PC mouse -PC -Upholstery	(Bohlin-Nizzetto, 2022)
#01- Adhesives and sealants	Netherlands	2019 (new products); 2007-2020 (used products)	Spray polyurethane foams (SPFs) - OCF (one component foam) sold as insulation and mounting foams for filling cracks, holes, gaps, and crevices	0.2 - 50 (new products) 0.1 – 22 (used products)	24 SPF samples: 10 were prepared from 10 new OCF-cans with different property descriptions (representing 7 different brands); the other 10 samples were collected from 9 houses and 1 office (used products). Quantities of CA:C14-17 were found in all samples from the group originated from new cans. However, the same was not verified for the second group, where only 5 out of 10 samples contained CA:C14-17.	(Brandsma et al., 2021)
Polymer (unknown)	EU	2020	Samples from waste stream (WEEE - waste from electric and electronic equipment) **Infeed stream**	0.0016	Presence of CA:C14-17 in post-consumer plastics, which are or may be subject to recycling. Samples from eight recycling facilities in Norway and abroad were collected and analysed.	(Norwegian Environment Agency, 2021)

Use number and name	Geographical area of the study	Year of the study	Specified Applications	Reported range concentration [% (w/w)]	Comments	Reference
Polymer (unknown)	EU	2020	Samples from waste stream (WEEE - waste from electric and electronic equipment) Sample corresponding to the **reject** that will be incinerated (i.e. after separation: all plastics expected to carry brominated or chlorinated contaminants)	0.017 - 0.17	Presence of CA:C14-17 in post-consumer plastics, which are or may be subject to recycling. Samples from eight recycling facilities in Norway and abroad were collected and analysed	(Norwegian Environment Agency, 2021)
Polymer (ABS)	EU	2020	Sample from waste stream (WEEE - waste from electric and electronic equipment)	0.0016 - 0.0043	Presence of CA:C14-17 in post-consumer plastics, which are or may be subject to recycling. Samples from eight recycling facilities in Norway and abroad were collected and analysed.	(Norwegian Environment Agency, 2021)
Polymer (PS)	EU	2020	Sample from waste stream (WEEE - waste from electric and electronic equipment)	< LOQ - 0.0004		
Polymer (PE/PP)	EU	2020	Sample from waste stream (WEEE - waste from electric and electronic equipment)	0.0026		
Polymer (unknown)	EU	2020	Sample from waste stream (ELV - end of life vehicle)	0.013 - 0.021		
Polymer (PE/PP)	EU	2020	Sample from waste stream (ELV - end of life vehicle)	0.013		
Polymer (unknown)	EU	2020	Sample from waste stream (LHA - large household appliance)	0.0026 - 0.0092		
#00 - PVC	EU	2020	Sample from waste stream - PVC flooring	0.0022		

Use number and name	Geographical area of the study	Year of the study	Specified Applications	Reported range concentration [% (w/w)]	Comments	Reference
#00 - PVC	EU	2020	Sample from waste stream - PVC pipes	<LOQ - 0.0004		
#00 - PVC	EU	2020	Sample from waste stream - PVC cable (B&CW - building and construction waste)	9.9		
#00 - PVC	Belgium	2019	Consumer products and toys (Yoga mat, Beach ball, Inflatable pool mat, Can holder, Jump rope, Electrical cable, Flip flop)	not detected – 0.0014	28 consumer product samples (19 PVC items and 6 rubber items). It was noted that CA:C14-17 were present in 2 PVC samples, 2 rubber samples and 1 sample of unknown composition (clothesline). Country of origin of the consumer products: essentially outside EU	(McGrath et al., 2021c)
#02 - Rubber	Belgium	2019	Consumer products and toys (Consumer Flip flop, Rubber duck, Corner cover)	not detected - 0.035		
Polymer (unknown)	Belgium	2019	Consumer products and toys (Clothesline, Anti-slip mat) - unknown composition of the clothesline	not detected – 0.35		
Polymer (PP)	China	2019	Plastic animal feed packaging made with PP (polypropylene)	0.000062 - 0.0378	A total of 31 unused commercial animal feed packaging samples were collected from different animal feed manufacturers in China. 19 of the samples were made from PP and 12 of the samples were made from PE. CA:C14-17 were detected in all the animal feed packaging samples (n = 31).	(Dong et al., 2020a)
Polymer (PE)	China	2019	Plastic animal feed packaging made with PE (polyethylene)	0.000027 - 0.00279		
#02 - Rubber	China	2018-2019	Commercial rubber track product (e.g. used in schools)	0.0008 - 16	30 samples (15 commercial rubber track product samples, 10 rubber granule samples and 5 adhesive samples). The presence of CA:C14-17 was verified in all samples.	(Xu et al., 2019a)
#02 - Rubber	China	2018-2019	Rubber granule (raw material to make rubber track)	0.00000202– 0.0024		
#01 - Adhesives and sealants	China	2018-2019	Adhesives (raw material to make rubber track)	0.00434 - 22		

Use number and name	Geographical area of the study	Year of the study	Specified Applications	Reported range concentration [% (w/w)]	Comments	Reference
#00 - PVC	China	2018-2019	PVC soft plastic curtains (n=14)	3.65 - 27.91	A total of 124 product samples from markets in China, including PVC products (n=47), rubber and other plastics (n=17), leather materials (n=9), metalworking fluids (n=5), polyurethane foam adhesives (n=6), paints and varnishes (n=21), and textiles (n=19).	(Chen et al., 2021a)
#00 - PVC	China	2018-2019	PVC hosepipes for plumbing (n=10)	0.59 - 19.29		
#00 - PVC	China	2018-2019	PVC electrical cable sheathing (n=13)	0.01 - 9.41		
#00 - PVC	China	2018-2019	PVC plastic flooring (n=6)	0.31 - 5.79		
#00 - PVC	China	2018-2019	PVC plastic films (n=4)	0.007 - 0.16		
#02 - Rubber	China	2018-2019	Exercise mats (n=5)	0.18 - 16.69		
#02 - Rubber	China	2018-2019	Rubber foam insulation materials (n=5)	2.29 - 18.06		
#02 - Rubber	China	2018-2019	Rubber protectors (n=2)	not detected - 5.78		
#02 - Rubber	China	2018-2019	Coal conveyor belts (n=5)	not detected - 0.01		
#03 - Metalworking fluids	China	2018-2019	Metalworking fluids (n=5)	0.008 - 1.06		
#05 - Leather	China	2018-2019	Furtniture leather materials (n=5)	0.58 - 3.69		
#05 - Leather	China	2018-2019	Garment leather materials (n=4)	n.a.		
#01 - Adhesives and sealants	China	2018-2019	Polyurethane foam adhesives (n=6)	4.67 - 25.08		
#07 – Other (Lubricants)	Germany	2018	Hinges of different types of kitchen appliances (refrigerators, baking ovens, dishwashers, freezers, microwave oven, pasta machine, food processor, steam cooker)	0.000009 - 0.075	A total of 29 hinges of kitchen appliances were sampled by wipe tests in private households in Southern Germany: screened samples included 9 refrigerators, 7 baking ovens, 5 dish washers, 4 freezers, 1 microwave oven, 1 steam cooker, 1 pasta machine (PM), and 1 food processor. The presence of CA:C14-17 was noted in 18 samples.	(Sprengel and Vetter, 2021)
Polymer (unknown)	China	2018	Protective cases of mobile phones (PCMPs)	0.000317 (average concentration)	A total of PCMP samples, manufactured in China, were mainly divided into two categories according to the trade type. One	(Li et al., 2021c)

Use number and name	Geographical area of the study	Year of the study	Specified Applications	Reported range concentration [% (w/w)]	Comments	Reference
					was for domestic sales and available in China (China-PCMP, CPCMP) (n=86) and the other one was for export trade and available in the United Kingdom and the United States (UK/U.S.-PCMP, UPCMP) (n=10). Since polycarbonate (PC), thermoplastic polyurethane (TPU), and silica gel (SG) account for 80 % of the PCMP market,7 the samples in this study were also classified into the above three categories by different materials.	
#07 – Other (Textiles and fabric)	Norway	2018	Pullover with print	0.91	1 sample - no details on the article's origin	(EU Commission, 2019)
#07 – Other (Textiles and fabric)	Norway	2018	T-shirt with print	0.07	1 sample - no details on the article's origin	
#07 – Other (Textiles and fabric)	Norway	2018	Sports gloves	<LOQ	2 samples - no details on the article's origin	
#07 – Other (Textiles and fabric)	Norway	2018	Sports textile	0.65	1 sample - no details on the article's origin	
#02 - Rubber	Norway	2018	Sports yoga mats	1.70	1 sample - no details on the article's origin	
#07 – Other (Textiles and fabric)	Norway	2018	Textile car	0.15 - 0.31	3 samples - no details on the article's origin	
#07 -Other (packaging)	Norway	2018	Children product pillow packaging	2.70	1 sample - no details on the article's origin	
#02 - Rubber	Norway	2018	Children stroller bag plastic anti-slip mats	13	1 sample - no details on the article's origin	
#07 - Other (packaging)	Norway	2018	Children stroller bag packaging	11	1 sample - no details on the article's origin	
#07 – Other (Textiles and fabric)	Norway	2018	Foam textile children car seat	1.20	1 sample - no details on the article's origin	
#07 – Other (Textiles and fabric)	Norway	2018	Raincoat hat	7.30	1 sample - no details on the article's origin	
#00 - PVC	Norway	2018	USB-speaker wire	1.60	1 sample - no details on the article's origin	
#07 – Other (Textiles and fabric)	Norway	2018	Reflective bands	<LOQ - 4	4 samples - no details on the article's origin	

Use number and name	Geographical area of the study	Year of the study	Specified Applications	Reported range concentration [% (w/w)]	Comments	Reference
#07 – Other (Textiles and fabric)	Norway	2018	Duffy bag plastic	1.80	1 sample - no details on the article's origin	
#00 - PVC	Norway	2018	Power bank wire	7.20	1 sample - no details on the article's origin	
#07 – Other (Textiles and fabric)	Norway	2018	Children's Jacket (plastic detail)	<LOQ - 0.76	2 samples - no details on the article's origin	
#00 - PVC	Norway	2018	Children's pencil case	0.34	1 sample - no details on the article's origin	
#05 - Leather	Norway	2018	Shoe	<LOQ	1 sample - no details on the article's origin	
#00 - PVC	Norway	2018	Plastic football goal	<LOQ	1 sample - no details on the article's origin	
#07 – Other (Textiles and fabric)	Norway	2018	Rain hat	<LOQ	1 sample - no details on the article's origin	
#05 - Leather (?)	Norway	2018	Purse	<LOQ	1 sample - no details on the article's origin	
#02 - Rubber (?)	Norway	2018	Door gym power trainer	<LOQ	1 sample - no details on the article's origin	
#00 - PVC	Norway	2018	Light chain	2.00 -7.40	6 samples - no details on the article's origin	
#07 – Other (Textiles and fabric)	Norway	2018	Slippers	<LOQ - 0.91	2 samples - no details on the article's origin	
#02 - Rubber (?)	Norway	2018	Sports wrist band	3.40	1 sample - no details on the article's origin	
#07 – Other	Germany	2016	Baking ovens	not detected - 9.32	A total of 21 home bakery ovens were sampled by volunteers and subjected to wipe tests - a non-destructive technique used to investigate the existence of HFRs (halogenated flame retardants), such as CA:C14-17, on surfaces. The presence of CA:C14-17 was noted in 10 samples.	(Gallistl et al., 2018)
Polymer (unknown)	China	2015	Plastic track dust	0.2323 - 5.9173 (winter) 0.2596 - 8.5739 (summer)	A total of 148 settled dust samples from outdoor plastic sports courts (plastic track, plastic basketball court, and plastic tennis court) and synthetic turf from 17 universities in Beijing were collected in February (winter) and August (summer) 2015. Additionally, 11 dust samples were collected from indoor plastic badminton courts randomly selected from the 17 universities during the winter. In total 159 dust samples were analysed.	(Cao et al., 2019)
Polymer (unknown)	China	2015	Plastic basketball court dust	0.0255 - 3.2457 (winter) 0.0740 - 7.0438 (summer)		

Use number and name	Geographical area of the study	Year of the study	Specified Applications	Reported range concentration [% (w/w)]	Comments	Reference
Polymer (unknown)	China	2015	Plastic tennis court dust	0.0068 - 0.3259 (winter) 0.0215 - 1.3711 (summer)		
#02- Rubber	China	2015	Synthetic turf dust	0.002 - 0.1731 (winter) 0.0061 - 0.1957 (summer)		
Polymer (unknown)	China	2015	Indoor plastic badminton court dust	0.0318 - 1.4405 (winter)		
#02- Rubber	Germany, The Netherlands, and Spain	2006-2014	Car tires	0.00012 - 0.006	In total 25 samples were collected: 10 end of life car tires, 9 samples of rubber granulates, 6 playground tiles. CA:C14-17 were detected in all samples.	(Brandsma et al., 2019)
#02- Rubber	Germany, The Netherlands, and Spain	2006-2014	Rubber granulates	0.00081 - 0.0054		
#02- Rubber	Germany, The Netherlands, and Spain	2006-2014	Playground tiles	0.001 - 0.0051		
Polymer (PE)	China	n.a.	Domestic polymeric products made with PET (polyethylene): plastic bottles, oil tankers	not detected - 0.00001	A total of 108 samples were collected from markets and waste tire recycling stations in China. According to the differences in the materials, samples were divided in six subgroups, including PET n= 19, PP n= 18, PE n= 5, rubber n= 25 and PVC n= 21. The rest of the samples (n= 20) were food packaging (FP). CA:C14-17 were detected in 63 % of the samples.	(Wang et al., 2018a)
Polymer (PP)	China	n.a.	Domestic polymeric products made with PP (polypropylene): lunch boxes	not detected - 0.0036		
Polymer (PE)	China	n.a.	Domestic polymeric products made with PE (polyethylene): lunch boxes	not detected - 0.000018		

Use number and name	Geographical area of the study	Year of the study	Specified Applications	Reported range concentration [% (w/w)]	Comments	Reference
Polymer (unknown)	China	n.a.	Food packaging (including chips packaging, cookie packaging, dried fruit packaging and pie packaging)	not detected - 0.00103		
#00 - PVC	China	n.a.	Domestic polymeric products (cables sheathes, floorings, PVC tubes)	not detected - 0.0145		
#02- Rubber	China	n.a.	Domestic polymeric products (rubber tracks, tires, conveyors)	not detected - 2.28		
Polymer (unknown)	China	n.a.	Food packaging	0.0000458 - 0.0004304	In total 6 food packaging materials were analysed. CA:C14-17 were detected in all samples.	(Wang et al., 2019a)

Note: all congeners detected relate to CA:C14-17 except Xu et al. (2019a) which relates to CA:C14-15 only

A.2.2.5. Other internet searches

Table 23: External database search for additional uses to those indicated in the registration dossiers

Use#	Indicated use	Substance identifier	Technical function (if reported)	Source
Use#00	Use in plastics	EC 701-376-5 EC 263-004-3 EC 283-931-7 EC 285-195-2 EC 287-504-6 EC 307-451-5 EC 307-202-0 EC 263-004-3 EC 287-196-3 CAS 198840-65-2 Di-, tri- and tetrachlorotetradecane	Flame retardants, plasticising additives	[1][4]
Use#01	Use in sealants	EC 701-376-5 EC 272-924-4 EC 263-004-3 EC 283-931-7 EC 285-195-2 EC 287-504-6 EC 307-451-5 EC 307-202-0 EC 263-004-3 EC 287-196-3 CAS 198840-65-2 Di-, tri- and tetrachlorotetradecane	Flame retardants, plasticising additives	[1][4][5]
Use#02	Use in rubber	EC 701-376-5 EC 263-004-3 EC 283-931-7 EC 285-195-2 EC 287-504-6 EC 307-451-5 EC 307-202-0 EC 263-004-3 EC 287-196-3 CAS 198840-65-2 Di-, tri- and tetrachlorotetradecane	Flame retardants, plasticising additives	[1][4]
Use#03	Use in metalworking fluids	EC 272-924-4 EC 263-004-3 CAS 108171-27-3		[1][2][3]
Use#04	Use in paints and coatings	EC 272-924-4 EC 263-004-3 CAS 68410-99-1		[1][2]

Use#	Indicated use	Substance identifier	Technical function (if reported)	Source
Use#05	Use in textiles	EC 701-376-5 EC 263-004-3 EC 283-931-7 EC 285-195-2 EC 287-504-6 EC 307-451-5 EC 307-202-0 EC 263-004-3 EC 287-196-3 CAS 198840-65-2 Di-, tri- and tetrachlorotetradecane	Flame retardants, plasticising additives	[1][4]
Use#06	Use in paper manufacturing/recycling	-		
Use#07	Use in automotive fluids (e.g. castrols/motor oils, coolants)	EC 287-477-0* EC 272-924-4 EC 263-004-3		[1][5]
Use#07	Other uses in automotive industry e.g. tires	EC 263-004-3		[1]
Use#07	Use in cleaning and washing agents	EC 287-477-0*	Plasticiser, Extreme pressure additive, Solvent	[1][2]
Use#07	Use in non-agricultural pesticides and preservatives	EC 287-477-0*		[2]
Use#07	Use in solvents	EC 287-477-0*	Plasticiser, Extreme pressure additive, Solvent	[2]
Use#07	Use in aerosol propellants	EC 287-477-0*	Plasticiser, Extreme pressure additive, Solvent	[2]
Use#07	Use in food additives	EC 264-150-0*		[1]
Use#07	Use in pesticides	EC 264-150-0*		[1]
Use#07	Use in biocides	EC 264-150-0*		[1][2]
Use#07	Use in softeners	EC 264-150-0*		[1][2]
Use#07	Use in personal care products (conditioner)	EC 264-150-0* EC 263-004-3		[3]
Use#07	Use in softeners	EC 269-145-7*		[1][2]
Use#07	Use in lubricants (e.g. Bicycle Chain Lube)	EC 272-924-4		[5]

Note: **the substance is registered under REACH but additional use found in external databases*
Source: *[1] ACToR / CPCat (EPA Chemical and Product Categories)*
[2] SPIN product database
[3] US EPA comptox
[4] Chemsec sinlist
[5] USA Household Product Database (CPID)

Appendix B: Information on hazard and risk

B.1. Identity of the substance(s) and physical and chemical properties

B.1.1. Manufacturing process of chloroalkanes

Chloroalkanes are manufactured in batch process by the direct chlorination of n-alkanes (paraffins) or n-alkene feedstock with chlorine gas.

$C_xH_{(2x+2)} + y\ Cl_2 \rightarrow C_xH_{(2x-y+2)}Cl_y + y\ HCl$

A range of individual products are manufactured from the same alkane feedstock, each differing in chlorine content and level. Each product may differ in physical properties such as viscosity, refractive index and density. For example, increasing the chlorine content, results in products with higher viscosity and density.

The degree of chlorination is determined by the contact time with the chlorine gas. Once the desired degree of chlorination has been reached (as determined by density, viscosity or refractive index measurements), the flow of chlorine gas into the reaction is stopped, and air or nitrogen is then used to purge the reactor of excess chlorine and hydrochloric acid gas. The purging allows to stop the chemical reaction. The product is then filtered and piped to batch storage tanks for filling drums, tankers or bulk storage tanks.

The chlorination process involves random substitution of chlorine (Cl) for hydrogen (H) along the carbon chain of the paraffin feedstock. The chlorination process does not impact carbon to carbon bonds, only carbon to hydrogen bonds, thus the carbon chain lengths of the chloroalkanes are the same as the one from the starting feedstock.

The presence of CA:C14-17 in chloroalkanes depends on the carbon chain distribution of the starting material. It is therefore inherent to the manufacturing process, and in particular to the quality and specifications of the feedstock used.

In addition to the quality and specification of the feedstock, a registrant indicated during the ECHA market Survey that the presence and concentration of CA:C14-17 is possible if substances containing CA:C14-17 were previously produced in the same reactor as a chloroalkane. Therefore, other process circumstances such as cross contamination from one manufactured batch to another may also affect the presence of CA:C14-17.

B.1.2. Name and other identifiers of the substances in scope of the investigation

The substances listed in Table 24 contain or may contain 'chloroalkanes with carbon chain lengths within the range from C14 to C17' (aka CA:C14-17) in concentration above 0.1 % .

This list of substances is provided to facilitate the identification of substances that are under investigation and may fall within the scope of the restriction proposal if they contain more than 0.1 % of CA:C14-17 with PBT and/or vPvB properties. The list is intentionally broad, but not exhaustive. It may also contain substances that are not placed on the market yet.

The first four entries in Table 24 are explicitly listed on the ECHA website under Candidate List entry 'UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17'. In its final agreement, the Member State Committee (MSC) concluded indeed that these substances would contain more than 0.1 % of CA:C14-17 with PBT and/or vPvB properties (ECHA, 2021a).

For all the other substances listed in Table 24, the presence and concentration of CA:C14-17 with PBT and/or vPvB properties may depend on the quality and specifications of the feedstock or on the manufacturing circumstances as described in section B.1.1. The presence and concentration of CA:C14-17 with PBT and/or vPvB properties is therefore specific to each supplier/manufacturer of the substances. Further information is provided below the table to explain why the chloroalkanes listed in Table 24 are considered relevant for the scope of the investigation.

Analytical methods applicable to identify and quantify CA:C14-17 with PBT and/or vPvB properties in the listed substances are described in section B.1.5.

Table 24: Substances potentially in the scope of the REACH restriction proposal depending on their composition

Entry	EC#	CAS#	Name	Source
1	287-477-0	85535-85-9	Alkanes, C_{14-17}, chloro (aka 'MCCP' in Europe)	[1], [2], [3]
2	-	-	Di-, tri- and tetrachlorotetradecane	[1], [2], [3]
3	-	1372804-76-6	Alkanes, C_{14-16}, chloro	[1], [2]
4	-	198840-65-2	Tetradecane, chloro derivs.	[1], [2]
5	264-150-0	63449-39-8	Paraffin waxes and Hydrocarbon waxes, chloro (aka 'LCCP' in Europe)	[3], [4], [5]
6	281-985-6	84082-38-2	Alkanes, C_{10-21}, chloro (aka CP52 in Asia)	[2], [5]
7	272-924-4	68920-70-7	Alkanes, C_{6-18}, chloro	[2]
8	283-930-1	84776-06-7	Alkanes, C_{10-32}, chloro	[2]
9	283-931-7	84776-07-8	Alkanes, C_{16-27}, chloro	[2]
10	285-195-2	85049-26-9	Alkanes, C_{16-35}, chloro	[2]
11	287-504-6	85536-22-7	Alkanes, C_{12-14}, chloro	[2]
12	307-451-5	97659-46-6	Alkanes, C_{10-26}, chloro	[2]
13	307-202-0	97553-43-0	Paraffins (petroleum), normal $C_{>10}$, chloro	[2]

Entry	EC#	CAS#	Name	Source
14	288-211-6	85681-73-8	Alkanes, C10-14, chloro	[2]
15	-	104948-36-9	Alkanes, C10-22, chloro	[6]
16	-	126207-70-3	Heptadecane, chloro-	[6]
17	-	129521-61-5	Alkanes, C14-32, chloro	[6]
18	-	159715-72-7	Pentadecane, 3,5,7,9,11,13-hexachloro-	[6]
19	-	221174-08-9	Tetradecane, 1,2,13,14,?-pentachloro-	[6]
20	-	221174-09-0	Tetradecane, 1,2,13,14,?,?-hexachloro-	[6]
21	-	2233595-19-0	Pentadecane, 2,5,6,11,14-pentachloro-	[6]
22	-	276673-41-7	Octachloropentadecane	[6]
23	-	276673-44-0	Hexachlorohexadecane	[6]
24	-	276673-45-1	Octachlorohexadecane	[6]
25	-	28085-66-7	Heptachloroheptadecane	[6]
26	-	308061-49-6	Chloroalkanes, C14-18	[6]
27	-	360790-74-5	Chloroalkanes, C17-20	[6]
28	-	3922-32-5	1,1,1,15-Tetrachloropentadecane	[6]
29	-	57437-53-3	Tetradecane, tetrachloro-	[6]
30	-	57437-56-6	Pentachloropentadecane	[6]
31	-	57437-57-7	Hexadecane, pentachloro-	[6]
32	-	57437-58-8	Heptachlorohexadecane	[6]
33	-	57437-60-2	Hexachloropentadecane	[6]
34	-	57437-61-3	Heptachloropentadecane	[6]
35	-	62108-59-2	1,1,1-Trichloropentadecane	[6]
36	-	67095-51-6	1,1,1,3-Tetrachloropentadecane	[6]
37	-	700864-25-1	Hexadecane, tetrachloro-	[2]
38	-	700864-27-3	Hexachloroheptadecane	[2]
39	-	700864-28-4	Octachloroheptadecane	[2]
40	-	700864-29-5	Nonachloroheptadecane	[2]
41	-	865306-25-8	Tetradecane, 1,1,1,3-tetrachloro-	[2]
42	-	866758-65-8	Chloroalkanes, C12-16	[2]
43	-	97262-09-4	Pentadecane, tetrachloro-	[2]
44	263-004-3	61788-76-9	Alkanes, chloro	[2]
45	287-196-3	85422-92-0	Paraffin oils, chloro	[2]
46	-	2097144-44-8	Slack Wax (petroleum), chloro	[6]
47	-	39443-51-1	WK 30 (chloroparaffin)	[6]
48	-	52737-80-1	KhP 1100	[6]
49	-	68410-99-1	Alkenes, polymd., chlorinated	[6]
50	-	68477-12-3	Alkanesulfonic acids, chloro	[6]
51	-	106232-85-3	Alkanes, C18-20, chloro	[6]
52	-	108171-27-3	Chloroalkanes, C22-26	[6]

Entry	EC#	CAS#	Name	Source
53	-	2097144-45-9	Alkanes, C20-24, chloro	[6]
54	-	308061-50-9	Chloroalkanes, C18-26	[6]
55	-	308061-51-0	Chloroalkanes, C22-24	[6]
56	287-478-6	85535-86-0	Alkanes, C18-28, chloro	[2]
57	-	106232-86-4	Alkanes, C22-40, chloro	[6]
58	-	127133-59-9	Alkanes, C21-38, chloro	[6]
59	-	1392825-28-3	Alkanes, C19-28-branched and linear, chloro	[6]
60	-	1401974-24-0	Alkanes, C22-30-branched and linear, chloro	[6]
61	-	1402738-52-6	Alkanes, C24-28, chloro	[6]
62	-	1417900-96-9	Alkanes, C21-34-branched and linear, chloro	[6]
63	-	1632986-67-4	Alkanes, C22-32, chloro	[6]
64	-	2097144-43-7	Alkanes, C20-28, chloro	[6]
65	-	288260-42-4	Alkanes, C22-30, chloro	[6]
66	-	-	Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated, saponified	[3], [4]
67	269-145-7	68188-19-2	Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated	[3], [4]
68	273-276-5	68955-41-9	Alkanes, C10-18, bromo chloro	[2]
69	-	-	Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified	[3], [4]

Source: [1] Candidate list
[2] (ECHA, 2021d)
[3] ECHA dissemination website consulted on 13 April 2022 (REACH registered substance fact sheet)
[4] Information submitted during the calls for evidence, or the Registrants' survey
[5] Literature review
[6] Expert judgement from substance identity experts only

Entry #1 to #4 in Table 24:

These substances fall within the scope of the Candidate List 'MCCP' entry (defined as 'UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17'). These substances contain CA:C14-17 with PBT and/or vPvB properties in concentration > 0.1 %.

Entry #5 in Table 24:

This entry corresponds to the chloroalkanes often described as 'long chain chlorinated paraffins (or 'LCCP')' in Europe.

These chloroalkanes predominantly consist of carbon chain lengths in the range of C18 to C36. These substances may have different compositions, for example:

- liquid 'LCCP' predominantly consisting of C18-20 carbon chain lengths (with a chlorination level between 40 % and 52 %)
- liquid 'LCCP' predominantly consisting of carbon chain lengths longer than C20 (with a chlorination level between 40 % and 54 %)

- solid 'LCCP' predominantly consisting of carbon chain lengths longer than C20 (with a chlorination level above 70 %)

'LCCP' having carbon chain lengths longer than C20 may also be referred to as very long chain chlorinated paraffins (vLCCP).

Neither the EC nor the CAS name associated to the EC and CAS numbers describe a specific carbon chain distribution, and although the predominant carbon chain lengths present in this substance are $\geq$18, its composition may include as well shorter carbon chain lengths than C18.

ECHA dissemination site[11] (consulted on 13 April 2022) lists seven active and two inactive registrations associated to EC 264-150-0. Fourteen legal entity compositions are reported in the REACH registrations, and among them, three compositions clearly indicate the presence of CA:C14-17. Information gathered from the BfR products database also indicates that a variety of substances having different carbon chain lengths have been identified using EC 264-150-0 (cf. section 0).

In the POP listing proposal (UK, 2021), UK indicates that the presence of C14-17 carbon chain lengths is indeed reported in the composition of the substance identified with EC 264-150-0 *("LCCP predominantly consisting of C18-20 carbon chain length"*).

This information was also confirmed by the REACH registrants during the Registrants' survey: CA:C14-17 and CA:C14-17 with PBT and/or vPvB properties may be present in EC 264-150-0.

As explained in section B.1.1, the presence of CA:C14-17 with PBT and/or vPvB properties in EC 264-150-0 may depend on the presence of C14-17 chain lengths in the alkane/alkene feedstock and on the manufacturing circumstances used to manufacture that substance and may be specific to the manufacturer/supplier.

According to the information available from the ECHA dissemination website, and received via the various industry consultations (CfE and Registrants' survey), it appears that CA:C14-17 with PBT and/or vPvB properties may be present in these chloroalkanes in various concentration levels up to ca.20 % . Concentration levels below 0.1 % are mostly expected when the feedstock to produce 'LCCP' predominantly consists of carbon chain lengths longer than C20. Concentration levels above 0.1 % and up to 20 % are mostly expected when the feedstock to produce 'LCCP' predominantly consists of carbon chain lengths C18-20.

It also appears that the downstream users of 'LCCP' do not have any information regarding the composition of the chloroalkanes they purchase, and therefore may not know if the substance contains or not CA:C14-17 with PBT and/or vPvB properties, and at which concentration levels.

A majority of registrants of 'LCCP' informed the Dossier Submitter, during the various industry consultations (CfE and Registrants' survey), that they would already fulfil the

[11] https://echa.europa.eu/registration-dossier/-/registered-dossier/14895

potential restriction conditions because the substances already contain <0.1 % of CA:C14-17 (and therefore <0.1 % of the CA:C14-17 with PBT/VPvB properties). However relevant data supporting these statements are currently not included in their registration dossiers.

Other registrants, who reported concentration levels of CA:C14-17 > 0.1 % indicated that they could comply with the restriction concentration limit by changing the supply source and specifications of their feedstock. In particular, the use of feedstocks with carbon chain lengths above 20 may enable reducing the concentration of CA:C14-17 below 0.1 %.

The restriction proposal may therefore be relevant for some of the 'LCCP' compositions placed on the market.

Entry #6 in Table 24:

This entry corresponds to the chloroalkanes often known as 'CP52' in Asia. This substance is not registered under REACH but may be present in imported articles from China.

Based on its name (Alkanes, C10-21, chloro), these chloroalkanes are likely to contain CA:C14-17. The presence and concentration of CA:C14-17 with PBT/vPvB properties may vary depending on the chlorine content.

Koh et al (2002) presents also the distribution of carbon chain lengths in CP-52 as corresponding to 33.66 % for C10-13 and 60.05 % for C14-17 (as well as 6.29 % for C18-21 and overall, 11 different chain lengths at >0.1 %).

Entry #7 to #43 in Table 24:

The names associated to these EC and CAS entries specify carbon chain lengths overlapping with the carbon chain lengths C14-17. These chlorinated paraffins contain or are likely to contain CA:C14-17. The presence and concentration of CA:C14-17 with PBT and/or vPvB properties may vary depending on the chlorine content.

Entry #44 to #50 in Table 24:

The chemical names corresponding to these EC and CAS entries do not specify the carbon chain lengths expected to be present in the composition of the substances described by these entries.

Nevertheless, the name of these chloroalkanes is generic and substances identified with a generic name may be covered by the restriction proposal. Therefore, even though it is not possible to conclude with certainty if these chloroalkanes would contain CA:C14-17 and CA:C14-17 with PBT and/or vPvB properties, the presence of these constituents in the composition cannot be excluded.

Entry #51 to #65 in Table 24:

The names associated to these entries do not specify carbon chain lengths that would correspond to C14-17. However, it should be noted that the naming conventions for substances having variable carbon chain lengths are such that the names, EC/CAS entries used for describing these substances may not specify all possible carbon chain lengths present in the composition. This may happen especially for the carbon chain lengths

present at lower concentration levels.

Therefore, it can be concluded that these entries may have been used to describe substances containing CA:C14-17 and CA:C14-17 with PBT and/or vPvB properties.

Entry #66 to #69 in Table 24:

According to the information available from the ECHA dissemination website, and received via the various industry consultations, it appears that CA:C14-17 with PBT and/or vPvB properties may be present in these substances in varying concentration levels. These constituents may be present from low concentration levels (below 0.1 %) to higher concentration levels (up to ca. 10 %).

Some companies using or manufacturing these substances indicate that the presence and concentration of CA:C14-17 congener groups with PBT and/or vPvB properties depends on (i) the feedstock (presence of C14-17) used and, (ii) the completion of the sulfonation/bromination reaction of the chloroalkanes during the manufacturing, (iii) the level of chlorination, and (iv) the potential of cross-contamination when the manufacturing vessel is not properly cleaned between batches of different chloroalkanes.

However, some users of these substances informed the Dossier Submitter, during the various industry consultations, that they would already fulfil the potential restriction conditions because the substances already contain <0.1 % of CA:C14-17 (and therefore <0.1 % of the CA:C14-17 with PBT/VPvB properties). These users also confirmed that their suppliers (i.e. the EU manufacturers or importers) are indeed already using alkanes/alkene feedstocks with < 0.1 % of C14-17 chain lengths.

The information disseminated on ECHA website, available in the registration dossiers, and provided via the consultations, did not allow to conclude that all the substances with these identifiers would fall within the scope of the proposed restriction.

Some substances may already have concentration levels of CA:C14-17 with PBT and/or vPvB properties below 0.1 %, while others may include CA:C14-17 at concentration levels >0.1 % up to 10 %.

The restriction proposal may therefore be relevant for these substances but may depend on the supply chain.

B.1.3. Theoretical chlorine content of CA:C14-17

Table 25 provides an overview of the theoretical chlorine content of CA:C14-17.

This allows a comparison with the scope proposed by UK in their POP identification proposal (UK, 2021). It should be noted that the UK POP listing proposal intend to restrict 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥ 45 %'. This differs in term of scope from the SVHC identification agreement (which covers in fact congener groups with C14-C17 chain lengths and chlorination levels that can be as low as 32.3 % (w/w)).

Table 25: Theoretical chlorine content of CA:C14-C17 congener groups

Chlorine content	Congener formula			
% w/w	C14	C15	C16	C17
<40 %	$C_{14}H_{29}Cl$ to $C_{14}H_{27}Cl_3$	$C_{15}H_{31}Cl$ to $C_{15}H_{29}Cl_3$	$C_{16}H_{33}Cl$ to $C_{16}H_{30}Cl_4$	$C_{17}H_{35}Cl$ to $C_{17}H_{32}Cl_4$
40-45 %	$C_{14}H_{26}Cl_4$	$C_{15}H_{28}Cl_4$	$C_{16}H_{29}Cl_5$	$C_{17}H_{31}Cl_5$
45-50 %	$C_{14}H_{25}Cl_5$	$C_{15}H_{27}Cl_5$	$C_{16}H_{28}Cl_6$	$C_{17}H_{30}Cl_6$
50-55 %	$C_{14}H_{24}Cl_6$	$C_{15}H_{26}Cl_6$ and $C_{15}H_{25}Cl_7$	$C_{16}H_{27}Cl_7$	$C_{17}H_{29}Cl_7$
55-65 %	$C_{14}H_{23}Cl_7$ to $C_{14}H_{21}Cl_9$	$C_{15}H_{24}Cl_8$ to $C_{15}H_{22}Cl_{10}$	$C_{16}H_{26}Cl_8$ to $C_{16}H_{23}Cl_{11}$	$C_{17}H_{28}Cl_8$ to $C_{17}H_{25}Cl_{11}$
>65 %	$C_{14}H_{20}Cl_{10}$ and higher no. of Cl atoms	$C_{15}H_{21}Cl_{11}$ and higher no. of Cl atoms	$C_{16}H_{22}Cl_{12}$ and higher no. of Cl atoms	$C_{17}H_{24}Cl_{12}$ and higher no. of Cl atoms

Source: Support document to the 'MCCP' Annex XV SVHC identification proposal (ECHA, 2021d)
Note: in blue, the congeners not covered by the UK POP proposal – outcome of the POP risk profile UNEP/POPS/POPRC.18/11/Add is available from http://www.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC18/Overview/tabid/9165/Default.aspx

$C_{14}H_{27}Cl_3$ is equivalent to 35.3 % Chlorine content

For information, according to the MSC agreement on the SVHC identification of 'MCCP' (ECHA, 2021a) which is reproduced in section B.4:

- $C_{14}Cl_{3–11}$ congener groups (with PBT and/or vPvB properties) are equivalent to 35.3—67.6 % Cl wt
- $C_{15}Cl_{3–8}$ congener groups (with PBT and/or vPvB properties) are equivalent to 33.8—58.2 % Cl wt.
- $C_{16}Cl_{3–8}$ congener groups (with PBT and/or vPvB properties) are equivalent to 32.3—56.6 % Cl wt.
- $C_{17}Cl_{6–9}$ congener groups (with PBT properties) are equivalent to 47.65—58 % Cl wt.

B.1.4. Substances listed in the UK POP proposal

Table 26 indicates a non-exhaustive list of chloroalkanes that *"may be associated with C14-17 chain lengths"* according to the UK in their POP listing proposal (UK, 2021). The entry number in the first column of the table corresponds to the entry number in Table 24.

It is important to note that this information does not pre-empt on the final scope of the POP listing process.

Table 26: Substances that may contain CA:C14-17 according to the UK POP listing proposal (non-exhaustive list)

Entry	EC#	CAS#	Name
1	287-477-0	85535-85-9	Alkanes, C_{14-17}, chloro (aka 'MCCP' in Europe)
3	-	1372804-76-6	Alkanes, C_{14-16}, chloro
4	-	198840-65-2	Tetradecane, chloro derivs.
5	264-150-0	63449-39-8	Paraffin waxes and Hydrocarbon waxes, chloro (aka 'LCCP' in Europe)
6	281-985-6	84082-38-2	Alkanes, C_{10-21}, chloro (aka CP52 in Asia)
7	272-924-4	68920-70-7	Alkanes, C_{6-18}, chloro
8	283-930-1	84776-06-7	Alkanes, C_{10-32}, chloro
9	283-931-7	84776-07-8	Alkanes, C_{16-27}, chloro
10	285-195-2	85049-26-9	Alkanes, C_{16-35}, chloro
11	287-504-6	85536-22-7	Alkanes, C_{12-14}, chloro
12	307-451-5	97659-46-6	Alkanes, C_{10-26}, chloro
13	307-202-0	97553-43-0	Paraffins (petroleum), normal $C_{>10}$, chloro
14	288-211-6	85681-73-8	Alkanes, C10-14, chloro
44	263-004-3	61788-76-9	Alkanes, chloro
45	287-196-3	85422-92-0	Paraffin oils, chloro
46	-	2097144-44-8	Slack Wax (petroleum), chloro

Source: (UK, 2021)

Entry #2 from Table 24 'Di-, tri- and tetrachlorotetradecane' has a chlorination level below 45 % and therefore does not fall within the scope of the UK POP proposal.

Entries #66 to 69 from Table 24 do not specify any chlorination degree. It may be that they were not listed by UK because these substances are chlorinated paraffins derivatives.

B.1.5. Analytical methods

B.1.5.1. Overview of analytical methods and techniques available

A wide range of analytical methods and techniques are nowadays available to detect and quantify CA:C14-17.

In recent years, the development of new technologies has significantly improved the performance of available analytical methods. These technologies are based on high

resolution mass spectrometers (HRMS) interfaced with gas chromatography (GC), two dimensional GC, high performance liquid chromatography (LC) or by means of direct injection combined with complex calculation algorithms to elaborate the measurement of very precise mass-fragments. Results with those technologies (GC-ECNI-HRMS, LC-ESI-HRMS and LC-ESI-TOF-MS) were found to be comparable both to each other in interlaboratory exercises (Mézière et al., 2020b).

Table 27 below provides an overview of the most commonly applied analytical methods and techniques that may be used for the identification and quantification of chloroalkanes, including CA:C14-17, in various types of samples (substances, mixtures, articles of different matrix types).

The instrumental analytical methods listed in Table 27 are either (i) validated by international recognised organisations (e.g. International Organization for Standardization), or (ii) developed in research laboratories, following a peer review process and published by recognised scientific journals.

Depending on the instruments and technologies, the most common analytical target (i.e. what is 'detected' from the sample) may be:

- the presence of halogenated compounds, or
- a group of compounds with specific carbon chain length, or
- a specific or several groups of chloroalkane congeners[12].

The analytical procedures standardised or described by scientific literature include sample preparations similar to other chlorinated organic persistent pollutants such as polychlorobiphenyls and dioxins. When attention is given to contamination and recovery, the selection of the sample preparation strategy is not a factor that seems to impact the results (cf. also section B.1.5.3 on challenges). Typically, samples are extracted with solvents by the use of Soxhlet or by pressurized liquid extraction (pressurised liquid extraction (PLE) or accelerated solvent extraction (ASE) and other solvent combinations).

The analytical methods and techniques in Table 27 vary from low-resolution 'screening' methods which provides a total concentration of chloroalkanes as a single value, to the most 'advanced' analytical methods that can provide more reliable and targeted results. This is achieved with the use of appropriate analytical instrumentations and their combination, such as GC (gas chromatography) and GCXGC (two-dimensional gas chromatography) coupled with different detection systems as HR-MS (high resolution mass spectroscopy), HRLC-MS (ultra-performance liquid chromatography coupled with quadrupole time-of-flight mass spectrometry) and recently also association with NMR (Nuclear magnetic resonance spectroscopy)(Yuan et al., 2020, Yuan et al., 2019a).

The (EI) GC-MS method (#03 in Table 27) is a well-known screening method. This type of equipment is commonly found in standard laboratories and can be used for determining chloroalkanes. It should also be noted that validated ISO methods (ISO 18219-1:2021, ISO 18219-2:2021, ISO 22818:2021) have been developed with GC-MS by using electron-

[12] i.e. a group of constituents sharing the same molecular formula irrespective of the position of the chlorine substituents on the carbon chain (e.g. the C15Cl7 congener group)

capture negative ionisation (GC-ECNI-MS) and are focused on the quantification of short- and medium-chain chloroalkanes. The analysis of chloroalkanes with longer chain may also be partially achieved. These methods are based on low resolution mass spectrometry. They are not fully accurate due to potential interferences and quantification issues. For example, interferences from longer chloroalkanes and other chlorinated organic substances can lead to an overestimation of short- and medium-chain chloroalkanes when applied for samples where, also such substances are present. This is particularly true for environmental samples and where the concentrations are low. Therefore, low resolution MS screening method may be considered adequate only as a measurement providing a "yes/no" type response, indicating the presence (or the absence) of the typical profile for the short- and medium-chain chloroalkanes - but not providing an accurate quantification and a sharp distinction of the congener groups. Generally, these methods should not be used to provide a quantification of individual chloroalkane congener groups.

The 'advanced' analytical methods can, instead, separately quantify:

- chloroalkanes with medium carbon chain lengths within the range from C14 to C17 (CA:C14-17) distinguished from short carbon chain lengths $\leq C_{13}$ (CA:C≤C13) and distinguished from long carbon chain lengths $\geq C_{18}$ (CA:C≥C18),
- up to detailed individual chloroalkane congener groups (C_nCl_m) and
- the isomeric distributions of CP mixtures with single chain lengths but varying degrees of chlorination.

It is important to mention that, in the absence of specific information regarding the manufacturing process, not even the most advanced analytical methods and techniques can differentiate signals generated by a specific chloroalkane substance described by an EC or CAS number because it is not possible to determine to which substance the constituents detected belong to.

Table 27: Analytical instruments and detectors used for detecting and quantifying chloroalkanes

Instrument	#	MODE	Resolution / Quality	Detection technique	Analytical target	CA	Short-chain CA:≤C13	Medium-chain CA:C14-17	Long-chain CA:≥C18	Possible use as a ' screening' method to confirm the absence of CA:C14-17	Possible use as an ' advanced' method to confirm the presence and concentration of CA:C14-17
Gas Chromatography (GC)	01	n.a.	LR	Electron Capture Detector (ECD)	Halogen	**x**				**YES**	NO
	02	n.a.	LR	Flame Ionisation Detector (FID)	Alkanes (dechlorination catalyst) – carbon skeleton analysis (Cn)	**x**	**x**	**x**	**(x)**	**YES**	NO
	03	Electron Impact ionisation (EI)	LR	Sector mass spectrometer (SECTOR MS)	1) Critical phase extraction and clean up 2) Deuterium derivatisation Target: Deuterated CPs generated "in situ" with the derivatisation	**x**				**YES**	NO
	04	EI	LR	Triple Quadrupole Tandem (QQQ-MS/MS)		**x**				**YES**	NO
	05	EI/ECNI	LR	Ion trap mass spectrometer (ION TRAP-MS)		**x**				**YES**	NO
	06	EI	HR	Quadrupole / time-of-flight mass spectrometry (Q-TOF - MS)		**x**				**YES**	NO
	07	ECNI	LR	SECTOR MS	M-Cl-,(M-HCl-)	**x**	**x**	**x**	**(x)**	**YES**	NO
	08	ECNI (+ DCM dichloromethane)	LR	SECTOR MS	M-Cl-,(M-HCl-)		**x**	**x**	**(x)**	**YES**	**YES**
	09	ECNI	HR	Q-TOF	M-Cl-,(M-HCl-)		**x**	**x**	**(x)**	**YES**	**YES**

Instrument	#	MODE	Resolution/ Quality	Detection technique	Analytical target	CA	Short-chain CA:≤C13	Medium-chain CA:C14-17	Long-chain CA:≥C18	Possible use as a ' screening' method to confirm the absence of CA:C14-17	Possible use as an ' advanced' method to confirm the presence and concentration of CA:C14-17
	10	ECNI	HR	ORBITRAP MS	M-Cl-,(M-HCl-)		**x**	**x**	**(x)**	**YES**	**YES**
	11	ECNI	HR	Q-ORBITRAP MS	M-Cl-,(M-HCl-)		**x**	**x**	**(x)**	**YES**	**YES**
	12	ECNI	LR	Quadrupole Mass Spectrometer (Q-MS)	M-Cl-,(M-HCl-)		**(x)**	**(x)**	**(x)**	**YES**	NO
Two dimensional Gas Chromatography (GCxGC or 2D – GC)	13			ECD	Halogen					**YES**	NO
	14	ECNI		Q-MS	M-Cl-,(M-HCl-)		**(x)**	**(x)**	**(x)**	**YES**	**YES**[1]
	15			QTOF-MS	M-Cl-,(M-HCl-)		**x**	**x**		**YES**	**YES**[1]
Ultra High Performance Liquid Chromatography UHPLC	16	Atmospheric Pressure Chemical Ionization CI-APCI		Q-MS	M+Cl-					**YES**	**YES** [1]
	17			Q-ORBITRAP-MS	M+Cl-					**YES**	**YES** [1]
	18	Electrospray Ionization CI-ESI	HR	Q-TOF-MS	M+Cl-		**x**	**x**	**x**	**YES**	**YES**
Direct injection in HR-MS (High Resolution Mass	19	Cl-APCI	HR	Q-TOF-MS	M+Cl-		**x**	**x**	**x**	**YES**	**YES**
	20	Br-APCI	HR	Q-TOF-MS	M+Br -		**x**	**x**	**x**	**YES**	**YES**

Instrument	#	MODE	Resolution/ Quality	Detection technique	Analytical target	CA	Short-chain CA:≤C13	Medium-chain CA:C14-17	Long-chain CA:≥C18	Possible use as a ' screening' method to confirm the absence of CA:C14-17	Possible use as an ' advanced' method to confirm the presence and concentration of CA:C14-17
Spectrometry)											

Note: [1] the analytical instrument and detector could be used as an 'advanced' method but would first need to be supported by additional publications and peer-review between laboratories.

Acronyms used in the table:

Br-APCI – Bromide-enhancement - Atmospheric-Pressure Chemical Ionization
CA:≤C13 – Chloroalkanes with carbon chain lengths shorter or equal than C13
CA: C14-17 - Chloroalkanes with carbon chain lengths within the range from C14 to C17
CA:≥C18 - Chloroalkanes with carbon chain lengths longer or equal to C18
CI: Chemical Ionisation (ionisation mode)
CI-APCI -- Atmospheric pressure chemical ionisation (ionisation mode)
DCM : Dichloromethane
ECD – Electron capture detector
ECNI - electron-capture negative ionisation (ionisation mode)
ESI: Electrospray Ionization
EI – Electron Impact ionisation (ionisation mode)
FID – Flame ionisation detector
GC – Gas Chromatography
GC x GC: Two dimensional Gas Chromatography
HR - High Resolution
LoD – Limit of detection
LoQ – Limit of quantification
LR - Low Resolution
MS - Mass Spectrometer
Q- MS – Quadrupole Mass spectrometer
ORBITRAP – orbital ion trap mass analyser consisting of an outer barrel-like electrode and a coaxial inner spindle-like electrode that traps ions in an orbital motion around the spindle
Q-ORBITRAP MS : Hybrid Quadrupole-Orbitrap mass analyser, mass spectrometer
Q-TOF-MS -Quadrupole – Time of flight Mass Spectrometer (high resolution)'hybrid' instrument combining quadrupole technologies with a time-of-flight mass analyser
UHPLC Ultra High Performance Liquid Chromatography

Additional details regarding the analytical methods:

For chloroalkanes, gas chromatography (#01 to 12 in Table 27) is the preferred separation technique. Commonly GC is coupled to either analogue detectors or mass spectrometer detectors. Each of these detection techniques have advantages and disadvantages. Analogue systems such as GC-flame ionization detectors (FID) or GC-electron capture detectors (ECD) suffer from poor selectivity, which makes it impossible to distinguish between chloroalkanes and other halogenated chemicals that may co-elute with the targeted chloroalkanes of interest. Therefore, an ordinary (low-resolution) mass spectrometer (ionisation with EI or with NCI) coupled with gas chromatography, may be preferred over GC with detection by the analogue detectors above. In particular, GC/MS by using electron capture negative ionization (ECNI) has been one of the most widely applied technique for chloroalkanes analysis due to the relatively simple and common instrumentation as well as the presence of validated analytical standards suitable for routine analysis that needs to be practicable and time-effective.

However, all the techniques mentioned above suffer from chemical interferences from other halogenated organic compounds. For an accurate detection of the congener group patterns, analytical laboratories are increasingly turning to GC systems coupled to "high-resolution accurate mass (HRAM)" mass spectrometry such as the quadrupole Orbitrap GC-MS/MS system, or Quadrupole – Time of flight Mass Spectrometer. The high resolving power and consistent 'sub-ppm' mass accuracy can provide selective detection and excellent quantification of chloroalkanes, even in complex matrices.

High resolution mass spectrometry is rapidly developing, showing the potential to be an excellent quantitation platform with the ability to distinguish homologue patterns and capable of compensating for the limited chromatographic separation. This is also the reason why the use of direct injection−APCI−Orbitrap/MS method (in absence of any pre-separation) has been further developed in the last years with successful results even though it does not allow for identification of a "fingerprint" profile of the chloroalkanes mixture by chromatography. For direct injection, in the scientific papers it is shown that reliable detection of chloroalkanes can be achieved when large number of homologues are present.

As opposite strategy, effective chromatographic separation of chloroalkanes congeners has been achieved using two-dimensional gas chromatography (GC×GC): two GC columns with different retention mechanisms are used in sequence. Undoubtedly, chromatographically separating congener groups combined with high resolution mass spectrometry improves the accuracy in quantification of chloroalkanes in samples.

A comparison of these two methods (i.e., GCxGC vs direct injection) shows that the calculated LOQs for the standard mixtures are lower for direct injection−APCI−Orbitrap/MS. However, the LOQ values are lower for the GC × GC−NCI−QTOF/MS method (Tien et al., 2021). This is due to the high separation capacity of this method, which enables the injection of sample extracts at increased concentrations. LOD values are lower for the GC × GC method because of the additional identification via the chromatographic pattern. Another difference is that direct injection does not include a separation of compounds. Therefore, potential interference is greater, both with other compounds and between different chloroalkane congeners. As a result of chromatographic

separation of interfering substances and identification of specific chloroalkanes homologues in the form of bands, more precise quantification can be achieved using the GC × GC−NCI−QTOF/MS method. GC/HR MS has been demonstrated to provide sensitive quantification of medium chain chloroalkanes.

Appropriate liquid chromatography-ESI-HRMS parameters enables optimal and simultaneous detection of short, medium and long chains chloroalkanes. This technique has been successfully applied more recently for the simultaneous analysis, in one single injection, of chloroalkanes of small, medium and long chain length (from 10 to 36 carbons) and provides significant advantages over GC/HRMS in its homologue resolving capabilities (Mézière et al., 2020a).

B.1.5.2. Overview of analytical standards available

Analytical standards are important to run the screening methods listed in Table 27 and are essential for quantifying the presence of CA:C14-17 by advanced analytical methods.

Certified[13] standard solutions for the analysis of chloroalkanes have been available on the market for years. However, the number of standards and the variety of specifications available on the market nowadays have increased exponentially, as shown in Table 28 and Table 29.

In the past, most of the available analytical standards were based on standard mixtures (so called "technical mixtures") that reflected the commercial products available on the market. A number of developed published methods refers to the use of standards selected by the authors mainly as 'medium chain chlorinated' mixture standards (C14 -C17 with 42 %, 52 %, and 57 % chlorine contents, 100 ng µL−1 in cyclohexane). These standards provide important information when determining the total concentration of chloroalkanes or the generic subdivision in the overall quantification of the short, medium or long chain chloroalkanes content.

For an appropriate quantification of specific chloroalkane congeners, laboratories depend on the selection of (a set of) standards with specific compositions. With high resolution mass spectrometry method, response factors for each congener group are required in order to perform accurate quantitative analysis of individual congener groups in complex samples. In the scientific literature, standards with single carbon chain length, were proven to provide good results (Yuan et al., 2016). This is also the reason why, in the past few years, the need for more single chain standards (or any commercially available single chain standards) was clearly identified as mandatory for an accurate quantification of CA:C14-17. Many standards of this type have been recently developed, as shown in Table 28 and Table 29.

In practice, a real sample to be analysed does not display the profile of an artificially manufactured standard having a pre-defined single chain length. It is therefore very important that the laboratory identifies the type (profile) of CA:C14-17 present in the

[13] A certified standard or reference material (CRM) is a compound certified by some trusted organization to be of consistent and very carefully measured quality and composition, often being used as a quality control in analytical laboratories.

sample and define the most appropriate set of standards to be used for the quantification. In particular, information on chain length specific concentrations is a key information for standards of high quality to provide the reliable results when it is required to quantify specific congener groups.

It is now possible to find a range of standards for CA:C14-17 chloroalkanes that cover congener groups with specific carbon chain length (C14, C15, C16, C17) and with different average chlorination degree (cf. Table 28 below). These standards are delivered with a specific certificate of analysis, meaning that that they are provided together with detailed information on chromatographic patterns and the quantitative results for the congener groups present in the standard.

Table 28: Single Chain Standards with different average chlorination level – Availability of standards useful to quantify congener groups by advanced analytical methods (state of play: December 2022)

Single Chain Standards with different average chlorination level
Chloroalkanes single chain length C14, 65 % Cl
Chloroalkanes single chain length C14, 60 % Cl
Chloroalkanes single chain length C14, 55 % Cl
Chloroalkanes single chain length C14, 52 % Cl
Chloroalkanes single chain length C14, 45 % Cl
Chloroalkanes single chain length C15, 65 % Cl
Chloroalkanes single chain length C15, 60 % Cl
Chloroalkanes single chain length C15, 55 % Cl
Chloroalkanes single chain length C15, 50 % Cl
Chloroalkanes single chain length C15, 45 % Cl
Chloroalkanes single chain length C16, 65 % Cl
Chloroalkanes single chain length C16, 60 % Cl
Chloroalkanes single chain length C16, 55 % Cl
Chloroalkanes single chain length C16, 50 % Cl
Chloroalkanes single chain length C16, 45 % Cl
Chloroalkanes single chain length C17, 60 % Cl

Source: Standard producers' website

CA:C14-17 single chain standards are commercially available from LGC/Dr. Ehrenstorfer. A full set of CA:C14-17 single chain length standards is also available upon request from the EURL[14] for method development purposes.

In addition, also 'pure' chlorinated compounds or specific isomers are available and can be used to improve the accuracy of quantification (cf. Table 29).

Recently, the project CHLOFFIN (Development of reference standards for the analysis of

[14] https://www.eurl-pesticides.eu/docs/public/home.asp?LabID=100&Lang=EN

chloroalkanes) aimed at producing around 89 individual standards of chloroalkane congener groups (including 20 CA:C14-17 individual and/or labelled), 8 labelled individual chloroalkane congener groups (including for CA:C14-17 specifically 3,4,7,8,11,12-Hexachlorotetradecane–1,2,3-$^{13}C_3$, 3,4,7,8,12,13-Hexachloropentadecane–13,14,15-$^{13}C_3$, 1,2,8,9,13,14- Hexachlorohexadecane–14,15,16-$^{13}C_3$), 10 congener mixtures that are well-characterised and purity assessed and one matrix certified refence material (CRM, CA:C10-13 and CA:C14-17)[15]. The objective is that the resulting standards would have a defined composition and response factors. These standards are intended for quantification of CA:C14-17 as well as helping distinguish the various congener groups according to carbon chain length and chlorine content.

The available reference standards including configurationally defined individual chloroalkane congener standards are synthetised by Chiron AS (Trondheim, Norway) and are available here: Reference Materials Environmental analysis CHLOFFIN Standards (chiron.no). New available reference standards are added on regular basis.

For CA:C14-17 an ultra-pure standard for the compound: 1,2,5,6,9,10,13,14-Octachlorotetradecane ($C_{14}H_{22}Cl_8$) with chlorination degree of Cl: 59.8 at a Conc.: 100 µg/mL in isooctane has also been prepared (http://chloffin.eu/index.php?id=chloffin-reference-materials).

Finally, with regard to the quantification of CA:C14-17, it should be noted that a more accurate quantification is achieved when using a combination of standards (e.g. single carbon chain standard with chlorination level, and single carbon chain standard with number of chlorine atoms) rather than one standard only.

[15] Matrix CRM commercially available: https://crm.jrc.ec.europa.eu/p/ERM-CE100

Table 29: Single Chain Standards with number of chlorine atoms – Availability of standards useful to quantify congener groups by advanced analytical methods (state of play: June 2022)

	Cl_1	Cl_2	Cl_3	Cl_4	Cl_5	Cl_6	Cl_7	Cl_8	Cl_9	Cl_{10}	Cl_{11}	Cl_{12}	Cl_{13}	Cl_{14}	Cl_{15}	Cl_{16}	Cl_{17}
C_{14}		√SI, √Mc	√Mc	√SI, √Mc	√Mc	√SI, √Mc	√SI, √Mc	√SI, √Mc	√Mc								
C_{15}	√M	√M	√M	√M	√M	√SI, √M	√M	√M	√M	√M	√M	√M	√M	√M	√M	√M	√M
C_{16}	√SI, √M	√M	√M	√M	√M	√SI, √M	√M	√SI, √M	√M	√M	√M	√M	√M	√M	√M	√M	√M
C_{17}	√M	√M	√M	√M	√M	√SI, √M	√SI, √M	√SI, √M	√M	√M	√M	√M	√M	√M	√M	√M	√M

Source: Standard producers' websites

Note: the yellow cells indicate the congener groups with PBT and/or vPvB properties

√ - congener standard available: $\surd_{MC}$ *single C-chain length and chlorine mixture with certified n° Cl*

$\surd_{M}$ *single C-chain length and chlorine mixture - without certified n° Cl*

$\surd_{SI}$ *single C&Cl isomer or single stereoisomer mix*

B.1.5.3. Challenges associated with analytical methods, techniques, and standards

Challenges associated with sample and testing preparations:

First, it is important to be aware that contamination issues in laboratories may often occur. The challenges presented below are not specific only to CA:C14-17 but applicable to all the (halogenated) ubiquitous environmental pollutants.

It should be considered that when performing analytical campaigns for CA:C14-17 a thorough study of the laboratory background and blanks including all the phases of the analytical procedure starting from the sample preparation, shall be performed in advance to the analysis.

All reagents and all the different apparatus and automated systems (for preparation, sampling, and detection) must be controlled to ensure that the background contamination shows concentration levels compatible with the objectives of the analyses and those levels should be monitored for each batch subject to be analysed. As far as possible the laboratory may choose to substitute plasticware with glassware, metal or other-non-PVC material. It is also mandatory to make use of pesticide-grade reagents and solvents and to conduct a careful assessment of the residual level of contaminants while performing the analytical procedure.

Challenges associated with the UVCB nature of CA:C14-17:

As explained in previous sections, it is recognised that for all chloroalkanes that the vast number of isomers and complexity of the groups of congeners (CnClm) creates complication in analytical measurements. This is one of the reasons why most of the experts and researchers in the field prefer to rely on the use of separation techniques (as chromatography) in combination with an appropriate detection method, and why the technological developments of technical instruments is a key pillar for the challenge posed by this analysis.

Please refer to section B.1.5.1 for further details.

Challenges associated with the availability of standards:

In the past, a limited number of analytical standards and the lack of certified reference materials has prevented the implementation of robust calibration/validation procedures. As explained in section B.1.5.2, research projects financed under public investment schemes have significantly improved the quality and the number/type of standards available. The notable results obtained (and still subject to further achievements) are also the results of the advances in the understanding of the composition of these mixtures obtained by using the most recent technological solution in instrumental analytical chemistry: the two dimensional GC further empowered by high resolution (HR) MS such as quadrupole time of flight (Q-TOF) as well as using ultra-high-performance liquid chromatography coupled with Orbitrap Fusion Tribrid mass spectrometry allowed the development of a variety of technical and certified standards that, being newly synthetised and better characterised, are now more effectively used in the analyses of short and

medium chain chlorinated alkanes.

B.1.5.4. Proposed analytical tiered approach for enforcement

As indicated in section B.1.5.1, semi-qualitative/low resolution analytical techniques and methods may be used as a 'screening' method to provide a "yes/no" type response to the question 'does the sample contains chloroalkanes'. Such screening methods, characterised by analogue and low resolution MS detection methods, may indicate the presence (or the absence) of the typical profile for the short- and medium-chain chloroalkanes providing an estimation of the concentration of all CPs detected in a sample, without distinction of groups, chain lengths or homologue groups. If liquid chromatography is used instead of gas chromatography, this parameter may include LCCPs.

Depending on the choice of instrument and quantification method among those listed in Table 27, the possible results include the qualitative assessment of the presence of chloroalkane and a quantitative estimation of total chloroalkane contamination levels however they cannot provide an accurate quantification and a sound distinction of the congener groups, and it cannot be used to provide a quantification for individual carbon-chlorine congener groups.

Nevertheless, by balancing the potential limitations of these low resolution screening methods and their advantages as they are less costly and they are widespread instruments, present nearly in every chemical-analytical laboratory (see ECHA survey to EU enforcement labs in section B.1.5.5), the following analytical tiered approach may be proposed for enforcing the proposed restriction on the presence of CA:C14-17 congeners with PBT and/or vPvB properties in substances, mixtures and articles, in a more efficient and wide-spread manner.

Figure 1 illustrates a possible analytical tiered approach that could be used by the enforcement authorities to enforce the proposed restriction.

Given that low-resolution methods (as identified in Table 27[16]) are commonly available in EU laboratories working for the EU enforcement authorities (ECHA survey). Such low-resolution methods could be used as first screening methods to confirm the absence of CA:C14-17. Indeed, in case the low-resolution screening method (Tier 1) provides a 'no' response for the presence of chloroalkanes (CP in the figure), then it can be concluded that the tested sample does not contain any CA:C14-17 congeners of concern.

In case the low-resolution screening method provides a 'yes' response, then the presence of CA:C14-17 of concerns would need to be confirmed and the quantification of individual carbon-chlorine congener groups shall be performed using advanced analytical methods (Tier 2).

[16] The last-but one two columns in the table indicate which analytical methods could be used as Tier 1 (low resolution screening methods), and/or Tier 2 (advanced analytical methods).

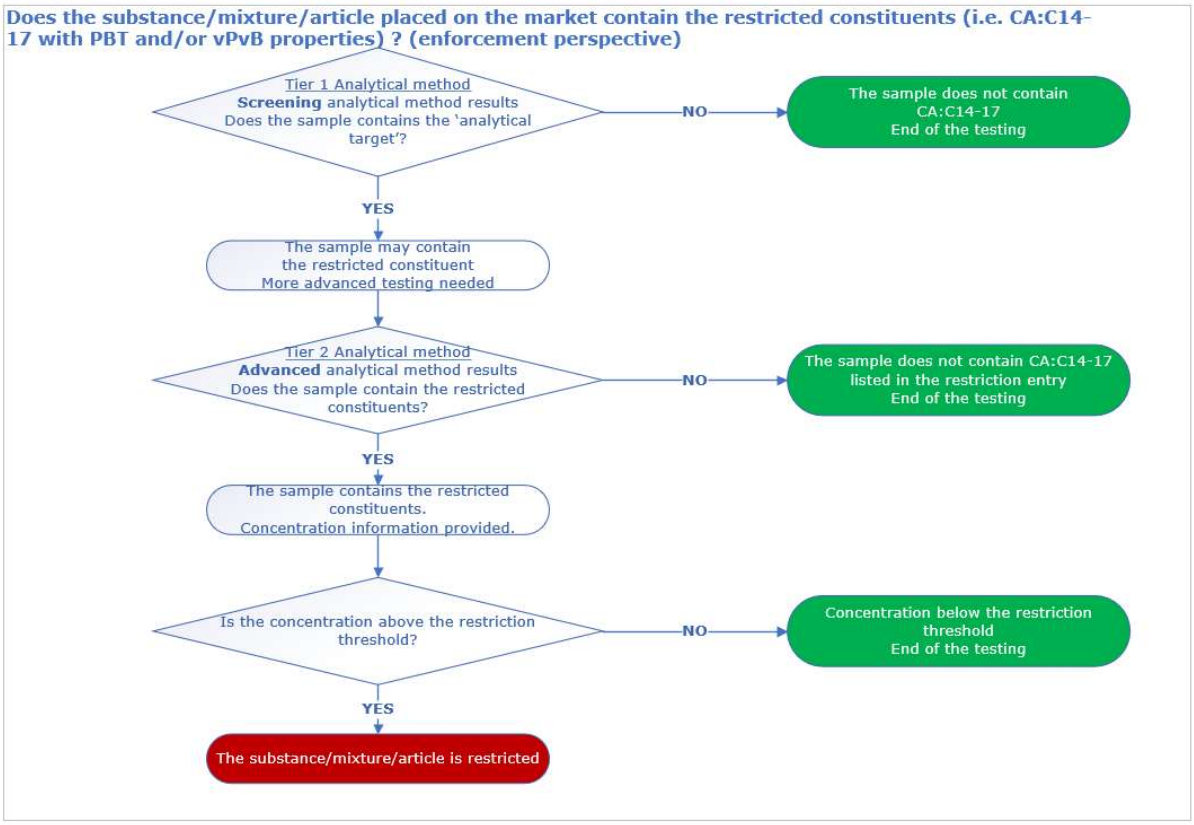


Figure 1: Proposed tiered approach

B.1.5.5. Results of the FORUM survey on laboratory equipment

Via the FORUM and its members, the Dossier Submitter conducted a survey in order to collect information and assess the availability of analytical methods for enforcing the proposed restriction on CA:C14-17 with PBT and/or vPvB properties.

The target audience of this survey were reference and official laboratories involved in enforcement activities including customs laboratories, but also private laboratories working for enforcement authorities.

The survey was open from 01/03/2022 to 08/04/2022.

The survey included a first set of questions to better understand the type of analytical instruments and methods available in the enforcement laboratories in Europe (corresponding to the analytical instruments and detectors listed in Table 27). The remaining questions were about the enforcement labs potential experience with testing and analysing chloroalkanes.

An overview of the results is presented below.

18 enforcement laboratories from 14 different EU MS responded to the survey. All of them have screening analytical methods available, and ~ 55 % of them (10 out of 18) are equipped with at least one of the advanced detection methods and instruments described

in Table 27.

Table 30: Number and type of respondents to the FORUM Survey

Country of origin of the enforcement laboratory	Type of laboratory	Countries for which laboratory activities are performed
Belgium	A public laboratory	Belgium
Belgium	A private laboratory	Global market
Belgium	A private laboratory	EU + USA + Middle East
Belgium	A private laboratory	Europe
Czech Republic	A private laboratory	more than 65 countries
Finland	A public laboratory	Finland
Germany	A public laboratory	Germany
Hungary	A private laboratory	Hungary
Ireland	A public laboratory	Ireland
Ireland	A public laboratory	Ireland
Latvia	A public laboratory	Latvia
Poland	A public laboratory	Poland
Portugal	A public laboratory	Portugal
Romania	A public laboratory	Not specified
Slovenia	A public laboratory	Slovenia
Spain	A public laboratory	Spain
Sweden	A public laboratory	Sweden
The Netherlands	A public laboratory	Sweden, Finland, England

Table 31: Number of enforcement laboratories equipped with analytical instruments suitable for the enforcement of the restriction proposal

Instrument	#	MODE	Resolution	Detection technique	Possible use as a ' screening' method to confirm the absence of CA:C14-17	Possible use as an ' advanced' method to confirm the presence and concentration of CA:C14-17	Number of laboratories equipped with the analytical instrument
Gas Chromatography (GC)	01	n.a.	LR	ECD	YES	NO	**6**
	02	n.a.	LR	FID	YES	NO	**12**
	03	EI	LR	SECTOR MS	YES	NO	**4**
	04	EI	LR	QQQ-MS/MS	YES	NO	**13** [2]
	05	EI/ECNI	LR	ION TRAP-MS	YES	NO	**4** [2]
	06	EI	HR	Q-TOF - MS	YES	NO	**1**
	07	ECNI	LR	SECTOR MS	YES	NO	**0**
	08	ECNI (+ DCM	LR	SECTOR MS	YES	YES	**3** [2]

Instrument	#	MODE	Resolution	Detection technique	Possible use as a ' screening' method to confirm the absence of CA:C14-17	Possible use as an ' advanced' method to confirm the presence and concentration of CA:C14-17	Number of laboratories equipped with the analytical instrument
		dichloromethane)					
	09	ECNI	HR	Q-TOF	YES	YES	**0**
	10	ECNI	HR	ORBITRAP MS	YES	YES	**0**
	11	ECNI	HR	Q-ORBITRAP MS	YES	YES	**0**
	12	ECNI	LR	Q-MS	YES	NO	**4** [2]
Two dimensional Gas Chromatography (GCxGC or 2D – GC)	13			ECD	YES	NO	**0**
	14	ECNI		Q-MS	YES	YES[1]	**0**
	15			QTOF-MS	YES	YES[1]	**2**
Ultra High Performance Liquid Chromatography UHPLC	16	CI-APCI		Q-MS	YES	YES [1]	**6**
	17			Q-ORBITRAP-MS	YES	YES [1]	**7** [2]
	18	CI-ESI	HR	Q-TOF-MS	YES	YES	**4** [2]
Direct injection in HR-MS (High Resolution Mass Spectrometry)	19	Cl-APCI	HR	Q-TOF-MS	YES	YES	**0**
	20	Br-APCI	HR	Q-TOF-MS	YES	YES	**0**

Note: list of analytical instruments based on Table 27
[1] the analytical instrument and detector could be used as an 'advanced' method but would first need to be supported by additional publications and peer-review between laboratories.
[2] analytical instrument and detector reported to be used by at least one laboratory for detecting chloroalkane in a sample

According to the survey, eight laboratories (i.e. ~ 45 % of the respondents) have already analysed the presence and/or quantification of chloroalkanes in samples, essentially article for enforcement activities (building material, PVC, leather), but also in environmental and food samples. Various carbon chain lengths of chloroalkanes were tested by these laboratories including CA:C10-13 and CA:C14-17. In average the analysis were performed per batch of 20 samples.

For analysing the samples, the enforcement laboratories followed analytical methods standardised according to /or internal methods based on ISO 12010, ISO 5667-3, ISO 22818, ISO 18219-1 (SCCP), ISO 18219-2 (MCCP), ISO 18635.

The main challenges reported by the enforcement laboratory when performing analysis re. the presence and/or quantification of chloroalkanes in samples were related to:

- Results calculations
- Preparation and clean-up of the samples (for environmental samples)

Regarding the costs associated to the analysis of samples containing chloroalkanes, some of the respondents indicated that testing chloroalkanes is in general more expensive than other types of substances for the following reasons:

- analytical standard costs,
- time to do results calculation which are performed by scientist rather than by laboratory technicians,
- instrumental cost,
- time in the lab.

B.1.6. Physicochemical properties

The substances in the scope of the restriction) are mainly UVCB substances and the constituents would have different physico-chemical properties[17] and thus behave differently. Therefore the Dossier Submitter did not use the physico-chemical properties of each 'substance', but rather the physico-chemical properties of the chloroalkanes with carbon chain lengths within the range from C14 to C17. The values that have been reported in (ECHA, 2021d) and/or the CSR of substance EC 287-477-0, which are representative for the chloroalkanes with carbon chain lengths within the range from C14-17, have been used and extrapolated to all the substances in the scope of the restriction. It is noted, however, that even within the CA:C14-17, the chain length and the chlorination level (which may be present in various proportions) influence these properties, and only a range of values may be available. This generic approach for the assessment of the fate of the substances in the WWTP is based on the chloroalkanes with carbon chain lengths within the range from C14-17, which are contained in all the substances in the scope of the restriction despite the variability of their compositions.

The physical chemical properties summarised in Table 32 are the most commonly found values for these parameters in the scientific literature. Use of these values does not represent an official position or acknowledgement of the validity of these values by the European Chemicals Agency.

[17] Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7a: Endpoint specific guidance, Version 6.0, July2017.

Table 32: Key physico-chemical properties

Property	Value
Vapour pressure	C14-17 chlorinated n-alkane 45 % Cl wt: 2.27 x 10-3 Pa at 40°C and 0.16 Pa at 80°C [1][2]
	C14-17 chlorinated n-alkane 52 % Cl wt: 1.3 - 2.7 x 10-4 Pa at 20 °C [3] (values used for the fate modelling), 1.07 x 10-3 Pa at 45 °C, 6 x 10-3 Pa at 60 °C and 0.051 Pa at 80 °C [2]
	A vapour pressure of 0 Pa at 20 °C has been considered in the CSR.
Water solubility	C14 chlorinated n-alkane 50 % Cl wt: 0.0061 mg/L at 20 °C [4]
	C15 chlorinated n-alkane 51 % Cl wt: 0.005-0.027 mg/L at 20 °C [5]
	C16 chlorinated n-alkane 52 % Cl wt: 0.01 mg/L (freshwater) – 0.004 mg/L (seawater) at 16-20 °C [6]
	The water solubility of 0.027 mg/L is considered to be a realistic upper limit for C14-17 chloroalkanes (CSR and Annex XV SVHC report)
Partition coefficient n-octanol/water (log Kow)	C14 chlorinated n-alkane 50 % Cl wt: 6.58 ± 0.09 [7]
	C16 chlorinated n-alkane 35 % Cl wt: 7.2 (4.7-8.3) [8]
	C14-17 chlorinated n-alkane 45 % Cl wt: 5.52 to 8.21 [9]
	C14-17 chlorinated n-alkane 52 % Cl wt: 5.47 to 8.01 [9]
	C14Cl1-14: 6.2-8.25 [10]
	C15Cl1-15: 6.63 – 8.76 [10]
	C16Cl1-16: 7.07 - 9.28 [10]
	C17Cl1-16: 7.33 - 9.8 [10]
	Approximate value: 7 (middle of the range of measured values) (CSR)
Boiling point	Decomposition at around 200 °C before boiling [1]

Source: Joint CSR submitted by the lead registrant of EC 287-477-0 on 13 January 2022; (ECHA, 2021d) ([1] EC, 2005, [2] BUA, 1992 (as cited in EC, 2005 and UK 2020), [3] Campbell and McConnell, 1980, [4] Unpublished, 2019a; non-GLP OECD Test Guideline (TG) 105. Analytical method: APCI-ToF-HRMS, [5] Madeley, et al., 1983; non-standard method. Analytical method: thin-layer chromatography and radioactivity measurements. Key study used in EC (2005), [6] Campbell and McConnell, 1980; method unknown. Analytical method: radioactivity measurements, [7] Unpublished, 2019b; non-GLP OECD TG 123 (slow stir). Analytical method: APCI-ToF-HRMS. Very little variability in Kow was observed between differently chlorinated constituent groups, [8] Fisk, 1998b; cited in EC (2005). Analytical method: high performance liquid chromatography (HPLC), [9] Renberg et al. (1980); non-GLP non-guideline study. Analytical method: reversed-phase high performance thin layer chromatography (RP-HPTLC), [10] Predicted log Kow with log P methods of ACD Percepta, ACD/Labs release 2019.2.1, Advanced Chemistry Development, Inc., 2019).

B.2. Environmental fate properties

Details on environmental fate properties are available in the corresponding agreement of the ECHA MSC (ECHA, 2021a) and support documents (ECHA, 2021d) available on the ECHA website. Readers are referred directly to these documents for additional information: https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e185e9de96

B.3. Human health hazard assessment

The restriction proposal is based on the concluded PBT/vPvB properties of CA:C14-17. The assessment of the human health hazard is therefore not relevant.

For information - the information below reproduces the brief summary of the human health

assessment from the support document to the SVHC identification of 'MCCP' (defined as UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17) (ECHA, 2021d).

Further details as the basis for this brief summary is available in the human health risk assessment report produced under the Existing Substances Regulation EC (No.) 793/93 (HSE, 2008). It should be noted that the human health risk assessment report was on EC 287-477-0 and that one commercial product type was used for the majority of regulatory studies.

- **Repeated dose toxicity:** The target organs for repeated oral dose toxicity are liver, thyroid and kidney. The lowest reliable NOAEL is 23 mg/kg/day from a 90-d study with F344 rats Rattus norvegicus (CXR Biosciences Ltd, 2005), based on increased relative kidney weights. The European Food Safety Authority (in prep.) has derived a BMDL1028of 36 mg/kg bw/day from this study.
- **Carcinogenicity:** No carcinogenicity studies have been conducted. EC 287-477-0 are generally unreactive and not mutagenic. The carcinogenic potential of EC 287-477-0 are expected to be similar – at least in qualitative terms – to that of SCCP, although direct read across is not appropriate. SCCP induce liver and thyroid adenomas and carcinomas and kidney tubular cell adenomas and carcinomas in animal studies. The liver and thyroid tumours are considered to be of little or no relevance to human health. It cannot be completely ruled out that the kidney toxicity observed for EC 287-477-0 might lead to kidney cancer in rats through a non-genotoxic mode of action. However, EC 287-477-0 are not classified for this end point under Regulation EC No. 1272/2008.
- **Toxicity to reproduction:** EC 287-477-0 have no apparent effect upon fertility in rats up to approximately 400 mg/kg/day in the diet. No adverse developmental effects occurred during gestation in rats or rabbits in two conventional developmental studies using maternal doses up to 5 000 and 100 mg/kg/day, respectively. In contrast, exposure of Wistar rats R. norvegicus to C14-17 n-chloroalkane 52 % Cl wt. at a maternal dietary dose of 74 mg/kg/day (1 000 ppm) up to approximately 400 mg/kg/day (6 250 ppm) produced internal haemorrhaging and deaths in the pups (IRDC, 1985). Follow-up studies with Sprague Dawley and CD rats (CXR Biosciences Ltd, 2003, CXR Biosciences Ltd, 2004, CXR Biosciences Ltd, 2006) demonstrated that EC 287-477-0 can perturb blood clotting. In adult females that had been treated for 7-8 weeks including pregnancy and lactation, decreased levels of vitamin K and of the clotting factors VII and X were found, and 5 out of 32 dams showed signs of haemorrhaging during parturition. However, these decreases did not affect their prothrombin times, indicating that the functional reserve in the majority of these adult animals was sufficient. The foetus in utero apparently receives sufficient vitamin K via the placenta, but after birth becomes severely deficient in vitamin K and related clotting factors and relies on the mothers' milk to receive them. Exposure to EC 287-477-0 in the milk may also further reduce their vitamin K levels. This in turn leads to a severe vitamin K deficiency in the neonates and consequently to haemorrhaging. This is the basis for the harmonised classification for effects via lactation (H362 – May cause harm to breast-fed children) according to Regulation EC No. 1272/2008.

From the studies available, an overall NOAEL of 47 mg/kg/day (600 ppm) as a maternal dose can be identified for these effects mediated via lactation. However, it should be noted that the effects (11 % reduction in pup survival and related haemorrhaging) observed at the LOAEL (74 mg/kg/day; 1 000 ppm) were not statistically significant. Haemorrhaging was also seen in one study at the time of parturition in 16 % of dams given 538 mg/kg/day (6 250 ppm), but not up to 100 mg/kg/day (1 200 ppm) in other studies. The NOAEL of 100 mg/kg/day (1 200 ppm) was therefore selected for the risk characterisation of haemorrhaging effects potentially occurring in pregnant women at the time of parturition.

B.4. PBT and vPvB assessment

Figure 2 and Figure 3 reproduce the key conclusions from the Member State Committee supporting the identification of 'MCCP' as SVHC with PBT and vPvB properties (ECHA, 2021a).

Further details as the basis for these conclusions are available in the corresponding agreement of the ECHA MSC (ECHA, 2021a) and support documents (ECHA, 2021d) available on the ECHA website. Readers are referred directly to these documents for additional information: https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e185e9de96

Conclusion on the P, B and T properties

On the basis of all the evidence available, it is concluded that the $C_{14}Cl_{3–11}$ congener groups of MCCP (equivalent to 35.3–67.6% Cl wt.) have PBT and/or vPvB properties, $C_{15}Cl_{3–8}$ congener groups of MCCP (equivalent to 33.8–58.2% Cl wt.) have PBT and/or vPvB properties, $C_{16}Cl_{3–8}$ congener groups of MCCP (equivalent to 32.3–56.6% Cl wt.) have PBT and/or vPvB properties and $C_{17}Cl_{6–9}$ congener groups of MCCP (equivalent to 47.65–58% Cl wt.) have PBT properties in accordance with Annex XIII of the REACH Regulation (see **Table 1**).

Based on the information available, as MCCP contain congener groups with PBT and/or vPvB properties (see **Table 1**) at a concentration ≥ 0.1 % (w/w), it is concluded that MCCP meet the criteria for a PBT and/or vPvB substance in accordance with Annex XIII of the REACH Regulation, and thereby they fulfil the criteria set out in REACH Articles 57(d) and/or (e).

*(Note - some of the PBT and/or vPvB congener groups of MCCP listed in **Table 1** have been identified in other substances than MCCP, thus suggesting that these substances also could be considered to meet the REACH Annex XIII criteria for a PBT and/or vPvB substance if these congener groups are present in a concentration ≥ 0.1 % (w/w)).*

9 (11)

Figure 2: Conclusion on the P, B and T properties of CA:C14-17 (extract 1)
Source: (ECHA, 2021a)

Table 1: Congener groups of MCCP concluded as PBT and/or vPvB in accordance with the criteria set out in Annex XIII of the REACH Regulation

Number chlorine atoms and Carbon chain length	Cl_1	Cl_2	Cl_3	Cl_4	Cl_5	Cl_6	Cl_7	Cl_8	Cl_9	Cl_{10}	Cl_{11}	Cl_{12}	Cl_{13}	Cl_{14}	Cl_{15}	Cl_{16}	Cl_{17}
C_{14}	-	-	**vPvB**	**vPvB PBT**	**vPvB PBT**	**vPvB PBT**	**vPvB PBT**	**vPvB**	**vPvB**	**vPvB**	**vPvB**	-	-	-			
C_{15}	-	-	**vPvB**	**vPvB**	**vPvB PBT**	**PBT**	**PBT**	**PBT**	-	-	-	-	-	-	-		
C_{16}	-	-	**vPvB**	**vPvB**	**vPvB PBT**	**PBT**	**PBT**	**PBT**	-	-	-	-	-	-	-	-	
C_{17}	-	-	-	-	-	**PBT**	**PBT**	**PBT**	**PBT**	-	-	-	-	-	-	-	-

Note: Symbol '-' means that not enough information is available to conclude whether the congener group has PBT and/or vPvB properties. Grey cells means congener groups not considered in the PBT/vPvB assessment.

Figure 3: Conclusion on the P, B and T properties of CA:C14-17 (extract 2)
Source: (ECHA, 2021a)

B.5. Exposure assessment

B.5.1. General discussion on releases and exposure

B.5.1.1. Summary of the existing legal requirements

Existing legal requirements under REACH

The use of substances satisfying the PBT and vPvB criteria has to comply with Annex I, 6.5 of the REACH regulation, which establishes that "the manufacturer or importer shall use the information as obtained in Section 5, Step 2 [exposure estimation] when implementing on its site, and recommending for downstream users, risk management measures which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses."

This obligation to implement and recommend risk management measures which minimise exposures and emissions to humans and the environment applies to the substances included in the Candidate List, but also to substances containing PBT/vPvB constituents above 0.1 %.

Information on existing legislations in European Union relevant for two of the registered substances is available on ECHA's website under EU Chemicals Legislation Finder (EUCLEF)[18]. They are listed in Table 33.

Please also refer to section E.1.4.

Table 33: Existing legal requirements (based on EUCLEF)

		EC 287-477-0	di-, tri- and tetrachlorotetradecane
REACH Regulation (Regulation (EC) No 1907/2006): Candidate List of SVHC for authorisation		x	x
CLP Regulation (Regulation (EC) No 1272/2008): Harmonised classification		x	
Active Implantable Medical Devices Directive-repealed (Directive 90/385/EEC amended by Directive 2007/47/EC)	About	x	
CAD - Chemical Agents Directive (Directive 98/24/EC)	About	x	
CMD - Carcinogens and Mutagens Directive (Directive 2004/37/EC (CMRD) amended by Directive (EU)	About	x	

[18] EC 287-477-0: https://echa.europa.eu/legislation-obligation/-/obligations/100.079.497; 'Di-, tri- and tetrachlorotetradecane': https://echa.europa.eu/legislation-obligation/-/obligations/100.275.290; 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified', 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified', EC 264-150-0, EC 269-145-7: not available. EUCLEF accessed 23 June 2022.

		EC 287-477-0	di-, tri- and tetrachlorotetradecane
2022/431)			
Construction Products Regulation (Regulation 305/2011/EU amended by Regulation 574/2014/EU)	About	x	x
End-of-Life Vehicles Directive (Directive 2000/53/EC amended by Directive 2020/363/EU)	About	x	
EU Ecolabel Regulation (Regulation 66/2010/EC)	About	x	x
Food Contact Active and Intelligent Materials and Articles Regulation (Regulation 450/2009/EC)	About	x	
General Product Safety Directive (Directive 2001/95/EC amended by Regulation 596/2009/EC)	About	x	x
In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC)	About	x	x
Marine Environmental Policy Framework Directive (Directive 2008/56/EC amended by Directive 2017/845/EU)	About	x	x
Medical Devices Directive-repealed (Directive 93/42/EEC amended by Directive 2007/47/EC)	About	x	
Medical Devices Regulation (Regulation 2017/745/EU amended by Regulation 2020/561/EU)	About	x	x
Protection of Pregnant and Breastfeeding Workers Directive (Directive 92/85/EEC)	About	x	
Safety and Health of Workers at Work Directive (Directive 89/391/EEC amended by Regulation 1137/2008/EC)	About	x	
WFD - Waste Framework Directive (Directive 2008/98/EC amended by Directive 2018/851/EU)	About	x	
Seveso III Directive (Directive 2012/18/EU)		x	

B.5.1.2. Summary of the effectiveness of the implemented operational conditions and risk management measures

Please refer to main report (section 1.5).

B.5.2. Key input parameters and assumptions for the exposure assessment

CA:C14-17 can be released to the environment at all stages of their life cycle: manufacture, formulation of mixtures, production of articles, use of mixtures at industrial sites, use of mixtures by professionals and consumers, service life, as well as from disposal as waste and waste treatment (ECHA, 2021b). The large diversity of products containing CA:C14-17 that are placed on the market and used lead to wide dispersive releases to the environment during their life cycle and especially when they turn into waste.

As these substances are mainly used as plasticisers and flame retardants, they are not intended to react or transform but are instead expected to remain in the final product or article. It is therefore expected that the main source for releases to the environment will be from service life and from waste. Furthermore, the substances do not degrade naturally and therefore the whole amount used, that is not destroyed intentionally, may end up in the environment. The total tonnage potentially released to the environment can be as high as the tonnage placed on the market minus the tonnage destroyed (e.g. by incineration), reused (e.g. by recycling), and exported.

This section aims to detail the assumptions made by the Dossier Submitter to estimate the emissions of CA:C14-17 to the environment.

B.5.2.1. Relevant exposure scenario per use

The starting point for the exposure assessment is a review of the latest[19] submitted CSRs by the registrants, to identify the relevant exposure scenarios.

Based on the further details gathered during the calls for evidence and the ECHA market study, exposure scenarios have been added, removed or revised. The overview of the uses which forms the basis of these exposure scenarios is described in the Annex XV report.

The list of selected exposure scenarios is depicted in Table 34 below. The exposure scenarios covered by the registrants in their CSRs are identified with the corresponding EC numbers. The Dossier Submitter assumed that these uses #00 to #07 also apply to unregistered substances.

[19] Joint CSR submitted by the lead registrant of EC 287-477-0 on 13 January 2022; joint CSR submitted by the lead registrant of 'Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated, saponified' on 31 October 2013; joint CSR submitted by the lead registrant of EC 264-150-0 on 6 August 2019; joint CSR submitted by the lead registrant of 'Paraffin waxes and hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified' on 22 February 2019. No CSR available for the other substances.

Table 34: Exposure scenarios of interest for the proposed restriction

Use name	Life cycle stages/sub-scenarios	Substances registered for these uses
Manufacturing	Manufacture	[1], [2], [3], [4], [6]
Use#00: Use in PVC	Formulation (compounding), industrial use (conversion – production of articles), service life	[1], [2]
Use#01: Use in adhesive and sealants	Formulation, industrial use, professional and consumer use, service life	[1], [2]
Use#02: Use in rubber	Formulation (compounding), industrial use (production of articles), service life	[1], [2]
Use#03: Use in metalworking fluids	Formulation, industrial use oil-based metalworking fluids	[1], [2]
Use#04: Use in paints and coatings	Formulation, industrial use, professional and consumer use, service life	[1], [2]
Use#05: Use in leather	Formulation of mixtures, incorporation in leather, service life	[3], [4]
Use#06: Use in paper manufacturing/recycling	Not assessed (obsolete use)	[1], [2]
Use#07: Other uses	Formulation, professional and consumer use	[1], [2], [5]
Use as an intermediate under strictly controlled conditions	Not assessed	[6]
Waste handling	Shredding, landfilling, incineration (see B.5.2.3)	Not addressed in registration dossiers

Note: *[1] EC 287-477-0*
[2] EC 264-150-0
[3] CAS 1469983-39-8, 'Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated, saponified'
[4] 'Paraffin waxes and hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified'
[5] 'Di-, tri- and tetrachlorotetradecane'
[6] EC 269-145-7

The sequence of 'sub-scenarios' listed in Table 34 are depicted schematically in Figure 4.

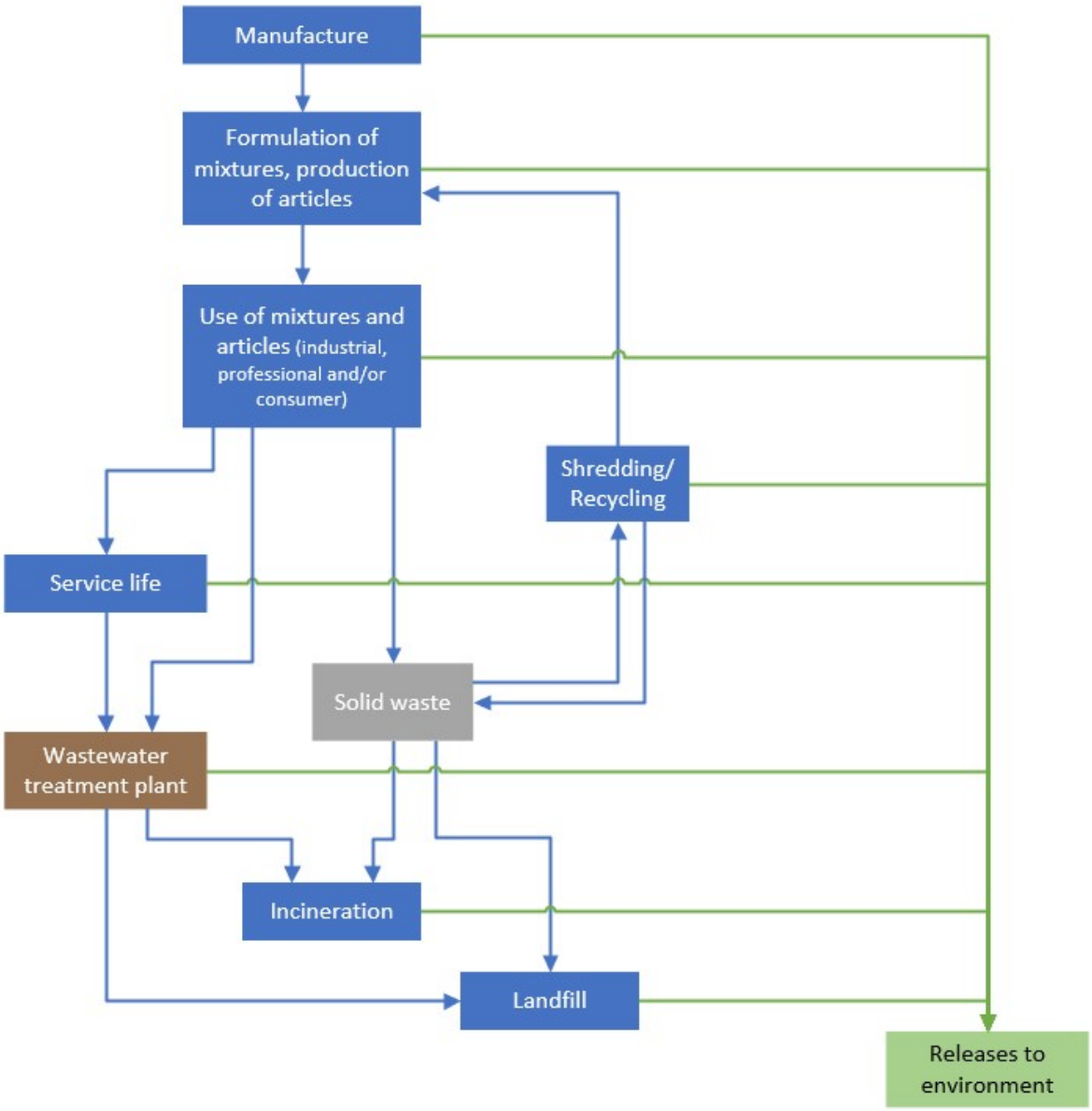


Figure 4. Generic sequence of exposure scenarios for substances containing CA:C14-17

The following additional releases are not quantified:

- Releases which occur outside of the EU and subsequently enter the EU via long-range transport.
- Releases from articles that were placed on the market prior to any restriction ("legacy articles") as well as from already landfilled waste. Release from legacy articles would be impacted under Restriction option 2.
- Releases from recycled materials and articles. Recycling leads to the incorporation of CA:C14-17 in new materials and articles, and the congeners will be released to

the environment during the incorporation, the service life, and when becoming waste, in a similar way as described in the exposure scenarios. Recycling is discussed in the Annex XV report. The releases are not quantified separately because the tonnage involved as well as the detail of the type of uses is unknown; however it can be assumed that they would be similar (and thus covered) by the release estimates for the 'virgin' materials.

- Releases from landfills in the after-care period (after closure of the landfills) and after the after-care period, when landfills are not monitored anymore. These closed and abandoned landfills constitute significant sinks for CA:C14-C17 (see section B.5.3.11).

B.5.2.2. Tonnage overview – manufacture and use

Tonnage manufactured and used in the EU:

The Dossier Submitter identified 69 substances that contain or may contain CA:C14-17 (non-exhaustive list) and these substances are therefore in the scope of the restriction. Tonnages estimates presented in Table 35 give an overview of the annual EU tonnage of CA:C14-17 taking into account all these identified substances containing CA:C14-17. The overview is based on information collected during the SVHC listing (ECHA, 2021b) complemented by more recent information received from registrants, other stakeholders in the calls for evidence, and market analysis. Tonnage values are rounded up to two significant digits.

Table 35: Tonnage manufactured and used in the EU (tonnes of CA:C14-17 per year) – excluding imported articles

	Tonnes of CA:C14-17 per year	**% of total**
Total tonnage manufactured in the EU	33 000	-
Total tonnage used in the EU, including imported substances (excluding imported articles)	55 000	-
Tonnage in Use#00 - PVC	14 000	26.2 %
Tonnage in Use#01 – adhesives and sealants	33 000	60.2 %
Tonnage in Use#02 - rubber	2 700	5 %
Tonnage in Use#03 – metalworking fluids	2 700	5 %
Tonnage in Use#04 – paints and coatings	650	1.2 %
Tonnage in Use#05 - leather	220	0.4 %
Tonnage in Use#07 - other uses	1 100	2.1 %

The following assumptions are used:

- For the six registered substances, the latest registered tonnage per registrant is assumed to remain constant as of today, in particular for registrations that have not been updated recently and when no information was received proving otherwise. The tonnages from inactive and revoked registrations are not included.

- For the unregistered substances, the tonnage limit triggering registration (1 tonne per year) is used as a worst-case of the tonnage manufactured and used in the EU.

- The Dossier Submitter takes into account 10 % of the registered tonnage of EC 264-150-0 (LCCP); EC 269-145-7; 'Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated, saponified'; and 'Paraffin waxes and hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified'. This value is deemed to represent the fraction of CA:C14-17 within the registered substance and is subject to sensitivity analysis. For unregistered substances, it is conservatively assumed that 100 % of the tonnage corresponds to CA:C14-17.

- Based on REACH Article 6(1), Article 7(1) and Guidance on registration v4.0 § 2.2.6, tonnage used in the EU (tonnage manufactured plus imported minus exported) represents the tonnage used at all stages of the life cycle (i.e. including tonnage in imported mixtures and tonnage in imported articles with intended releases, above 1 tonne per year per importer). However, the Dossier Submitter highlights that the real imported tonnage may in reality be much higher and not accounted for, as tonnages imported below 1 tonne/year of substance per company, or, for articles, above 1 tonne/year per company with no intended releases, are not registered. The tonnage in imported articles is unknown.

- It is assumed that in general the same use patterns and tonnage breakdown than EC 287-477-0 apply also to all other substances, unless available information allowed to consider narrower use patterns separately, in which case the tonnage was allocated only to the relevant uses.

- It is assumed that the tonnage in imported articles (i.e. PVC articles, rubber articles, leather articles, articles containing adhesives, sealants, paints, coatings, and any other articles) is 0. Based on the use description and stakeholders information, it is unlikely that some large articles (e.g. conveyor belts) are imported. The import of other types of articles cannot be excluded. (KEMI, 2018) assumes that imports and exports of substances containing CA:C14-17 in PVC and/or EEE are largely equivalent. No tonnage in imported articles is reported in registration dossiers (REACH Article 7(1) and (5)). Six 'substance in article' notifications (REACH Article 7(2)) were received for the substances listed on the Candidate List, all describing uses in cables and indicating tonnage produced in the EU but no imported tonnage. Neither PRODCOM information (see section A.1.2), nor SCIP data (see section A.2.2.1) do not enable to estimate the tonnage imported in each of the identified use. In summary, the imported tonnage in articles cannot be quantified and is assumed to be 0 in the calculations. As a consequence, the releases may be underestimated.

- Conservatively, it is assumed that there is no export of mixtures and articles, or that export is equivalent to import.

Mass flow overview:

Figure 5 below represents the mass flow of the substances in their life cycle, from

manufacture to service life. Waste generated at each step are not included in the diagram and neither is recycling. The fraction of the tonnage for each use is based on Table 35.

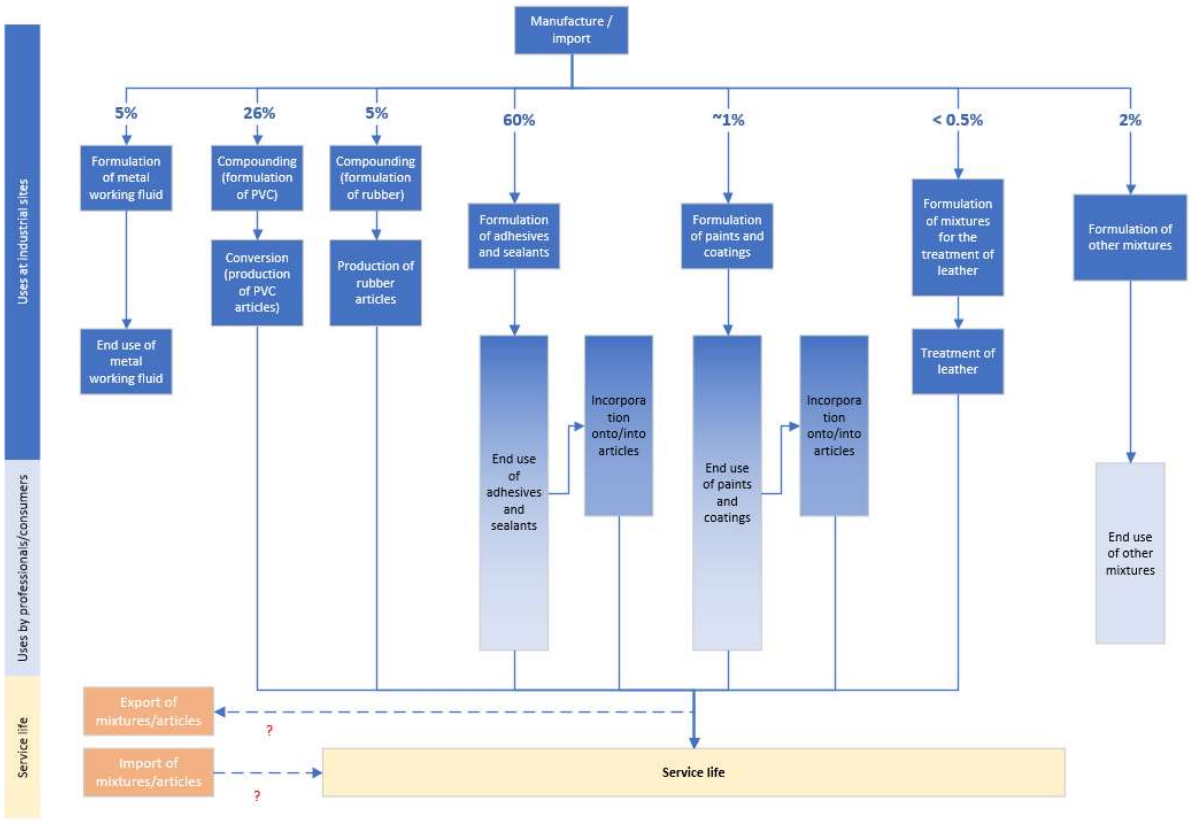


Figure 5. Mass flow overview

B.5.2.3. Tonnage disposed of as waste

Waste management is described in section 1.3 of the main report. No or very minor information on releases from waste is available in registration dossiers.

Based on the use description and information from ECHA R18 guidance (ECHA, 2012b), SpERCs, Eurostat data, recent reports detailing waste managements in some sectors and for some types of waste , and in line with approaches developed in other recent restriction proposals, three generic exposure scenarios have been considered:

- W1: Dismantling and shredding of waste/articles
- W2: Disposal of waste/articles to landfill
- W3: Disposal of waste/articles by incineration or other destructive treatments.

The total tonnage of substances going to waste has been aggregated across all uses and life cycle stages and allocated to one or several of the exposure scenarios W1 to W3. These aggregated tonnages have been used as inputs for the calculation of releases to the environmental compartments (aquatic, air and soil) from waste handling, by combining input tonnages to release factors (see section B.5.2.5).

Fractions of waste tonnage to be considered in exposure scenarios W1 to W3 have been assumed by the Dossier Submitter for each use and life cycle stage, based on ECHA R18 guidance (ECHA, 2012b), SpERCs of FEICA / EFCC (Use#01), CEPE (Use#04) and ESIG / ESVOC (Use#07), Eurostat data and other reports listed below. The assumptions are summarised as follows:

Industrial waste (pre-consumer waste) from manufacture, formulation and industrial uses (residues (e.g. lost from application process), off-specifications products, waste from equipment and surfaces cleaning, waste from RMM (e.g. PPE, filters, sludges, particles), used metalworking fluids, etc. from industrial sites are assumed to be handled as hazardous waste due to the presence of CA:C14-17 with PBT/vPvB properties[20]. Classification of waste as hazardous is rather complex and depend on a risk assessment if not listed as "absolute hazardous" in the European List of Waste. In Norway, the concentration limit to render waste as being hazardous is 2 500 mg/kg (Danish EPA, 2014). The EU legislation stipulates that hazardous waste have to be handled so as to provide protection for the environment and human health, which includes traceability, mixing ban, labelling, and treatment in specially designated facilities that have obtained a special permit[21]. The most common treatment methods are incineration and hazardous landfilling (EU Commission, 2021b). For the estimation of the releases, the Dossier Submitter has adopted a generic approach considering that 100 % of industrial waste are treated in a way that aims at destroying the substances, assessed in the exposure scenario "W3: Disposal of waste/articles by incineration or other destructive treatments". In absence of specific data, it is assumed that the release factors to the environment from incineration (ECHA, 2012b) can be extrapolated to other destructive treatment methods. This may however underestimate the releases if waste treatment is not aimed at destruction of the substances. This is subject to sensitivity analysis (assuming as a worst-case that all industrial waste are treated as municipal waste). By-products directly recycled/reused (e.g. scrap PVC, metalworking fluids, scrap metal) are not accounted for in the calculation of the releases from waste.

Post-consumer[22] waste from professional and consumer uses generated from Uses #01, #04 and #07 are assumed to be eliminated as municipal waste without specific

[20] In the Waste Framework Directive, 'hazardous waste' is defined as 'waste which displays one or more of the hazardous properties listed in Annex III'. The classification into hazardous and non-hazardous waste is based on the system for the classification and labelling of dangerous substances and preparations. This ensures that similar principles are applied over the whole life cycle of materials. Although PBT and vPvB properties are not included in CLP and thus neither in Annex III, CA:C14-17 fulfil the classification as "HP 14 – ecotoxic" (other categories may also apply).

[21] Directive 2008/98/EC; Commission notice on technical guidance on the classification of waste (2018/C 124/01)

[22] Waste produced by end consumers or commerce (EU Commission, 2022), on the contrary to pre-consumer waste (waste generated during the production of final and intermediate products, which are not themselves by-products)

treatment[23]. For this purpose, based on Eurostat data[24], the Dossier Submitter assumed that 47 % of waste are landfilled (assessed under exposure scenario "W2: Disposal of waste/articles to landfill") and 53 % are incinerated (assessed under exposure scenario "W3: Disposal of waste/articles by incineration or other destructive treatments").

Post-consumer waste from the end of life of materials and articles include building and construction waste, WEEE, end-of life vehicles (ELV), mixed waste (Use#02: rubber, Use#05: leather; and any other materials and uses relevant under Uses #01, #04, #07 but not specifically accounted for). Building and construction waste, WEEE and ELV all undergo separate collection (at least to some extent), dismantling, sorting, shredding (breaking down into smaller pieces), and the material is further separated for disposal and recycling. The fraction of waste collected separately (versus disposed of as unsorted municipal waste) and the treatment of collected waste vary depending on the type of articles and materials, the country in the EU and the facilities (Norwegian Environment Agency, 2021). For instance, PVC waste are collected and sorted to some extent but with greater effectiveness in the construction sector than others where it remains challenging (EU Commission, 2022). As the estimation aims to be representative of the whole EU and of the wide diversity of the waste containing CA:C14-17, and as the fraction of the tonnage of CA:C14-17 relevant for each category is not known (these substances may be present in several components and may overlap across several categories, e.g. cables, which are used in construction, EEE, vehicles, etc (CfE3 #1521)), a generic approach has been used. Releases occurring during all dismantling, shredding and sorting steps are estimated together in the exposure scenario "W1: Dismantling and shredding of waste/articles". Ultimately, the separated fractions will be disposed of in landfills or incinerated (which leads to more releases, quantified under exposure scenarios "W2: Disposal of waste/articles to landfill" and "W3: Disposal of waste/articles by incineration or other destructive treatments") or recycled (which may lead to contamination of the recycled material if the substances of concern are not specifically removed). Accordingly, post-consumer waste from end of life of materials and articles are addressed in the exposure scenario W1 but also W2 and W3 and hence the fraction of the tonnage to W1 can also (partly) be transferred to W2 and W3 (hence sums that exceed 100 %).

- WEEE (mainly Use#00: cables): the Dossier Submitter assumed that mainly cables will be disposed as WEEE. They are included in all the categories of WEEE which encompass different collection and treatment processes. They would also be collected when tearing down buildings and vehicles. According to the Plastics Recyclers Europe Association (CfE3 #1522), cables from demolition activities are sent to copper recyclers, who remove the plastic fraction and send it to other specialised recyclers, who in turn remove the impurities and recycle the flexible PVC into e.g. road furniture. Other electrical and electronic equipment would be

[23] The Danish Environmental Protection Agency (Danish EPA, 2014) noted that "the property "ecotoxic" is among the properties which may render waste hazardous. It is, therefore, the responsibility of the municipalities, on the basis of a risk assessment, to define if and when waste containing MCCPs should be managed as hazardous waste."

[24] Municipal waste by waste management operations (env_wasmun) https://ec.europa.eu/eurostat/web/main/data/database , accessed 15/03/2022

shredded to separate the "shredder light fraction" (SLF) containing plastics, from which PVC (on the contrary to other plastics) is incinerated due to the concomitant presence of PBDEs at levels exceeding the limits set under the POP regulation. However, the fraction of WEEE containing CA:C14-17 in the various sectors is not known. In the dossier to support a restriction under ROHS, (KEMI, 2018) estimated that 40 % of medium chain chlorinated paraffins from WEEE generated is collected separately and treated in the EU and 13 % is disposed of as municipal waste. The remaining would be either not accounted for or exported to third countries. Based on the figures in the report, and disregarding the fraction of waste exported outside the EU, the Dossier Submitter considers that 22 % of waste is shredded, 43 % is landfilled (directly and after shredding), 38 % is incinerated (directly and after shredding) and 20 % recycled (after shredding).

- Building and construction waste (mainly Use#01: OCF, window insulants, PU foams): the Dossier Submitter assumes that 100 % of the waste are dismantled and shredded during the tearing down of building and further processing of the waste and separation of materials. Based on Eurostat data[25] from 2018, it is estimated that in general 80 % of building and construction waste are recycled, 1 % are incinerated, and 19 % are disposed of in landfills, used as backfilling or undergo other treatment. However, the purpose of the recycling is not the recovery of the sealants and the coatings (CA:C14-17 are contaminants of recycled materials if any) and therefore the recycled fraction is not relevant to consider for these substances. Disregarding the recycled fraction, 95 % of the CA:C14-17 in building and construction waste is eliminated in landfill/backfilling and 5 % is incinerated. These figures do not take into account cables, as they are considered as WEEE even when separated during demolition of constructions.

- ELV: uses in vehicles has been mentioned in the calls for evidence. Several uses of CA:C14-17 in articles/materials appear relevant in vehicles (CfE2 #1470, #1484, #1488, #1493, #1499, #1506, CfE3 #1529): adhesives, PVC, rubber, paints and coatings, lubricants, polyurethane foam. According to the Plastics Recyclers Europe Association (CfE3 #1522), flexible PVC from ELV is not recycled but sent to incineration due to the concomitant presence of PBDEs at levels exceeding the limits set under the POP regulation. Lubricants would be removed and discarded, according to the measures defined in the ELV Directive (2000/53/EC). As the tonnage used in ELV is unknown, waste from ELV is not considered specifically in the assessment.

- For other waste, the Dossier Submitter assumed that waste from Use#02 are landfilled, waste from Use#04 are shredded and disposed of in landfill or incinerated, and waste from Use#05 are disposed of in landfill or incinerated.

[25] Treatment of waste by waste category, hazardousness and waste management operations (env_wastrt) available at https://ec.europa.eu/eurostat/web/main/data/database, accessed 18/03/2022

Table 36 summarises the fractions of the tonnage used in the Dossier Submitter's assessment, as described above:

Table 36: Fractions tonnage in waste exposure scenarios

		W1 shredding	W2 landfill	W3 incineration/ destruction
Pre-consumer waste from industrial uses		-	-	100 %
Post-consumer waste from professional and consumer uses		-	47 %	53 %
Post-consumer waste from end of life of materials and articles	Use#00 (PVC) - WEEE	22 %	43 %	38 %
	Use#02 (rubber) - conveyor belts	-	100 %	-
	Uses #01 (adhesives and sealants) – building and construction waste	100 %	95 %	5 %
	Use#04 (paints and coatings)	100 %	47 %	53 %
	Use#05 (leather)	-	47 %	53 %

Although waste can also be exported outside the EU, this is not taken into account by the Dossier Submitter in the absence of any specific data for exported waste containing CA:C14-17. This represents a worst-case for the estimation of the releases from waste in the EU.

Descriptions of releases pathways and key input parameters are described in sections B.5.3.10 to B.5.3.12.

B.5.2.4. Municipal WWTP efficiency and connection rate

It is assumed that waste water from all uses (after any on-site treatment for uses in industrial sites) is generally discharged to sewage and treated in municipal WWTP.

WWTP efficiency:

Removal of substances from waste water in WWTP depends on the physico-chemical properties of the substances and whether biodegradation occurs. The Dossier Submitter used the Simple Treat v.4.0 model to estimate in general the fate in WWTP of all the substances in the scope of the restriction proposal. Due to the variability of the compositions of substances containing CA:C14-17, and considering that the CA:C14-C17 with PBT and/or vPvB properties are the congeners of concern, the physico-chemical properties of CA:C14-C17 (as reported in section B.1.4) have been used as inputs to the model, disregarding other constituents of the substances.

Based on the following inputs, the average removal of municipal WWTP has been calculated and is summarised in Table 37.

- Molecular weight: 300 to 800 g/mol

- Vapour pressure: 0.00027 Pa
- Water solubility: 0.027 mg/L
- K_{ow}: 10^7 (log K_{ow} of 7)
- Biodegradability: not biodegradable (this is subject to sensitivity analysis)
- Suspended concentration of solids in effluent: 0.03 kg/m^3 (to reflect the situation of municipal WWTP across Europe).

Table 37: Municipal WWTP efficiency

WWTP efficiency (i.e. removal of substances from waste water) (%)	91.7 %
Release directed to air at the WWTP (%)	0.1 %
Release directed to sludges at the WWTP (%)	91.6 %
Release directed to surface water (%)	8.3 %

In the Annex XV report for the identification of 'MCCP' as SVHC (ECHA, 2021b), the removal of 'MCCP' in waste water treatment plant that uses activated sludge secondary treatment had been modelled with STPWIN model of EPI Suite (v. 4.11) of the US EPA. The removal was estimated to 93-94 % for $C_{14}Cl_6$ and $C_{16}Cl_7$ respectively, directed to sludges, with very minor biodegradation (< 0.8 %). In their CSR, the registrants of substance EC 287-277-0 estimated a removal rate of 97.1 % directed to sludges using Simple Treat v.4.0 assuming no biodegradation, based on effluent concentration from (Coelhan, 2010a).

Sludges handling:

The Dossier Submitter has assumed that the sludges from municipal WWTP are either applied on land (i.e. directly applied on agricultural land as fertiliser, or to other lands e.g. parks or gardens after composting), incinerated, or landfilled/undergoing other treatment (Eurostat, 2022 [26]), as displayed in Table 38.

Table 38: Municipal WWTP sludge disposal

Fate of municipal WWTP sludges	**Average of EU countries (2015-2019)**
WWTP sludges applied on land (agricultural or other)	48 %
WWTP sludges incinerated	18 %
WWTP sludges landfilled or undergoing other treatment	32 %

Connection rate:

The Dossier Submitter has considered a connection rate of 90 % to municipal WWTP for

[26] Sewage sludge production and disposal (env_ww_spd) available at https://ec.europa.eu/eurostat/web/main/data/database, accessed 17/02/2022

all the uses and life cycle stages (except waste), in line with the tenth report on the implementation of the Urban Waste Water Treatment Directive which states that about 95 % of the waste waters in the EU were collected and 88 % received secondary treatment, in compliance with the provisions of the Urban Waste Water Treatment Directive[27] (EU Commission, 2020). Therefore, a small fraction of the waste water (10 %) is assumed to be discharged to surface water directly. Two exceptions to this approach are Use#02 (use of conveyor belts in mines) and Use#04 (marine coatings) where no connection to WWTP is assumed.

In addition, with regard to the releases associated to waste (exposure scenarios W2 and W3), 100 % connection rate to municipal WWTP is assumed: meaning that releases to water from operating landfill (via leachate) and incineration (via scrubbing), will be treated and not go directly to surface water. It is further assumed that the sludges from WWTP connected to landfill and incinerating plant would be incinerated.

B.5.2.5. Release factors

Release factors are considered for all environmental compartments (aquatic, air, soil) from all life cycle stages including for the treatment of waste. These are initial receiving compartment but further transfers are expected, e.g. via deposition to soil (Guida et al., 2020). These transfers are not considered by the Dossier Submitter.

In the absence of specific information on release factors, estimates are made based on the best available information at the time of the Annex XV restriction proposal preparation. Publicly available information was used as much as possible.

For industrial sites (manufacture, formulation, industrial uses), it is assumed that risk management measures (RMMs) are implemented at least to some extent, due to the hazardous nature of the substances, which aim to reduce releases and enable proper waste management. Thus, release factors used in the estimates represent the releases after on-site risk management measures. However, as explained in B.5.1.2, the RMMs effectiveness in the EU in the current time period is not known. Despite analysis of registration dossiers, calls for information and evidence (February and March 2022) and investigations conducted by contractors on specific sectors, little information was collected and no data was received to substantiate the RMMS effectiveness. Release factor are taken from the ECHA guidance R16 (ECHA, 2016), EU RAR (EU Commission, 2005), OECD Emission Scenario Documents on plastic additives (OECD, 2009b), SpERCs, and from registrations.

For professional and consumer uses, it is assumed that no particular risk management measures are implemented and default release factors from SpERCs or from the ECHA guidance R16 (ECHA, 2016) are considered.

Releases during service life occur through volatilisation, leaching, abrasion, and any degradation of the material. Due to the wide diversity of uses of the substances, a generic approach based on defaults release factors from the ECHA guidance R16 (ECHA, 2016) is regarded as providing reasonable estimates for the purpose of the restriction proposal.

[27] Council Directive 91/271/EEC concerning urban waste-water treatment.

For the waste stage, release factors are taken from ECHA guidance R18 (ECHA, 2012a).

Release factors selected for the assessment are presented in section B.5.3 within each exposure scenario.

B.5.2.6. Release calculation formula

For each path emission, the release calculation is made with the following general formula: [Release] = [Tonnage] x [Release factor].

Releases have been calculated at continental scale for each environmental compartment (aquatic, soil, air) for each contributing exposure scenario (i.e. each use and each life cycle stage) taking into account the tonnage per contributing scenario and release factor per contributing scenario and environmental compartment.

In addition release to surface water has been calculated considering the WWTP efficiency and the WWTP connection rate, as follows: [Total release to surface water] = [Direct release to surface water] + [Release to surface water from WWTP]

Although the WWTP efficiency (removal from waste water) is very high for CA:C14-17, a small portion of the influent is likely to remain in the effluent. In some cases (cf. WWTP connection rate), the waste water might not be treated in a WWTP and released therefore directly to surface water. The formulae below depict the total release to surface water, air and soil:

[Total release to surface water] = ([Release to WW] x [WWTP connection rate] x (1 – (WWTP efficiency rate)) + ([Release to WW] x (1 – [WWTP connection rate]) = [Release to waste water] x (1 – ([WWTP connection rate] x [WWTP efficiency]).

[Total release to air] = [Release to air from use] + [Release to air from WWTP] where [Release to air from WWTP] = [Release to waste water] x [Fraction to air]

[Total release to soil] = [Release to soil from use] + [Release to soil from WWTP], where [Release to soil from WWTP] = [Release to waste water] x [Fraction to sludges] x [Fraction of sludges applied to agricultural soil]

The output of the calculations is the tonnage released per year for each annual tonnage placed on the market (assuming steady state for service life).

B.5.3. Release and exposure assessment per use

B.5.3.1. Manufacturing

B.5.3.1.1. Source of release and pathway

The tonnage manufactured is estimated to be about 33 000 tonnes per year of CA:C14-17 congeners.

One environmental exposure scenario is considered:

- M: Manufacture of the substance.

Chloroalkanes are produced without contact with water and emissions to the environment should mainly occur through volatilisation and dust drift; however, since the chlorine gas and hydrochloric acid are recovered and the volatility of chloroalkanes is low, this loss is likely to be low (ECHA, 2021b). Dusts would likely settle and be eliminated via cleaning. Overall, little specific information on risk management measures applied at manufacturers' site is available. Additional information was collected from registration dossiers and following direct request by the Dossier Submitter to manufacturers. The following risk management measures are cited:

- Closed systems
- No contact with water during manufacture
- Cleaning water (if any) reused or treated as waste
- Spill containment measures and disposal of collected spills as waste
- Limit concentration in effluent (environmental permits)
- On-site or local waste water treatment plant
- Waste and sludges disposed of according to national law; incineration of waste and sludges.

Due to the variability in available information, it is likely that risk management measures are applied and able to reduce releases, but their efficiencies in terms of quantitative abatement of concentration in effluents are uncertain. For this reason, the Dossier Submitter used the release factors from the RAR (EU Commission, 2005) as a conservative estimate.

No recent data on releases from manufacturing sites in European geographical area could be found in monitoring registers nor in literature[28] showing a minimisation of the releases (in particular after the SVHC identification of some substances containing CA:C14-17).

B.5.3.1.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 39.

Table 39: Input parameter for the calculation of releases from manufacture

Input parameter/assumption	Value	Unit	Source
Tonnage for this exposure scenario	33 000	tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.3	%	(EU Commission, 2005)
Release factor to air	0	%	(EU Commission, 2005)
Release factor to soil	0	%	(EU Commission, 2005)
Fraction of the tonnage to solid waste	2 - 5	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

[28] Search performed in Google Scholar; Science Direct; PubMed; Research Gate; Web of Science between December 2021 and March 2022.

B.5.3.1.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 40. These releases estimates don't take into account releases from waste. Values are rounded up.

Table 40: Releases estimates to the environment from manufacture (tonnes of CA:C14-17 per year)

Exposure scenario	Surface water	Air	Soil	Total
M: Manufacture of the substance	17	0.1	39	**57**

It is also estimated that the tonnage of CA:C14-17 in waste generated from manufacturing represents about 26 tonnes to landfill and 675-1665 tonnes to incineration/destruction (these values include WWTP sludges from treatment of waste water from manufacture that are incinerated/landfilled).

Releases from waste to the environment are estimated in sections B.5.3.10 to B.5.3.12.

B.5.3.2. Use#00: Use in PVC

B.5.3.2.1. Source of release and pathway

The tonnage used in PVC is estimated to be about 14 000 tonnes of CA:C14-17 per year. The main types of products and applications are cables, as well as conveyor belts to a lesser extent. Uses in flooring, PVC-coated textile, tubes, pipes, hoses, fittings, films appear to have been substituted already (see main report).

Three environmental exposure scenarios are considered:

- #00-1: Compounding (plastisol and dry blending)
- #00-2: Conversion - production of PVC articles
- #00-3: Service life of PVC articles

The Dossier Submitter considers that the description and default approach of the Emission Scenario Document (ESD) on plastic additives (OECD, 2009b) represent reasonable worst-case assumptions for plasticisers and flame retardants for the compounding and conversion phase for all PVC articles.

The compounding (formulation) is the step where the additives (e.g. plasticisers, flame retardants) are added to the PVC polymer. Based on available information, both dry blending and plastisol blending can be relevant, but as the fraction of the tonnage allocated to each of this compounding method is uncertain (plastisol being less prominent than dry blending), dry blending has been considered as a worst-case. The defaults from the ESD (OECD, 2009b) for the handling of raw material (releases to waste water) and dry blending (releases to waste water and air) (medium volatility group by analogy with DEHP) have been used.

For the conversion (production of articles), the ESD indicates defaults release factors for plasticisers and flame retardants depending on whether the process (injection moulding, extrusion, calendering) is known or unknown, the extent of containment, and the size of

the site. As no specific information is available on each of the substances containing CA:C14-17 in the scope of the restriction, a generic assessment is proposed to estimate the releases from PVC conversion, assuming that cable extrusion and to a lesser extent calendering would be the dominating techniques. The default release factors for partially open processes in large sites (medium volatility group by analogy with DEHP) have been used.

Although initial releases during compounding and conversion would be to air, a fraction would condense and deposit, and would ultimately be eliminated to waste water.

It should also be noted that the recycling of PVC would require similar processes than for virgin PVC, i.e. compounding and conversion, and subsequent service life of articles (which may be more diverse than from virgin PVC, such as road equipment, etc) (KEMI, 2018).

Service life is assumed to be mostly indoor, but outdoor use cannot be excluded (e.g. outdoor cables, articles made of recycled PVC). The default values from ERC 10a and 11a are taken into account (ECHA, 2016) which lead to releases expressed as minimum and maximum range.

The majority of the releases are expected to come from waste. The approach is described in section B.5.2.3.

B.5.3.2.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 41 to Table 43.

#00-1: Compounding (plastisol and dry blending):

Table 41: Input parameter for the calculation of releases from Exposure scenario #00-1: Compounding (plastisol and dry blending)

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	14 000	tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.015	%	(OECD, 2009b)
Release factor to air	0.005	%	(OECD, 2009b)
Release factor to soil	0	%	(OECD, 2009b)
Fraction of the tonnage to solid waste	2.5	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

#00-2: Conversion - production of PVC articles:

Table 42: Input parameter for the calculation of releases from Exposure scenario #00-2: Conversion - production of PVC articles

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-

Tonnage for this exposure scenario	14 000	tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.015	%	(OECD, 2009b)
Release factor to air	0.015	%	(OECD, 2009b)
Release factor to soil	0	%	(OECD, 2009b)
Fraction of the tonnage to solid waste (type of waste)	5	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

#00-3: Service life of PVC articles:

Table 43: Input parameter for the calculation of releases from Exposure scenario #00-3: Service life of PVC articles

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	14 000	tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.05 – 3.2	%	ERC 10a, ERC 11a (ECHA, 2016)
Release factor to air	0.05	%	ERC 10a, ERC 11a (ECHA, 2016)
Release factor to soil	0 – 3.2	%	ERC 10a, ERC 11a (ECHA, 2016)
Fraction of the tonnage to solid waste	100	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

B.5.3.2.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 44. These releases estimates don't take into account releases from waste. Values are rounded up.

Table 44: Releases estimates to the environment from Use#00 (tonnes of CA:C14-17 per year)

Exposure scenarios	Surface water	Air	Soil	Total
#00-1: Compounding (plastisol and dry blending)	0.4	0.7	0.8	**1.9**
#00-2: Conversion - production of PVC articles	0.4	2.1	0.8	**3.3**
#00-3: Service life of PVC articles				
max for indoor service life	1.2	7	2.8	**11**
max for outdoor service life	78	7.4	625	**711**
Total	**-**	**-**	**-**	**16 - 716**

It is also estimated that the tonnage of CA:C14-17 in waste generated from PVC use represents (these values include WWTP sludges from treatment of waste water from this use that are incinerated/landfilled):

- Compounding: about 1 tonne per year to landfill and 350 tonnes per year to incineration/destruction;
- Conversion: about 1 tonne per year to landfill and 700 tonnes per year to incineration/destruction;
- Service life: about 3 080 tonnes per year to shredding, 6 022 tonnes per year to landfill and 5 321 tonnes per year to incineration/destruction.

Releases from waste to the environment are estimated in sections B.5.3.10 to B.5.3.12.

B.5.3.3. Use#01: Use in adhesives and sealants

B.5.3.3.1. Source of release and pathway

The tonnage used in adhesives and sealants is estimated to be about 33 000 tonnes of CA:C14-17 per year. The main types of products and applications are mainly one-component foam (OCF) used for insulation of constructions, polysulfide sealants for insulating glass (IG) (double/triple glazing), and to a lesser extent self-adhesive foam strips, tapes and adhesives and sealants in electronic component. Other polyurethane insulation foams (e.g. rigid polyurethane foams) are also included in this scenario.

Four environmental exposure scenarios are considered:

- #01-1: Formulation of adhesives and sealants (mixtures)
- #01-2: Industrial end-use[29] of adhesives and sealants (including incorporation in articles)
- #01-3: Professional and consumer end-use of adhesives and sealants
- #01-4: Service-life of adhesives and sealants (indoor)

As illustrated in Figure 6, releases may occur to all environmental compartment (aquatic, air, soil). Contact with water has to be avoided during the formulation of mixtures due to the reactivity of the other components of the mixtures (e.g. isocyanates in OCF) with water from the formulation (registrations, CfE1 #1340, #1346, #1350, #1357, #1363). Adhesive and sealants containing CA:C14-17 can be incorporated in articles (e.g. double/triple glazed windows, electronic equipment, etc); they can also be applied directly on-site (e.g. OCF applied around doors, windows, etc) by professionals. Although consumer uses have not been registered, it appears that the products can be used by consumers (e.g. OCF) including in Do-It-Yourself activities (Brandsma et al., 2021). However, no data is available to differentiate the tonnage used by consumers from the tonnage used by professionals. Based on information from OCF and IG sealants producers, it is assumed that 20 % of the tonnage is used in IG sealants by industrial users and 80 % in OCF by professionals/consumers. This assumption is tested in a sensitivity analysis. After application, the adhesives and sealants cure, and releases from service life are assumed to be low. For insulating polyurethane foams, a similar release pattern is expected although the curing occurs in an earlier step, during the industrial production of the foam. It is expected that most uses will be indoor or covered from weathering (CfE1

[29] 'End-use' means the use of a substance as such or in a mixture, as a last step before the end-of-life of the substance, namely before the substance is consumed in a process by reaction during use (including intermediate use), is emitted to waste streams or the environment or is included into an article (ECHA, 2015).

#1346, #1350, #1357).

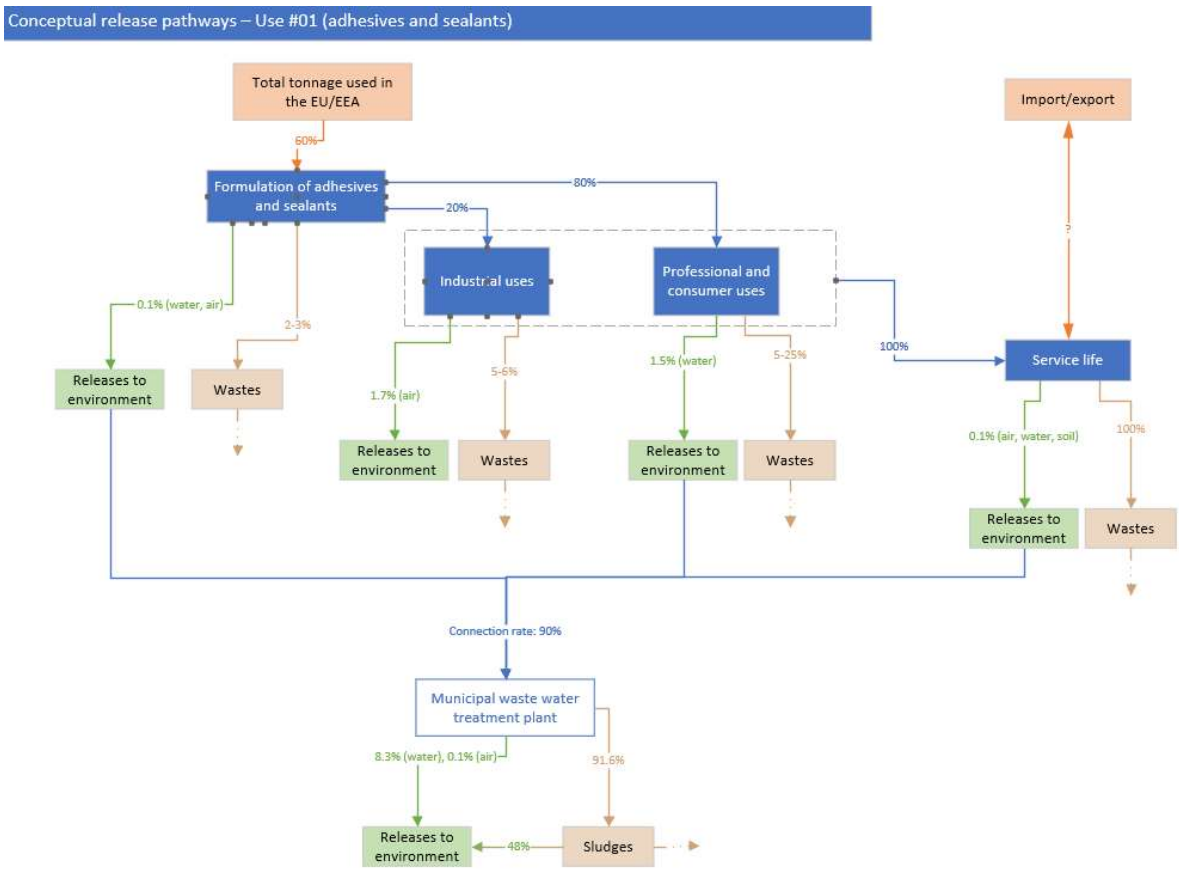


Figure 6: Conceptual release pathways – Use#01 (adhesives and sealants)

Release factors from FEICA / EFCC SPERCs for solvent-borne and non-volatile substances are taken into account for the formulation and use of adhesives and sealants, and default values from ERC 11a for the service life.

As described in section B.5.2.3, waste generated during formulation and industrial uses are assumed to be handled as hazardous waste. On the contrary, solid waste generated during the use of the mixtures by professionals and consumers (i.e. empty or still partly full canisters, excess adhesives/sealants, etc) are assumed to be disposed of as municipal waste (i.e. landfilled and incinerated). It is further assumed that at the end of life of articles and buildings, tearing down/dismantling and shredding will take place for further disposal and recycling. This process would generate releases of the substances to the environment. Ultimately, the main purpose of this process is not the recovery of the adhesives/sealants, which will be discarded and thus directed to landfill or incineration.

B.5.3.3.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 45 to Table 48.

#01-1: Formulation of adhesives and sealants (mixtures):

Table 45: Input parameter for the calculation of releases from Exposure scenario #01-1: Formulation of adhesives and sealants (mixtures)

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	33 000	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.02	%	FEICA / EFCC SPERC 2.1a.v3
Release factor to air	0.08	%	FEICA / EFCC SPERC 2.1a.v3
Release factor to soil	0	%	FEICA / EFCC SPERC 2.1a.v3
Fraction of the tonnage to solid waste	2 - 3	%	(ECHA, 2012b), FEICA / EFCC SPERC 2.1a.v3
WWTP connection rate and efficiency	As described in section B.5.2.4		

#01-2: Industrial end-use of adhesives and sealants (including incorporation in articles):

Table 46: Input parameter for the calculation of releases from Exposure scenario #01-2: Industrial end-use of adhesives and sealants (including incorporation in articles)

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	0.2	-	DS assumption
Tonnage for this exposure scenario	6 600	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0	%	FEICA / EFCC SPERC 5.1a.v3
Release factor to air	1.7	%	FEICA / EFCC SPERC 5.1a.v3
Release factor to soil	0	%	FEICA / EFCC SPERC 5.1a.v3
Fraction of the tonnage to solid waste	5 - 6	%	(ECHA, 2012b), FEICA / EFCC SPERC 5.1a.v3
WWTP connection rate and efficiency	As described in section B.5.2.4		

#01-3: Professional and consumer end-use of adhesives and sealants:

Table 47: Input parameter for the calculation of releases from Exposure scenario #01-3: Professional and consumer end-use of adhesives and sealants

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	0.8	-	DS assumption
Tonnage for this exposure scenario	26 400	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	1.5	%	FEICA SPERC 8c.3.v3
Release factor to air	0	%	FEICA SPERC 8c.3.v3
Release factor to soil	0	%	FEICA SPERC 8c.3.v3
Fraction of the tonnage to solid waste	5 - 25	%	(ECHA, 2012b), FEICA SPERC 8c.3.v3
WWTP connection rate and efficiency	As described in section B.5.2.4		

#01-4: Service-life of adhesives and sealants (indoor):

Table 48: Input parameter for the calculation of releases from Exposure scenario #01-4: Service-life of adhesives and sealants (indoor)

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	33 000	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.05	%	ERC 11a (ECHA, 2016)
Release factor to air	0.05	%	ERC 11a (ECHA, 2016)
Release factor to soil	0	%	ERC 11a (ECHA, 2016)
Fraction of the tonnage to solid waste	100	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

B.5.3.3.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 49. These releases estimates don't take into account releases from waste. Values are rounded up.

Table 49: Releases estimates to the environment from Use#01 (tonnes of CA:C14-17 per year)

Exposure scenarios	Surface water	Air	Soil	Total
#01-1: Formulation of adhesives and sealants (mixtures)	1.2	26	2.6	**30**
#01-2: Industrial end-use of adhesives and sealants (including incorporation in articles)	0	112	0	**112**
#01-3: Professional and consumer end-use of adhesives and sealants	69	0.4	157	**226**
#01-4: Service-life of adhesives/sealants (indoor)	2.9	17	6.5	**26**
Total	**-**	**-**	**-**	**395**

It is also estimated that the tonnage of CA:C14-17 in waste generated from Use#01 represents (these values include WWTP sludges from treatment of waste water from this use that are incinerated/landfilled):

- Formulation: about 2 tonnes per year to landfill and 661-991 tonnes per year to incineration/destruction;
- Industrial end-use: about 330-396 tonnes per year to incineration/destruction;
- Professional and consumer end-use: about 725-3 206 tonnes per year to landfill and 758-3 557 tonnes per year to incineration/destruction;
- Service life: up to 33 000 tonnes per year to shredding, 31 354 tonnes per year to landfill and 1 652 tonnes per year to incineration/destruction.

Releases from waste to the environment are estimated in sections B.5.3.10 to B.5.3.12.

B.5.3.4. Use#02: Use in rubber

B.5.3.4.1. Source of release and pathway

The tonnage used in rubber is estimated to be about 2 700 tonnes of CA:C14-17 per year. This excludes any use of rubber-based adhesives (included in Use#01) and rubber-based paints/coatings (included in Use#04). The main application of CA:C14-17 in rubber is in conveyor belts and tubes used in mining and underground activities. Other types of articles are also produced, e.g. O-rings in automotive applications (e.g. oil tanks), sleeves for cooling systems, rubber grommet in electrical components. CA:C14-17 have been

quantified in various rubber consumer products recently[30], placing on the market in the EU but originating from outside EU (McGrath et al., 2021c, Brandsma et al., 2019) and outside the EU (Xu et al., 2019a, Wang et al., 2018a, Cao et al., 2019, Chen et al., 2021a).

Three environmental exposure scenarios are considered:

- #02-1: Compounding (rubber)
- #02-2: Production of rubber articles
- #02-3: Service life of rubber articles.

According to the EU RAR (EU Commission, 2005), the processes involved are generally similar for both rubber and plastic, i.e. it includes compounding (mixing of the plasticiser/flame retardant with the polymer) and shaping/curing (production of articles), and thus the same release factors than those used in Use#00 are taken into account. Regarding service life of the articles, the Dossier Submitter considers that the releases from conveyor belts are representative of the releases from rubber articles incorporating CA:C14-17 in general, as this involves the highest tonnage and worst-case use conditions. Conveyor belts are produced by calendaring in production sites located close to the mines. They are used under abrasive conditions to convey mining extraction products. It is further assumed that there is no connection to any WWTP during service life.

Release factors from the ESD on plastic additives (OECD, 2009b) (considering substance of medium volatility group by analogy with DEHP) are taken into account as well as defaults from ERC 10a (ECHA, 2016) for the service life.

Waste generated during the formulation and production of these articles are assumed to be either directly recycled (reused in the production process) or handled as hazardous waste. Based on information from stakeholders, after their service life, end-of life conveyors belts are dumped into old mines and thus no measures are taken to reduce emissions at the waste stage. Although some recycling schemes exist (e.g. as infill granules), such recycling for these specific types of conveyor belts is not confirmed by stakeholders; however CA:C14-17 have been measured in some recycled rubber (e.g. in sport track, playground tiles, dust of sport facilities, in the EU (McGrath et al., 2021c, Brandsma et al., 2019) and outside the EU (Xu et al., 2019a, Wang et al., 2018a, Cao et al., 2019, Chen et al., 2021a) and thus contamination of recycled material cannot be excluded (but cannot be quantified). For the purpose of the release estimation, the Dossier Submitter assumes that 100 % of rubber articles are landfilled at the end of their service life. This is likely an underestimation of the releases from the waste stage (see section B.5.3.11).

30 Search performed in Google Scholar; Science Direct; PubMed; Research Gate between December 2021 and January 2022. Only publications from 2018 to present are considered.

B.5.3.4.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 50 to Table 52.

#02-1: Compounding (rubber):

Table 50: Input parameter for the calculation of releases from Exposure scenario #02-1: Compounding (rubber)

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	2 700	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.015	%	(OECD, 2009b)
Release factor to air	0.005	%	(OECD, 2009b)
Release factor to soil	0	%	(OECD, 2009b)
Fraction of the tonnage to solid waste	2.5	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

#02-2: Production of rubber articles:

Table 51: Input parameter for the calculation of releases from Exposure scenario #02-2: Production of rubber articles

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	2 700	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.025 (large sites) - 0.25 (small sites)	%	(OECD, 2009b)
Release factor to air	0.025 (large sites) - 0.25 (small sites)	%	(OECD, 2009b)
Release factor to soil	0	%	(OECD, 2009b)
Fraction of the tonnage to solid waste	5	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

#02-3: Service life - rubber articles:

Table 52: Input parameter for the calculation of releases from Exposure scenario #02-3: Service life - rubber articles

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	2 700	Tonnes per year	-
Release factor to waste water (after on-site	3.2	%	ERC 10a (ECHA,

Input parameter/assumption	Value	Unit	Source
WWTP but before municipal WWTP)			2016)
Release factor to air	0.05	%	ERC 10a (ECHA, 2016)
Release factor to soil	3.2	%	ERC 10a (ECHA, 2016)
Fraction of the tonnage to solid waste	100	%	(ECHA, 2012b)
WWTP connection rate and efficiency	Connection rate to WWTP: 0		-

B.5.3.4.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 53. These releases estimates don't take into account releases from waste. Values are rounded up.

Table 53: Releases estimates to the environment from Use#02 (tonnes of CA:C14-17 per year)

Exposure scenarios	Surface water	Air	Soil	Total
#02-1: Compounding (rubber)	0.1	0.1	0.2	0.4
#02-2: Production of rubber articles (large sites – small sites)	0.12 – 1.2	0.7 – 7	0.3 - 3	1.1 - 11
#02-3: Service life - rubber articles	86	1.4	86	174
Total	**-**	**-**	**-**	**176 - 185**

It is also estimated that the tonnage of CA:C14-17 in waste generated from rubber use represents (these values include WWTP sludges from treatment of waste water from this use that are incinerated/landfilled):

- Compounding: about 0.1 tonnes per year to landfill and 68 tonnes per year to incineration/destruction;
- Conversion: about 0.2 tonnes per year to landfill and 135 tonnes per year to incineration/destruction;
- Service life: about 2 700 tonnes per year to landfill.

Release from waste to the environment are estimated in sections B.5.3.10 to B.5.3.12.

B.5.3.5. Use#03: Use in metalworking fluids

B.5.3.5.1. Source of release and pathway

The tonnage used in metalworking fluid is estimated to be about 2 700 tonnes of CA:C14-17 per year of which most is used in oil-based (neat oil) metalworking fluids. Oil-based metalworking fluids are not diluted prior to use and can contain between 5 % and 70 % of CA:C14-17. The historical use in water-based metalworking fluid (emulsions) appears to be largely phased out and substituted already and is therefore not considered further in the releases estimations.

Two environmental exposure scenarios are considered:

- #03-1: Formulation of metalworking fluids
- #03-2: End-use of oil-based metalworking fluids

Available documentation on environmental releases from the use of metalworking fluids cover both diffuse releases during the use, and amount disposed as waste. The amount of substances released to the environment from the use as opposed to the amount disposed of as waste depend on the efficiency of the risk management measures, of the waste collection, and the conditions of disposal. Indeed, risk management measures (e.g. mist and fume collection equipment) would reduce the emissions during the use, but this collected amount would instead be disposed as waste (e.g. filters). A highly efficient risk management system in metalworking facilities would therefore lead to a comparatively higher fraction of the total used tonnage that is disposed of as waste.

Losses during the use of metalworking fluids are expected to come from misting/evaporation, cleaning of the facilities, overalls, leaks/spills, dragout and workpiece (rinsing) (OECD, 2011, EU Commission, 2005). They can be significant due to baths replacement and carry-off from workpieces (Guida et al., 2020). Fluids become more and more contaminated overtime with metal particles; however they can be filtered and reused onsite (CfE1 #1337) until they are no longer usable and are disposed of. Waste oils are regulated under Directive 2008/98/EC on waste. In accordance with the Directive, waste oils shall be collected and treated. Waste oils from metal work are even more hazardous than the initial "clean" metalworking fluids due to metal contamination on top of the chloroalkanes constituents, therefore it is expected that these oils are treated as hazardous waste and incinerated. This has been generally confirmed by stakeholders in their responses to the calls for evidence. Waste include also metal scraps (EU Commission, 2005). It is assumed that metal scraps/swarfs are recycled (melted) which would lead to the destruction of any substances attached to it, but this may however not be a proper hazardous waste incineration. A fraction of the metal scraps could also be disposed of which could lead to release of CA:C14-17, however this is difficult to quantify.

When consulted, stakeholders reported high level of risk management able to reduce the releases to the minimum (CfE1 #1328, CfE1 #1334, CfE1 #1336, CfE1 #1337, CfE1 #1361, CfE2 #1467, CfE2 #1480, CfE2 #1488, CfE2 #1492, CfE2 #1493, CfE3 #1513, CfE3 #1521, CfE3 #1524); however no recent data has been provided to support the claimed efficiency and it is not known how representative these RMMs are in the whole EU. The following RMMs were mentioned:

- Closed vessels, barrels, closed circuits (however unsuitable for larger pieces), retention systems
- Topping up of fluids instead of full disposal
- Mist and fume collection equipment
- The products are sticky, making cleaning from spills especially undesirable
- Very effective safety rules
- Industrial cleaning processes (e.g. of gloves, exhaust ventilation, produced parts)
- Collection of cleaning fluids
- Cleaning residues incinerated in special facilities
- Appropriate, highly regulated waste disposal

- Waste classified as halogenated hazardous waste, disposed of by incineration by third party waste contractors
- Blending the substance with non-chlorinated oils to reach a chlorine concentration in effluent that is compliant for discharge within the environmental permit or trade effluent consents
- Recycling of used oils / no recycling

For the formulation stage, release factors proposed by the industry (registration dossiers) and default from ERC 2 (ECHA, 2016) are taken into account as a best and worst-case. For the use phase, release factors proposed by the industry (registration dossiers) and from the EU RAR (EU Commission, 2005) are taken into account as a best and worst-case. Values from registration dossiers are given as ranges in the tables below due to confidentiality. Release factors from the ESD on metalworking fluids (OECD, 2011, EU Commission, 2005) were not used as their calculation requires information that is not available.

The release pathway is illustrated in Figure 7.

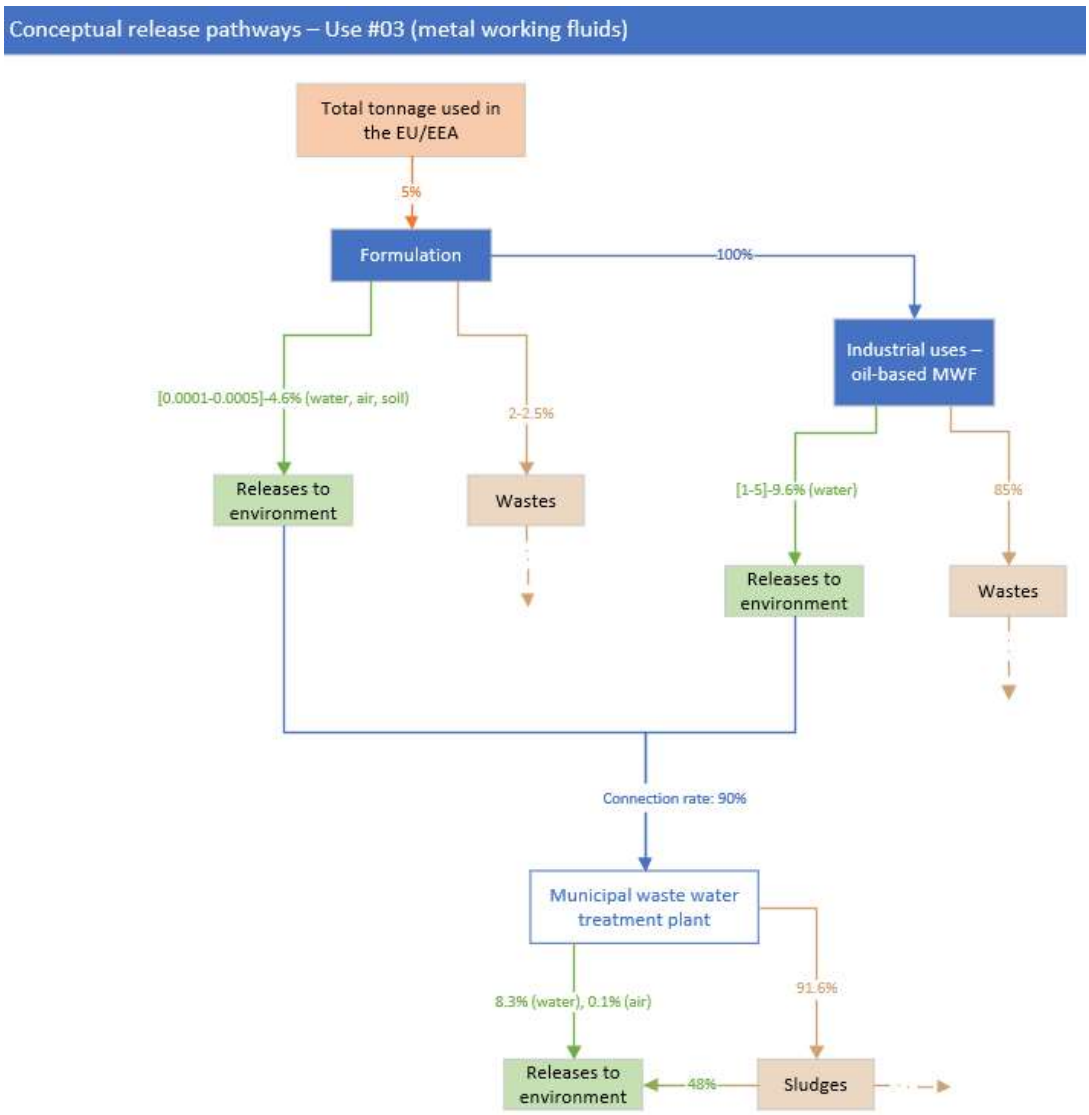


Figure 7: Conceptual release pathways – Use#03 (metalworking fluids)

No recent data in European geographical area could be found in monitoring registers nor in literature[31] on releases from metalworking sites showing a minimisation of the releases (in particular after the SVHC identification of some substances containing CA:C14-17).

B.5.3.5.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 54 and Table 55. These releases estimates don't take into account waste generated from the use (these are considered under the dedicated scenarios on releases from waste). Values are rounded up.

#03-1: Formulation of metalworking fluids:

Table 54: Input parameter for the calculation of releases from Exposure scenario #03-1: Formulation of metalworking fluids

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	2 700	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	[0.0001-0.0005] - 2	%	Industry data, ERC 2 (ECHA, 2016)
Release factor to air	0 – 2.5	%	Industry data, ERC 2 (ECHA, 2016)
Release factor to soil	0 – 0.1	%	Industry data, ERC 2 (ECHA, 2016)
Fraction of the tonnage to solid waste	2 – 2.5	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

#03-2: End-use of oil-based metalworking fluids:

Table 55: Input parameter for the calculation of releases from Exposure scenario #03-2: End-use of oil-based metalworking fluids

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	2 700	tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	[1-5] – 9.6	%	Industry data, EU RAR (EU Commission, 2005)
Release factor to air	0	%	EU RAR (EU Commission, 2005)

[31] Search performed in Google Scholar; Science Direct; PubMed; Research Gate; Web of Science between December 2021 and March 2022.

Input parameter/assumption	Value	Unit	Source
Release factor to soil	0	%	EU RAR (EU Commission, 2005)
Fraction of the tonnage to solid waste	85	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

B.5.3.5.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 56. These releases estimates don't take into account releases from waste. Values are rounded up.

Table 56: Releases estimates to the environment from Use#03 (tonnes of CA:C14-17 per year)

Exposure scenarios	Surface water	Air	Soil	Total
#03-1: Formulation of metalworking fluids	0.001 – 9.4	0.00001 - 68	0.003 - 22	0.005 - 99
#03-2: End-use of oil-based metalworking fluids	9.4 - 45	0.1 – 0.3	21 - 103	31 - 148
Total	**-**	**-**	**-**	**31 - 247**

It is also estimated that the tonnage of CA:C14-17 in waste generated from metalworking fluids represents (these values include WWTP sludges from treatment of waste water from this use that are incinerated/landfilled):

- Formulation: about 0.002 tonnes per year to landfill and 54-68 tonnes per year to incineration/destruction;
- End-use: about 14 tonnes per year to landfill and 2 303 tonnes per year to incineration/destruction.

Releases from waste to the environment are estimated in sections B.5.3.10 to B.5.3.12.

Under RO4b, a derogation for Use#03 is assessed which would lead to releases from all life cycle stages related to this use. Therefore, it is necessary to calculate the total releases from all life cycle stages, including the releases from manufacture and from waste stage strictly related to Use#03. Taking into account the corresponding input tonnages and parameters described in the related sections on manufacture and waste, the Dossier Submitter estimates that the total releases to the environment from the full life cycle of Use#03 represents 34 - 250 tonnes per year of CA:C14-17.

B.5.3.6. Use#04: Use in paints and coatings

B.5.3.6.1. Source of release and pathway

The tonnage used in paints and coatings is estimated to be about 650 tonnes of CA:C14-17 per year. The main types of products and applications are protective (solvent-based) coatings in e.g. in industrial sites and marine environment. Historical uses in intumescent coatings and flame retardants paints are also reported but appear to have been

substituted; if not release from these uses would still be covered by the assessment presented below and the sensitivity analysis.

Four environmental exposure scenarios are considered:

- #04-1: Formulation of paints and coatings (mixtures)
- #04-2: Industrial end-use[29] of paints and coatings
- #04-3: Professional and consumer end-use of paints and coatings
- #04-4: Service-life of paints and coatings

The release pathways are similar to those of adhesives and sealants (Figure 6). For the use phase, spraying indoor (industrial uses) and outdoor (professional) are considered as realistic worst-case. The main uses are the coating of industrial structures by industrial users, and the coating of marine infrastructures, such as ships, by industrial users, professionals and consumers. Consumer uses have not been registered, but it cannot be excluded that consumers have access to this type of products (section A.2.2.2, CfE1 #1330). In absence of information, it is assumed that 50 % of the tonnage is used in industrial protective coatings (by industrial users) and 50 % in marine coatings (split equally between industrials, professionals and consumers). This assumption is tested in a sensitivity analysis. No data is available to differentiate the tonnage used by consumers from the tonnage used by professionals, and both user types are therefore covered by a unique scenario. The service life scenario covers the service life of coatings (after in situ application onto industrial and marine infrastructures).

Waste generated during the uses at industrial sites (formulation and industrial uses) are assumed to be handled as hazardous waste and destroyed (incinerated). Solid waste generated during the use of the mixtures by professionals and consumers are assumed to be disposed of in municipal waste (i.e. landfilled and incinerated) as a conservative assumption.

For marine coatings, releases and waste can be generated during the preparation of the surface before a new coating is applied. As described in the ESD on coating industry (OECD, 2009a), abrasive blasting is the most common method for removal of existing paint layers and this process emits particles (mix of blasting abrasive and paint chips) to the immediate surrounding area (soil) and surface waters. In absence of specific information, the proposed releases factors take into account general containment methods. The collected fraction would be disposed of as waste.

Release factors from CEPE SPERCs for organic solvent borne coatings and non-volatile substances are taken into account for the formulation and use of adhesives and sealants, and default values from ERC 11a and from ESD on coating industry (OECD, 2009a) for the service life for industrial protective coatings and marine coatings respectively.

B.5.3.6.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 57 to Table 60.

<u>#04-1: Formulation of paints and coatings (mixtures)</u>:

Table 57: Input parameter for the calculation of releases from Exposure scenario #04-1: Formulation of paints and coatings (mixtures)

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	650	tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.005	%	CEPE SPERC 2.4c.v2
Release factor to air	0.01	%	CEPE SPERC 2.4c.v2
Release factor to soil	0	%	CEPE SPERC 2.4c.v2
Fraction of the tonnage to solid waste	1 – 2.5	%	CEPE SPERC 2.4c.v2, R18 guidance (ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

#04-2: Industrial end-use of paints and coatings:

Table 58: Input parameter for the calculation of releases from Exposure scenario #04-2: Industrial end-use of paints and coatings

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	0.67	-	DS assumption
Tonnage for this exposure scenario	436	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0	%	CEPE SPERC 5.1a.v2
Release factor to air	1.5	%	CEPE SPERC 5.1a.v2
Release factor to soil	0	%	CEPE SPERC 5.1a.v2
Fraction of the tonnage to solid waste	10 - 52	%	CEPE SPERC 5.1a.v2
WWTP connection rate and efficiency	As described in section B.5.2.4		

#04-3: Professional and consumer end-use of paints and coatings:

Table 59: Input parameter for the calculation of releases from Exposure scenario #04-3: Professional and consumer end-use of paints and coatings

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	0.33	-	DS assumption
Tonnage for this exposure scenario	215	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	2	%	CEPE SPERC 8f.3a.v2
Release factor to air	0	%	CEPE SPERC 8f.3a.v2
Release factor to soil	2	%	CEPE SPERC 8f.3a.v2
Fraction of the tonnage to solid waste	9 - 30	%	CEPE SPERC 8f.3a.v2
WWTP connection rate and efficiency	As described in section B.5.2.4		

#04-4: Service-life of paints and coatings:

Table 60: Input parameter for the calculation of releases from Exposure scenario #04-4: Service-life of paints and coatings

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	DS assumption
Tonnage for this exposure scenario	650	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.05 - 6.5	%	ERC 11a, (ECHA, 2016), (OECD, 2009a)
Release factor to air	0 - 0.05	%	(OECD, 2009a), ERC 11a, (ECHA, 2016)
Release factor to soil	0 - 5	%	ERC 11a, (ECHA, 2016), (OECD, 2009a)
Fraction of the tonnage to solid waste	100	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4 for industrial coatings No connection to WWTP assumed for marine coatings		

B.5.3.6.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 61. These releases estimates don't take into account releases from waste. Values are rounded up.

Table 61: Releases estimates to the environment from Use#04 (tonnes of CA:C14-17 per year)

Exposure scenarios	Surface water	Air	Soil	Total
#04-1: Formulation of paints and coatings (mixtures)	0.006	0.06	0.01	**0.08**
#04-2: Industrial end-use of paints and coatings	0	6.5	0	**6.5**
#04-3: Professional and consumer end-use of paints and coatings	0.75	0.004	6.0	**6.7**
#04-4: Service-life of paints and coatings (max for industrial infrastructures – max for marine infrastructures)	0.06 – 42	0 – 0.33	0.13 – 33	**0.5 – 75**
Total	**-**	**-**	**-**	**14 - 88**

It is also estimated that the tonnage of CA:C14-17 in waste generated from Use#04 represents (these values include WWTP sludges from treatment of waste water from this use that are incinerated/landfilled):

- Formulation: about 0.01 tonnes per year to landfill and 7-16 tonnes per year to incineration/destruction;
- Industrial end-use: about 44-226 tonnes per year to incineration/destruction;

- Professional and consumer end-use: about 10-31 tonnes per year to landfill and 11-35 tonnes per year to incineration/destruction;
- Service life: up to 650 tonnes per year to shredding, 306 tonnes per year to landfill and 345 tonnes per year to incineration/destruction.

Releases from waste to the environment are estimated in sections B.5.3.10 to B.5.3.12.

B.5.3.7. Use#05: Use in leather

B.5.3.7.1. Source of release and pathway

The tonnage used in the processing of leather is estimated to be about 220 tonnes of CA:C14-17 per year, as a minor constituent in the substance used in fatliquoring. This value may be an overestimation but is used as a conservative estimate. Indeed, the results of the market survey suggest that CA:C14-17 congeners can be removed from the substances used in fatliquor if made mandatory under the proposed restriction (this is the assumption taken in the impact assessment), but in the baseline estimate, i.e. without restriction, the Dossier Submitter assumes that the substances still contain the congeners up to 10 % based on current data (as discussed in section B.5.2.2) which lead to releases calculated below. This percentage is subject to sensitivity analysis. The main types of relevant articles appear to be shoes, but other leather articles – requiring a high degree of softness - can also be produced using this substance.

Three environmental exposure scenarios are considered:

- #05-1: Formulation of mixtures for leather
- #05-2: Incorporation in leather
- #05-3: Service life of leather articles

Leather processing in tanneries includes many steps and the substances in the scope of the restriction proposal are used only during the fatliquoring (part of post-tanning) step, where they are applied as an oil emulsion to the leather in drums. The degree of fixation of fatliquor in leather is estimated 95-99 % (Danish EPA, 2014), leading to no more than 2 % of residual amount in the spent fatliquor emulsion at the end of the process (EU Commission, 2005). Releases occur mainly to waste water. Releases occur mainly to waste water. In principle these effluents have to be treated before discharge to surface water but the extent of the treatment depends on the local conditions (OECD, 2004). Registrants confirmed that waste water containing these substances are treated before any release to the environment to conform with national legislations regulating the discharging of industrial water; however, no data was provided to quantify the efficiency of such treatment in removing the substance from liquid effluents and sludges.

For the formulation of the fatliquor and the processing of leather, release factors from registrations, from ECHA guidance R16 (ECHA, 2016) and EU RAR (EU Commission, 2005) are taken into account to estimate lower and upper releases. Values from registration dossiers are given as ranges in the tables below due to confidentiality. For the use phase, the upper bound is a worst case representing a situation where post-tanning effluents would be discharged to municipal WWTP without prior treatment or with a prior treatment unable to destroy these substances effectively. Service life can occur indoor or outdoor;

defaults factors from ECHA guidance R16 (ECHA, 2016) are used.

It is further assumed that all articles are disposed of as municipal waste when reaching their end of life. The fraction of the tonnage ending up in waste is taken from ECHA guidance R18 (ECHA, 2012b).

B.5.3.7.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 62 to Table 64.

#05-1: Formulation of mixtures for leather:

Table 62: Input parameter for the calculation of releases from Exposure scenario #05-1: Formulation of mixtures for leather

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	220	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	[0.001-0.1] - 2	%	Industry data, ERC 2 (ECHA, 2016)
Release factor to air	[0.001-0.1] – 2.5	%	Industry data, ERC 2 (ECHA, 2016)
Release factor to soil	0 – 0.01	%	Industry data, ERC 2 (ECHA, 2016)
Fraction of the tonnage to solid waste	2.5	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

#05-2: Incorporation in leather:

Table 63: Input parameter for the calculation of releases from Exposure scenario #05-2: Incorporation in leather

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	220	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	[0.01-0.1] - 2	%	Industry data, EU RAR (EU Commission, 2005)
Release factor to air	0 – [0.01-0.1]	%	EU RAR (EU Commission, 2005), industry data
Release factor to soil	0 – [0.01-0.1]	%	EU RAR (EU Commission, 2005), industry data
Fraction of the tonnage to solid waste	5	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

#05-3: Service life of leather articles:

Table 64: Input parameter for the calculation of releases from Exposure scenario #05-3: Service life of leather articles

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	220	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.05 – 3.2	%	ERC 10a, ERC 11a (ECHA, 2016)
Release factor to air	0.05	%	ERC 10a, ERC 11a (ECHA, 2016)
Release factor to soil	0 – 3.2	%	ERC 10a, ERC 11a (ECHA, 2016)
Fraction of the tonnage to solid waste	100	%	(ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

B.5.3.7.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 65. These releases estimates don't take into account releases from waste. Values are rounded up.

Table 65: Releases estimates to the environment from Use#05 (tonnes of CA:C14-17 per year)

Exposure scenarios	Surface water	Air	Soil	Total
#05-1: Formulation of mixtures for leather	0.004 – 0.8	0.02 – 5.5	0.009 – 1.8	**0.03 – 8.0**
#05-2: Incorporation in leather	0.03 – 0.8	0.2 - 0	0.2 – 1.7	**0.36 – 2.5**
#05-3: Service life of leather articles	0.02 – 1.2	0.11 – 0.12	0.04 – 9.8	**0.17 – 11**
Total	**-**	**-**	**-**	**0.6 - 22**

It is also estimated that the tonnage of CA:C14-17 in waste generated from Use#05 represents (these values include WWTP sludges from treatment of waste water from this use that are incinerated/landfilled):

- Formulation: about 0.01 tonnes per year to landfill and 6 tonnes per year to incineration/destruction
- Incorporation in leather: about 0.05 tonnes per year to landfill and 11 tonnes per year to incineration/destruction
- Service life: 103 tonnes per year to landfill and 117 tonnes per year to incineration/destruction.

Releases from waste to the environment are estimated in sections B.5.3.10 to B.5.3.12.

B.5.3.8. Use#06: Use in paper manufacturing/recycling [obsolete use]

The use has not been confirmed and is thus considered obsolete.

Releases may still exist from any pre-existing stock, however this cannot be quantified.

B.5.3.9. Use#07: Other uses

B.5.3.9.1. Source of release and pathway

The tonnage in other uses is estimated to be about 1 100 tonnes of CA:C14-17 per year. This category includes all other mixtures and articles as listed in section A.2. As no quantitative and reliable information is available on these uses, the assessment of the releases is based on the assumption that the main 'other use' is in lubricants, e.g. lubricants for automotive and bicycles (professional and consumer use); lubricants can also be incorporated in articles (e.g. hinges) but this is not assessed separately.

Two environmental exposure scenarios are considered:

- #07-1: Formulation of other mixtures
- #07-2: Professional and consumer end-use of other mixtures.

Release factors are based on ERC 2 defaults from ECHA guidance R16 for the formulation (ECHA, 2016) and SpERCs of ESIG ESVOC for professional use of lubricants for low vapour pressure substances.

The Dossier Submitter assumes that waste will be disposed as municipal waste.

B.5.3.9.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 66 to Table 67.

#07-1: Formulation of other mixtures:

Table 66: Input parameter for the calculation of releases from Exposure scenario #07-1: Formulation of other mixtures

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	1 100	tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	2	%	ERC 2 (ECHA, 2016)
Release factor to air	2.5	%	ERC 2 (ECHA, 2016)
Release factor to soil	0.01	%	ERC 2 (ECHA, 2016)
Fraction of the tonnage to solid waste	2.5	%	R18 guidance (ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

#07-2: Professional and consumer end-use of other mixtures:

Table 67: Input parameter for the calculation of releases from Exposure scenario #07-2: Professional and consumer end-use of other mixtures

Input parameter/assumption	Value	Unit	Source
Fraction of Use tonnage for the exposure scenario	1	-	-
Tonnage for this exposure scenario	1 100	tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	5	%	ESIG ESVOC SPERC 8.6c.v2
Release factor to air	0.5	%	ESIG ESVOC SPERC 8.6c.v2
Release factor to soil	5	%	ESIG ESVOC SPERC 8.6c.v2
Fraction of the tonnage to solid waste	35-89.5	%	ESIG ESVOC SPERC 8.6c.v2, mass balance
WWTP connection rate and efficiency	As described in section B.5.2.4		

B.5.3.9.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 68. These releases estimates don't take into account releases from waste. Values are rounded up.

Table 68: Releases estimates to the environment from Use#07 (tonnes of CA:C14-17 per year)

Exposure scenarios	Surface water	Air	Soil	Total
#07-1: Formulation of other mixtures	3.8	27.5	8.8	**40**
#07-2: Professional and consumer end-use of other mixtures	9.6	5.6	77	**92**
Total	**-**	**-**	**-**	**132**

It is also estimated that the tonnage of CA:C14-17 in waste generated from Use#07 represents (these values include WWTP sludges from treatment of waste water from this use that are incinerated/landfilled):

- Formulation: about 6 tonnes per year to landfill and 31 tonnes per year to incineration/destruction
- Professional and consumer end-use: about 195-477 tonnes per year to landfill and 212-530 tonnes per year to incineration/destruction.

Releases from waste to the environment are estimated in sections B.5.3.10 to B.5.3.12.

B.5.3.10. W1: Dismantling and shredding of waste/articles

B.5.3.10.1. Source of release and pathway

As presented in section B.5.2.3, it is considered that a fraction of waste will undergo dismantling/shredding as a first step when collecting the waste and sorting them for recycling or disposal. Releases from these processes are estimated together in the exposure scenario :

- W1: Dismantling and shredding of waste/articles.

The Dossier Submitter estimated that the tonnage of CA:C14-17 in end of life articles and waste undergoing dismantling/shredding is about 37 000 tonnes of CA:C14-17 per year (the value is rounded up), from Uses #00, #01 and #04 (see underlying assumptions in section B.5.2.3):

- Up to 3080 tonnes per year from end of life of PVC articles
- Up to 33 000 tonnes per year from end of life of adhesives and sealants
- Up to 650 tonnes per year from end of life of paints and coatings.

Releases are expected to occur to air via dust. This initial release is expected to settle and be transferred to other constituents, but this is not quantified as the emission of dust can occur outdoor (e.g. from tearing down buildings) and can be transported by wind before settling. Release factors for scenario W1 are taken from the ECHA guidance R18 for plastics and minerals (ECHA, 2012a).

B.5.3.10.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 69.

W1: Dismantling and shredding of waste/articles:

Table 69: Input parameter for the calculation of releases from Exposure scenario W1: Dismantling and shredding of waste/articles

Input parameter/assumption	Value	Unit	Source
Tonnage for this exposure scenario	37 000	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0	%	R18 guidance (ECHA, 2012b)
Release factor to air	10	%	R18 guidance (ECHA, 2012b)
Release factor to soil	0	%	R18 guidance (ECHA, 2012b)
WWTP connection rate and efficiency	As described in section B.5.2.4		

B.5.3.10.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 70. Values are rounded up.

Table 70: Releases estimates to the environment from Exposure scenario W1 (tonnes of CA:C14-17 per year)

Exposure scenarios	Surface water	Air	Soil	Total
W1: Dismantling and shredding of waste/articles	0	3 700	0	**3 700**

B.5.3.11. W2: Disposal of waste/articles to landfill

B.5.3.11.1. Source of release and pathway

The Dossier Submitter estimated that up to 41 000-44 000 tonnes of CA:C14-17 is landfilled per year (the values are rounded up), from all uses and from landfilling of WWTP sludges as detailed in Table 71 (see underlying assumptions in section B.5.2.3).

Table 71: Tonnage to landfill (tonnes of CA:C14-17 per year)

Exposure scenarios	Lower bound	Higher bound
M-1: Manufacture of the substance	26	26
#00-1: Compounding (plastisol and dry blending)	1	1
#00-2: Conversion - production of PVC articles	1	1
#00-3: Service life of PVC articles	6 022	6 022
#01-1: Formulation of adhesives and sealants (mixtures)	2	2
#01-2: Industrial end-use of adhesives and sealants	0	0
#01-3: Professional and consumer end-use of adhesives and sealants	725	3 206
#01-4: Service-life of adhesives/sealants	31 354	31 354
#02-1: Compounding (rubber)	0.1	0.1
#02-2: Production of rubber articles	0.2	0.2
#02-3: Service life of rubber articles	2 700	2 700
#03-1: Formulation of metalworking fluids	0.002	0.002
#03-2: End-use of oil-based metalworking fluids	14	14
#04-1: Formulation of paints and coatings (mixtures)	0.01	0.01
#04-2: Industrial end-use of paints and coatings	0	0
#04-3: Professional and consumer end-use of paints and coatings	10	31
#04-4: Service-life of paints and coatings	306	306
#05-1: Formulation of mixtures for leather	0.01	0.01
#05-2: Incorporation in leather	0.05	0.05
#05-3: Service life of leather	103	103

Exposure scenarios	Lower bound	Higher bound
#07-1: Formulation of other mixtures	6	6
#07-2: Professional and consumer end-use of other mixtures	195	477

One exposure scenario is considered:

- W2: Disposal of waste/articles by landfill

In this assessment, the "landfill" scenario (W2) aims at covering standard landfill as well as backfilling and any other waste disposal not included in scenario W3. It lead to releases to the environment via volatilisation and leaching (EU Commission, 2005). Although backfilling is a recovery process rather than waste treatment, it is assumed to lead to similar releases than from landfilling. As CA:C14-17 are not volatile and adsorb to soil, it is expected that releases would be mainly to waste water (adsorbed to particulate matter) and soil. During the operating phase of a landfill, the Landfill Directive[32] require that RMM are in place to ensure that leachates are collected and treated. Due to the complex composition of landfill leachates, which evolves as the landfill ages, a variety of treatment methods exist (Teng et al., 2021). In principle no significant releases would be expected if these RMM efficiently prevent releases to the environment. However, the efficiency of these RMM on the actual risk reduction for chloroalkanes is unknown; furthermore, in its report on the implementation of EU waste legislation (2018)[33], the Commission highlighted that 'the number of facilities that are not in line with the requirements of the Directive remains a matter of concern' in the EU. To account for the variability of implementation of efficient RMMs in landfills, especially for the treatment of leachates, the default release factors of the ECHA R18 guidance are used (ECHA, 2012a) assuming a residence time of 20 years in landfill and 50 % efficiency of onsite RMM, in combination with 100 % connection to WWTP (see section B.5.2.4). This calculation underestimates the releases from backfilling (no RMM in place) and from uncontrolled disposal of used conveyor belts by dumping them in old mines. It is assumed that the sludges from WWTP connected to landfills are incinerated. However, it is also possible that a fraction is landfilled and recirculates through landfill.

Furthermore, since CA:C14-17 don't degrade, they remain of concern even after the closure of a landfill, during the after-care period and after the final capping. It can be assumed that the releases from the after-care don't exceed the releases during the actual operating phase of the landfill. After a landfill is finally capped and 'abandoned', it becomes an important reservoir of CA:C14-17. Releases from any further remediation, landfill mining or excavation are not addressed by the Dossier Submitter.

[32] Council Directive 1999/31/EC on the landfill of waste amended by Directive (EU) 2018/850.

[33] https://eur-lex.europa.eu/resource.html?uri=cellar:1dfc5184-c003-11e8-9893-01aa75ed71a1.0006.02/DOC_1&format=PDF

B.5.3.11.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 72.

W2: Disposal of waste/articles by landfill:

Table 72: Input parameter for the calculation of releases from Exposure scenario W2: Disposal of waste/articles by landfill

Input parameter/assumption	Value	Unit	Source
Tonnage for this exposure scenario	41 000 – 44 000	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	1.6	%	R18 guidance (ECHA, 2012b)
Release factor to air	0	%	R18 guidance (ECHA, 2012b)
Release factor to soil	1.6	%	R18 guidance (ECHA, 2012b)
WWTP connection rate and efficiency	Connection rate and efficiency: as described in section B.5.2.4 Sludge handling: worst case assumption that 100 % is incinerated		

B.5.3.11.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 73. Values are rounded up.

Table 73: Releases estimates to the environment from Exposure scenario W2 (tonnes of CA:C14-17 per year)

Exposure scenarios	Surface water	Air	Soil	Total
W2: Disposal of waste/articles by landfill	55 -59	0.7 – 0.8	660 - 710	**720 - 770**

These values underestimate the releases from backfilling (no RMM in place) and from uncontrolled disposal of used conveyor belts by dumping them in old mines. This underestimation cannot be quantified.

By applying a simple mass balance calculation on the landfill scenario (subtracting tonnage released during the operating period as reported in Table 73 from the total tonnage that entered the operating landfill reported in B.5.3.11.1), it is possible to estimate roughly the potential tonnage that remains sunk in after-care and 'abandoned' landfills after their closure. This sunk tonnage represents up to 40 000-43 000 tonnes of CA:C14-17 per year. This value assumes no degradation and does not take into account any mass balance in the life cycle stages before landfilling and is therefore an overestimation. The Dossier Submitter did not attempt to quantify the releases from landfills over a very long period of time (i.e. beyond the operating phase of a landfill, shown above), as the conditions for after-care and closure that affects releases depend on the specificities of each site, and there may be subsequent events (reuse of the area for other purposes) that would also

affects the releases. Qualitatively, taking into account any additional releases would result in a more favourable C/E ratio under each RO.

B.5.3.12. W3: Disposal of waste/articles by incineration or other destructive treatments

B.5.3.12.1. Source of release and pathway

The Dossier Submitter estimated that about 14 000-19 000 tonnes of CA:C14-17 is incinerated or destroyed by other means per year (the values are rounded up), from all uses and from incineration of WWTP sludges as detailed in Table 74 (see underlying assumptions in section B.5.2.3).

Table 74: Tonnage to incineration (tonnes of CA:C14-17 per year)

Exposure scenarios	Lower bound	Higher bound
M-1: Manufacture of the substance	675	1 665
#00-1: Compounding (plastisol and dry blending)	350	350
#00-2: Conversion - production of PVC articles	700	700
#00-3: Service life of PVC articles	5 321	5 321
#01-1: Formulation of adhesives and sealants (mixtures)	661	991
#01-2: Industrial end-use of adhesives and sealants	330	396
#01-3: Professional and consumer end-use of adhesives and sealants	758	3 557
#01-4: Service-life of adhesives/sealants	1 652	1 652
#02-1: Compounding (rubber)	68	68
#02-2: Production of rubber articles	135	135
#02-3: Service life of rubber articles	0	0
#03-1: Formulation of metalworking fluids	54	68
#03-2: End-use of oil-based metalworking fluids	2 303	2 303
#04-1: Formulation of paints and coatings (mixtures)	7	16
#04-2: Industrial end-use of paints and coatings	44	226
#04-3: Professional and consumer end-use of paints and coatings	11	35
#04-4: Service-life of paints and coatings	345	345
#05-1: Formulation of mixtures for leather	6	6
#05-2: Incorporation in leather	11	11
#05-3: Service life of leather	117	117
#07-1: Formulation of other mixtures	31	31
#07-2: Professional and consumer end-use of other mixtures	212	530

One exposure scenario is considered:

- W3: Disposal of waste/articles by incineration or other destructive treatments

This scenario covers incineration with and without energy recovery for hazardous and non-hazardous waste. The default release factors of ECHA R18 guidance (ECHA, 2012a) for the incineration of waste are used.

It is assumed that the connection rate of incinerators to WWTP is 100 %. It is also assumed that sludges from WWTP connected to incinerators are incinerated. However, it is possible that a fraction is landfilled and recirculates through landfill. Releases from incineration residues (ashes) disposed of to landfill are not quantified because they are assumed to be negligible compared to releases from other sources.

B.5.3.12.2. Key input parameters

The input parameters and assumptions used in the exposure assessment are presented in Table 73.

W3: Disposal of waste/articles by incineration or other destructive treatments:

Table 75: Input parameter for the calculation of releases from Exposure scenario W3: Disposal of waste/articles by incineration or other destructive treatments

Input parameter/assumption	Value	Unit	Source
Tonnage for this exposure scenario	14 000 – 19 000	Tonnes per year	-
Release factor to waste water (after on-site WWTP but before municipal WWTP)	0.01	%	R18 guidance (ECHA, 2012b)
Release factor to air	0.01	%	R18 guidance (ECHA, 2012b)
Release factor to soil	0	%	R18 guidance (ECHA, 2012b)
WWTP connection rate and efficiency	Connection rate and efficiency: as described in section B.5.2.4 Sludge handling: worst case assumption that 100 % is incinerated		

B.5.3.12.3. Emission and releases estimates

The release estimates after municipal WWTP are presented in Table 75. Values are rounded up.

Table 76: Releases estimates to the environment from Exposure scenario W3 (tonnes of CA:C14-17 per year)

Exposure scenarios	Surface water	Air	Soil	Total
W3: Disposal of waste/articles by incineration or other destructive treatments	0.1 - 0.2	1.4 – 1.9	0	**1.5 - 2**

B.5.3.13. Summary of the releases

Table 77: Total releases per environmental compartment (from use and waste) (tonnes of CA:C14-17 per year)

	Lower bound	Upper bound
Total releases (all environmental compartments)	5 214	6 284
Total releases (all environmental compartments) – rounded values for the main report	**5 200**	**6 300**

Note: central estimate for the cost calculation: 5 749 tonnes per year

B.5.4. Other sources (for example natural sources, unintentional releases)

Substances containing CA:C14-17 are manufactured substances. There are no known natural sources of CA:C14-17 (EU Commission, 2005).

B.5.5. Monitoring data

The monitoring data reported in Annex III to the SVHC Annex XV proposal, and already assessed by the ECHA Member State Committee were complemented by a literature review. The newly reported studies are indicated in the last column of Table 78 to Table 87.

It should be noted that C14-17 chloroalkanes are currently not listed in the European **Industrial Emissions Portal** (https://industry.eea.europa.eu/) which has replaced the European Pollutant Release and Transfer Register (**E-PRTR**) since June 2021. They are neither listed in IPCHEM (checked on 11/03/2022). SCCP/ chloroalkane C10-13 are.

B.5.5.1. Monitoring data of CA:C14-17 in surface water and sludge

Table 78: Summary of levels of CA:C14-17 in surface water and sludge in the EU

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Zurich area, Switzerland (sewage sludge)	2007	ng/g	5.1-160	$C_{14}Cl_{5\text{-}12}$ $C_{15}Cl_{5\text{-}15}$ $C_{16\text{-}17}Cl_{5\text{-}16}$	The set of analysed field samples included seven sewage sludge samples from municipal wastewater treatment plants around Zurich, Switzerland, from 2007 and two urban air samples from Zurich, Switzerland, from summer 2012.	(Bogdal et al., 2015)
River Lech at Augsburg	1994	µg/L	<0.05			(Ballschmiter, 1994)
River Lech at Gersthofen (upstream from a chlorinated paraffin production plant)	1994	µg/L	0.094			(Ballschmiter, 1994)
River Lech at langweid (downstream from a chlorinated paraffin production plant)	1994	µg/L	0.185			(Ballschmiter, 1994)
River Lech at Rain	1994	µg/L	0.17			(Ballschmiter, 1994)
River Danube at Marxheim (downstream from the mouth of the River Lech)	1994	µg/L	0.072			(Ballschmiter, 1994)
River Danube at Marxheim (upstream from the mouth of the River Lech)	1994	µg/L	≤0.055			(Ballschmiter, 1994)
River Lech at Gersthofen (upstream from a chlorinated paraffin production plant)	1987	µg/L	4.5			(Ballschmiter, 1994)
River Lech at langweid (downstream from a chlorinated paraffin production plant)	1987	µg/L	4			(Ballschmiter, 1994)
River Danube at Marxheim (downstream from the mouth of the River Lech)	1987	µg/L	20			(Ballschmiter, 1994)
River Danube at Marxheim (upstream from the mouth of the River Lech)	1987	µg/L	4			(Ballschmiter, 1994)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Irish Sea: Site a		µg/L	1	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Irish Sea: Site b		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Irish Sea: Site c		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Irish Sea: Site d		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Irish Sea: Site e		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Irish Sea: Site f		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Upstream of sewage treatment plant, Germany		µg/L	not detected			(Rieger and Ballschmiter, 1995)
Downstream of sewage treatment plant, Germany		µg/L	not detected			(Rieger and Ballschmiter, 1995)
Tibutary, upstream of sewage treatment plant, Germany		µg/L	not detected			(Rieger and Ballschmiter, 1995)
Water samples from Norway		µg/L	1.49		Two samples. Concentration refers to total (dissolved + particulate) in one sample. The concentrations present in the other sample was much lower (shown graphically only but was probably <0.1 µg/L.	(Petersen et al., 2006)
Sludge (Norway)		µg/kg	3 964 (77-11 800)			(Fjeld et al., 2005)
Filtered river water samples, Europe		µg/L	<0.10		8 Samples filtered using a membrane glass fibre filter before analysis	(Coelhan, 2009, Coelhan, 2010b)
Influent to waste water treatment plants, Europe		µg/L (particulate)	not detected – 4.6		15 Samples. CA:C14-17 detectable in 12 samples.	(Coelhan, 2009, Coelhan, 2010b)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Effluent from waste water treatment plants, Norway		µg/L	not detected – 0.942		Samples from 8 waste water treatment plants (4 samples from each location). CA:C14-17 detectable in 13 % of samples analysed.	(Thomas et al., 2011)
Dewatered sludge from waste water treatment plants, Norway		µg/L	14 - 7 000 (median 385)		Samples from 8 waste water treatment plants (4 samples from each location). CA:C14-17 detectable in all samples.	(Thomas et al., 2011)
Snow (melted) from urban areas of Gothenburg, Sweden		µg/L	0.33 - 32		8 Samples. CA:C14-17 detectable in 2 samples (the concentrations may relate to CA:C10-13 + CA:C14-17 in the samples)	(Björklund et al., 2011)
Storm water (Norway)		µg/L	0.0685			(Ruus et al., 2018)
Effluent water, Norway		µg/L	0.08		Bekkelaget STP, Norway	(Ruus et al., 2018)
Sludge, Norway		ng/g dry weight	2 470-2 500		Bekkelaget STP, Norway	(Ruus et al., 2018)
Sludge (Norway)		µg/kg	4 031 (120-17 000)			(Norsk Vann, 2018)

Table 79: Summary of levels of CA:C14-17 in surface water and sludge outside the EU

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Ya'Er lake area (China)	2019	µg/L	Not detected	Relates to C_{14-17}	175 environmental samples were collected from this region, of which 20 were water samples. CA:C14-17 in all water samples were below the detection limit.	(Li et al., 2021a) [1]

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Beijing (China)	2017	ng/L	35 - 217	$C_{10-27}Cl_{5-14}$	A total of 24 water samples were taken from the inflows and outflows of the different units in the wetland system.	(Wang et al., 2021a) [1]
Haungpu River and its main tributaries (Shanghai)	2016	ng/L	40.3 - 3870	$C_{14-17}Cl_{5-10}$	A total of 74 sampling locations were selected from Huangpu River and its main tributaries. CA:C14-17 were detected in all samples.	(Wang et al., 2019c) [1]
Persian Gulf, Iran	2015	ng/L	13.2 - 43.6	$C_{14-17}Cl_{8-10}$	50 surface sediment were collected from the coral reef fields.	(Ranjbar Jafarabadi et al., 2021) [1]
Upper reaches to the estuary of the Xiaoqing River (China)	2014	ng/L	4.0 - 120	$C_{14-17}Cl_{6-10}$	30 water samples were obtained from the upper reaches to the estuary of the Xiaoqing River.	(Pan et al., 2021) [1]
Australia (sewage sludge)	2014	ng/g dw	542 - 3645	$C_{14-17}Cl_{4-11,14}$	Pooled (eight subsamples from each WWTP) sewage sludge samples were collected in 2014 at 15 different WWTPs in Australia. The WWTPs were located in five states of Australia, servicing populations of between 25 000 and 600 000 people, representing a combined population of app. 2.5 million people.	(Brandsma et al., 2017)
Surface water near to industrial sites, UK	1998	µg/L	<0.1			(Cefas, 1999)
Derwent Reservoir	1986	µg/L	1.46			(ICI, 1992, Willis et al., 1994)
River Trent, Newark	1986	µg/L	0.86			(ICI, 1992, Willis et al., 1994)
Trent Mersey Canal	1986	µg/L	0.62			(ICI, 1992, Willis et al.,

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
						1994)
River Derwent, Derby	1986	µg/L	0.64			(ICI, 1992, Willis et al., 1994)
Walton on Trent	1986	µg/L	1.07			(ICI, 1992, Willis et al., 1994)
River Ouse, Goole	1986	µg/L	0.94			(ICI, 1992, Willis et al., 1994)
River Don, Rotherham	1986	µg/L	1.13			(ICI, 1992, Willis et al., 1994)
River Aire/Ouse	1986	µg/L	1.13			(ICI, 1992, Willis et al., 1994)
River Ouse, York	1986	µg/L	1.36			(ICI, 1992, Willis et al., 1994)
River Cover, Wilton	1986	µg/L	0.84			(ICI, 1992, Willis et al., 1994)
River Ure, Mickley	1986	µg/L	1.46			(ICI, 1992, Willis et al., 1994)
River Trent, Gainsborough	1986	µg/L	2.49			(ICI, 1992, Willis et al., 1994)
River Trent, Burton	1986	µg/L	2.46			(ICI, 1992, Willis et al., 1994)
River Rother	1986	µg/L	2.11			(ICI, 1992, Willis et al., 1994)
River Trent, Humber	1986	µg/L	3.75			(ICI, 1992, Willis et al., 1994)
Hull Docks	1986	µg/L	2.69			(ICI, 1992, Willis et al., 1994)
Barmouth Harbour		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Menai Straights (Caernarvon)		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Tremadoc Bay (Llandanwg)		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
North Minch: Ardmair		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
North Minch: Port Bùn á Ghlinne		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
North Minch: Port of Ness		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Goile Chròic (Lewis)		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Sound of Taransay (Harris)		µg/L	4	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Sound of Arisaig		µg/L	1	Relates to C_{10-20}		(Campbell and McConnell, 1980)
North Sea: N55° 5.7' W1° 9.3'		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
North Sea: N57° 26.2' W1° 17.0'		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
North Sea: N57° 56.5' W1° 22.0'		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Banwy, Llangadfan		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Lea, Welwyn		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Lea, Batford		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Clwyd, Ruthin		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Bala Lake		µg/L	1	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Dee, Corwen		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Wnion, Merioneth		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Firth of Lorne, Ganevan		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Loch Linnhe, Corran Narrows		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Firth of Clyde, Ashcraig		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Firth of Clyde, Girvan		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
An Garbh Allt		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Five drinking water reservoirs, Manchester area		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Aire, Leeds		µg/L	2	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Aire, Woodlesford		µg/L	2	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Ouse, Boothberry edge		µg/L	1 - 2	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Trent, West Bromwich		µg/L	1 - 2	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Trent, Walton-upon-Trent		µg/L	2 - 3	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Trent, Swarkestone		µg/L	1 - 2	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Trent, Newark		µg/L	4	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Trent, Gainsborough		µg/L	2	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Trent, confluence with Humber		µg/L	6	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Humber Estuary, Hull		µg/L	1 - 2	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Humber Estuary, Grimsby		µg/L	3	Relates to C_{10-20}		(Campbell and McConnell, 1980)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Mersey Estuary, New Brighton		µg/L	3	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Mersey Estuary, Liverpool Pier Head		µg/L	4	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Thames, Oxford		µg/L	2	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Thames, Sanford		µg/L	1 - 2	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Wyre Estuary		µg/L	not detected - 1.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Tees, Low Dinsdale		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Tees, North Gare breakwater		µg/L	0.5	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Tees, Middlesbrough		µg/L	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Sugar Creek, upstream of discharge		µg/L (particulate)	not detected			(Murray et al., 1987a, Murray et al., 1987b)
Sugar Creek, just upstream of discharge		µg/L (particulate)	0.05 - 0.17			(Murray et al., 1987a, Murray et al., 1987b)
Sugar Creek, just downstream of discharge		µg/L (particulate)	0.16 - 0.2			(Murray et al., 1987a, Murray et al., 1987b)
Sugar Creek, downstream of discharge		µg/L (particulate)	0.20 - 0.24			(Murray et al., 1987a, Murray et al., 1987b)
Downstream of a chlorinated paraffin manufacturing plant, Canada		µg/L	<1			(Tomy et al., 1998)
Great Lakes Basin		µg/L	9×10^{-7}		Mean concentration based on an analysis of published studies	(Klecka et al., 2010)

Note: [1] new studies which were not reported in the SVHC support document (ECHA, 2021d)

B.5.5.2. Monitoring data of CA:C14-17 in air

Table 80: Summary of levels of CA:C14-17 in air in the EU

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Birkenes, Norway	2019	pg/m^3	267 (January)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	<190 (Feb.)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	<190 (March)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	<190 (April) <190 (May)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	287 (June)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	1507 (July)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	336 (August)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	<190 (Sept.)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	414 (October)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	460 (Nov.)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	<190 (Dec.)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)
Birkenes, Norway	2019	pg/m^3	327 (mean in 2019)		Air samples (bulk concentrations: sum gas- and particle phase), 2019, monthly and annual mean concentrations	(Bohlin-Nizzetto et al., 2020)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Zurich, Switzerland	2012	ng/m^3	1.32 - 25.9	$C_{14}Cl_{5\text{-}11}$ $C_{15}Cl_{5\text{-}10}$ $C_{16}Cl_{6\text{-}10}$ $C_{17}Cl_{5\text{-}9}$	The set of analysed field samples included seven sewage sludge samples from municipal wastewater treatment plants around Zurich, Switzerland, from 2007 and two urban air samples from Zurich, Switzerland, from summer 2012.	(Bogdal et al., 2015)
Apartments in Stockholm, Sweden (indoor air)	2006-2007	ng/m3	65	$C_{14}Cl_{4\text{-}8}$ $C_{15}Cl_{4\text{-}6}$ $C_{16}Cl_6$ $C_{17}Cl_{6,10}$	44 indoor air and six dust samples from apartments in Stockholm, Sweden, were analysed. The median concentration reported gives the total CA:C10-13 and CA:C14-17, concentrations separately to CA:C14-17 not reported.	(Friden et al., 2011)

Table 81: Summary of levels of CA:C14-17 in air outside the EU

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Dar es Salaam, Tanzania	2018	ng/m^3	<0.4 - 35	Relates to $C_{14\text{-}17}$	Air samples were collected in 2018 -2019 from 19 locations including densely populated and industrialized urban areas, suburban areas, and rural areas with little anthropogenic activity .	(Nipen et al., 2022a) [1]
Dar es Salaam, Tanzania	2018	ng/m^3	1 - 33	Relates to $C_{14\text{-}17}$	Air samples were collected in 2018 -2019 from 9 locations targeting specifically the city's main municipal waste dumpsite and an e-waste handling facility on the outskirts of Dar es Salaam. CA:C14-17 detetected in 93 % of the air samples	(Nipen et al., 2022a) [1]
Australia	2016	ng/m^3	<MDL - 1.8	$C_{14}Cl_{3\text{-}9}$ $C_{15}Cl_{3\text{-}11}$ $C_{16}Cl_{4\text{-}10}$ $C_{17}Cl_{3\text{-}11}$	Air samples were collected from 15 different geographic zones of Australia: 5 remote, 6 rural and 4 urban sites. CA:C14-17 were detected in 13 out of the 16 samples (detection frequency 81 %).	(van Mourik et al., 2020b) [1]
King George Island, Antarctica	2014	pg/m^3	<0.26 - 27.4	$C_{14\text{-}17}Cl_{5\text{-}10}$	120 samples (polyurethanefoam (PUF) plugs and glass fiber filters (GFF)) from 2014 - 2018. CA:C14-17 were detected in all samples.	(Jiang et al., 2021)
China	2013	ng/m^3	5.57 - 27.3	$C_{14\text{-}17}Cl_{6\text{-}10}$	$PM_{2.5}$ (fine particule matter) samples were collected from 10 cities in China in 2013 - 2014. CA:C14-17 were detected in all cities.	(Liu et al., 2020a) [1]

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Shenzhen, Guangzhou Province, China	2013	ng/m^3	0.70–12.2		Air samples (28 samples collected over 4 seasons, September 2013 to August 2014)	(Li et al., 2018b)
Dongjiang River, China		µg/sampler	4.1	$C_{14\text{-}17}Cl_{6\text{-}10}$	Air samples	(Wang et al., 2013)
Dongjiang River, China		µg/(m^{2}d)	5.3	$C_{14\text{-}17}Cl_{6\text{-}10}$	Atmospheric depositions (wet and dry) at 11 sites	(Wang et al., 2013)
India		ng/m^3	3.62	$C_{14\text{-}17}Cl_{6\text{-}10}$	Air samples (average)	(Chaemfa et al., 2014)
Pakistan		ng/m^3	4.21	$C_{14\text{-}17}Cl_{6\text{-}10}$	Air samples (average)	(Chaemfa et al., 2014)

Note: [1] new studies which were not reported in the SVHC support document (ECHA, 2021d)

B.5.5.3. Monitoring data of CA:C14-17 in sediment and soil

Table 82: Summary of levels of CA:C14-17 in sediment and soil in the EU

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Norway	2020	µg/kg dw	29 - 529	Relates to $C_{14\text{-}17}$	Measurement from marine sediment: 7 samples	(Boitsov and Sanden, 2021)[1]
Germany	2018	ng/g dw	11.0 - 49.0	Relates to $C_{14\text{-}17}$	8 soil samples were collected from 8 sites, in 2018 - 2019.	(Yuan et al., 2022)[1]
Germany	2018	ng/g dw	110 - 520	$C_{14\text{-}15}Cl_{4\text{-}16}$ $C_{16\text{-}17}Cl_{4\text{-}17}$	8 river suspended particule matter were collected from 8 sites.	(Yuan et al., 2022)[1]
Inner Oslofjord,	2017	mg/kg dw	0.14			(Ruus et al., 2018)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Norway						
Czech Republic	2001 - 2004	µg/kg	5 575	Relates to C_{14-17}	Highest concentration	(Pribylova et al., 2006)
England and Wales		mg/kg dw	0.2 – 65.1	Relates to C_{14-17}	Sample from 20 aquatic and eight agricultural sites selected from industrial areas (metal working, PVC, rubber, sealants, textiles and paints industry)	(Nicholls et al., 2001)
River Lech, upstream from chlorinated paraffin production plant	1994	µg/kg dry wt.	<10			(Ballschmiter, 1994)
River Lech, downstream from chlorinated paraffin production plant	1994	µg/kg dry wt.	325			(Ballschmiter, 1994)
Bodensee (middle) - 0 to 5 cm depth	1994	µg/kg dry wt.	70			(Ballschmiter, 1994)
River Rhein (141 km) at Rheinfelden	1994	µg/kg dry wt.	60			(Ballschmiter, 1994)
River Rhein (152 km) at Rheinfelden, upper layer	1994	µg/kg dry wt.	140			(Ballschmiter, 1994)
River Rhein (152 km) at Rheinfelden, lower layer	1994	µg/kg dry wt.	85			(Ballschmiter, 1994)
River Rhein (853.8 km), near German-Dutch border	1994	µg/kg dry wt.	205			(Ballschmiter, 1994)
River Rhein (863.8 km), near German-Dutch border	1994	µg/kg dry wt.	145			(Ballschmiter, 1994)
River Main (16.2 km)	1994	µg/kg dry wt.	260			(Ballschmiter, 1994)
River Main (at Griesheim)	1994	µg/kg dry wt.	190			(Ballschmiter, 1994)
River Main (55 km)	1994	µg/kg dry wt.	160			(Ballschmiter, 1994)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Outer Alster, Hamburg	1994	µg/kg dry wt.	370			(Ballschmiter, 1994)
River Elbe, Hamburg (610 km)	1994	µg/kg dry wt.	130			(Ballschmiter, 1994)
River Elbe, Hamburg (629.9 km)	1994	µg/kg dry wt.	230			(Ballschmiter, 1994)
River Lech, upstream from chlorinated paraffin production plant	1987	µg/kg dry wt.	2200			Unpublished (1987) in (ECHA, 2021d)
River Lech, downstream from chlorinated paraffin production plant	1987	µg/kg dry wt.	1 700			Unpublished (1987) in (ECHA, 2021d)
Irish Sea: Site a		µg/kg	100	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Irish Sea: Site b		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Irish Sea: Site c		µg/kg	not measured	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Irish Sea: Site d		µg/kg	100	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Irish Sea: Site e		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Irish Sea: Site f		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Barmouth Harbour		µg/kg	500	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Menai Straights (Caernarvon)		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Tremadoc Bay (Llandanwg)		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
North Minch: Ardmair		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
North Minch: Port Bùn á Ghlinne		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
North Minch: Port of Ness		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Goile Chròic (Lewis)		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Sound of Taransay (Harris)		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Sound of Arisaig		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
North Sea: N55° 5.7' W1° 9.3'		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
North Sea: N57° 26.2' W1° 17.0'		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
North Sea: N57° 56.5' W1° 22.0'		µg/kg	50	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Danube, downstream of the confluence with the River Lech		µg/kg dry wt.	1800			(BUA, 1992)
Rotterdam harbour mud		µg/kg	7 - 10			(Greenpeace, 1995)
Hamburg harbour mud		µg/kg	8			(Greenpeace, 1995)
Mud flats, Kaiser Wilhelm Koog		µg/kg	98			(Greenpeace, 1995)
Mud flats, Den Helder		µg/kg	3			(Greenpeace, 1995)
Mersey and Seine estuaries		µg/kg dry wt.	10.5		Mean levels of total chlorinated paraffins - predominantly LCCP (only traces of CA:C14-17 present)	(van Zeijl, 1997)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Schelde estuary		µg/kg dry wt.	5.5		Mean levels of total chlorinated paraffins - predominantly LCCP (only traces of CA:C14-17 present)	(van Zeijl, 1997)
Liffey River estuary		µg/kg dry wt.	4.8		Mean levels of total chlorinated paraffins - predominantly LCCP (only traces of CA:C14-17 present)	(van Zeijl, 1997)
Lake Zürich		µg/kg	5			(Schmid and Müller, 1985)
North and Baltic Sea		µg/kg dry weight	499		Highest concentration - relates CA:C10-13 + CA:C14-17 (CA:C14-17 / CA:C10-13 ratio 1.7 - 2.4)	(Hüttig and Oehme, 2005)
North and Baltic Sea		µg/kg dry weight	87	C_{14}-C_{15} chlorinated paraffins	Sample 1	(Huttig and Oehme, 2006)
North and Baltic Sea		µg/kg dry weight	48	C_{14}-C_{15} chlorinated paraffins	Sample 2	(Huttig and Oehme, 2006)
North and Baltic Sea		µg/kg dry weight	34	C_{14}-C_{15} chlorinated paraffins	Sample 3	(Huttig and Oehme, 2006)
North and Baltic Sea		µg/kg dry weight	149	C_{14}-C_{15} chlorinated paraffins	Sample 4	(Huttig and Oehme, 2006)
North and Baltic Sea		µg/kg dry weight	23	C_{14}-C_{15} chlorinated paraffins	Sample 5	(Huttig and Oehme, 2006)
North and Baltic Sea		µg/kg dry weight	43	C_{14}-C_{15} chlorinated paraffins	Sample 6	(Huttig and Oehme, 2006)
North and Baltic Sea		µg/kg dry weight	85	C_{14}-C_{15} chlorinated paraffins	Sample 7	(Huttig and Oehme, 2006)
North and Baltic Sea		µg/kg dry weight	72	C_{14}-C_{15} chlorinated paraffins	Sample 8	(Huttig and Oehme, 2006)
North and Baltic Sea		µg/kg dry weight	39	C_{14}-C_{15} chlorinated paraffins	Sample 9	(Huttig and Oehme, 2006)
North and Baltic Sea		µg/kg dry weight	22	C_{14}-C_{15} chlorinated paraffins	Sample 10	(Huttig and Oehme, 2006)
North and Baltic Sea		µg/kg dry weight	33	C_{14}-C_{15} chlorinated paraffins	Sample 11	(Huttig and Oehme, 2006)
Sediments from Norway		µg/kg dry weight	50 - 3 240	$C_{14}Cl_{5\text{-}9}$, $C_{15\text{-}17}Cl_{6\text{-}9}$	Twenty sediments analysed	(Petersen et al., 2006)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Oslo, Norway		ng/g dw	Mean = 183		Soil	(Heimstad et al., 2018)
Oslo, Norway		ng/g dw	Median = 193		Soil	(Heimstad et al., 2018)
Oslo, Norway		ng/g dw	Minimum = 57		Soil	(Heimstad et al., 2018)
Oslo, Norway		ng/g dw	Maximum = 282		Soil	(Heimstad et al., 2018)

Note: [1] new studies which were not reported in the SVHC support document (ECHA, 2021d)

Table 83: Summary of levels of CA:C14-17 in sediment and sludge outside the EU

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
South China Sea	2020	ng/g dw	Up to 23.4	$C_{14\text{-}17}Cl_{4\text{-}11}$	Four sediment cores were collected from the non-cold seep area, the inactive cold seep area, the active cold seep area and the extinct cold seep area in the South China Sea. C14 homologs were the predominant components in the upper sediment.	(Lyu et al., 2023)
Ya'Er lake area, China	2019	ng/g dry weight	143 - $1.30x10^6$ (a) Not detected - 222 (b)	$C_{14\text{-}17}Cl_{6\text{-}10}$	175 environmental samples were collected, of which 131 were sediment samples. The detection rate of CA:C14-17 in all soil samples was 85.8 %. Results show that the concentration of CPs in sediments varied significantly with the water flow direction: the oxidation pond closest to a sewage outlet had the highest concentrations of CA:C14-17 (a), whereas in the oxidation pond farthest from the sewage outlet, CA:C14-17 concentrations in the sediments were significantly reduced (b).	(Li et al., 2021a)[1]

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Hebei Province, China	2019	ng/g	47 - 6079	$C_{14\text{-}17}Cl_{5\text{-}10}$	In total, 18 soil samples were collected from 18 sites.	(Weng et al., 2022)[1]
East -Africa	2019	ng/g dw	<22 (LOD) - 6100 for the most recent sediments	$C_{14\text{-}17}Cl_{5\text{-}10}$	27 samples collected from different depth of sediments (between 0 and 39 cm). Age of the sediments estimated to date from 2019 (0cm) to pre-1962 (39 cm). EstimaLonger chain length dominance was found with depth of sediment . Trends towards longer chain lengths and lower chlorination degree with increasing sediment depth is consistent with studies from China and North America (Tomy et al., 1999; Marvin et al., 2003; Chen et al., 2011; Zeng et al., 2011), although it remains unclear whether this is related to degradation processes or shifts in production	(Nipen et al., 2022b)[1]
Dar es Salaam, Tanzania	2019	ng/g dw	<19 - 3200	Relates to $C_{14\text{-}17}$	Soil samples were collected from 19 locations including densely populated and industrialized urban areas, suburban areas, and rural areas with little anthropogenic activity. Soil samples were collected at a depth of approximately 5 cm.	(Nipen et al., 2022a)[1]
Dar es Salaam, Tanzania	2019	ng/g dw	<19 - 5100	Relates to $C_{14\text{-}17}$	Soil samples were collected 9 locations targeting specifically the city's main municipal waste dumpsite and an e-waste handling facility on the outskirts of Dar es Salaam. At the e-waste facility, soil was collected from the courtyard used for storing electrical components. At the municipal dumpsite, soil was collected within ~30 m of the waste piles. Soil samples were collected in February 2019.	(Nipen et al., 2022a)[1]
Yellow River, China	2018	ng/g	89	$C_{14\text{-}17}Cl_{6\text{-}10}$	(mean, wet season)	(Li et al., 2018a)
Yellow River, China	2018	ng/g	35	$C_{14\text{-}17}Cl_{6\text{-}10}$	(mean, normal season)	(Li et al., 2018a)
Yellow River, China	2018	ng/g	167	$C_{14\text{-}17}Cl_{6\text{-}10}$	(mean, dry season)	(Li et al., 2018a)
Yangkou Chemical Industrial Park, China	2018	ng/g dry weight	15.1 - 739.6	$C_{14\text{-}17}Cl_{5\text{-}10}$	20 soil samples were collected from Yangkou Chemical Industrial Park: 3 were collected from near the industrial park and the other 17 were collected from within the park. CA:C14-17 were detected in all samples.	(Huang et al., 2020)[1]

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Plant brownfield site located in Guangzhou City, China	2018	ng/g dry weight	Not detected - 6670	Relates to C_{14-17}	In total 7 soil core columns were collected at the plant site six months after its complete shutdown. From these soil core columns, 33 soil samples were collected using Geoprobe system. CA:C14-17 were found in 29 samples.	(Wu et al., 2020c)[1]
Dongzhai Harbor, Hainan Island, China	2018	ng/g dw	58.8 - 834	$C_{14-17}Cl_{5-10}$	15 surface mangrove sediment samples were collected.	(Xia et al., 2021)[1]
South China Coast	2017	ng/g dw	103 - 4160	$C_{14-17}Cl_{5-10}$	72 sediment samples were collected in 16 mangrove wetlands, in 2017 - 2019.	(Chen et al., 2022)[1]
Northern China	2017	ng/g	Not detected – 6760	$C_{14-17}Cl_{5-10}$	398 surface soil samples were collected in 2017 - 2018. CA:C14-17 were detected in most soil samples with detection rate of 84 %.	(Li et al., 2021b)[1]
Pearl River Delta, China	2017	ng/g dw	102 - 6650	$C_{14-17}Cl_{5-10}$		(Zeng et al., 2017)
Shenzhen, China	2017	ng/g dw	10.9 - 2500	$C_{14-17}Cl_{5-10}$		(Zeng et al., 2017)
Hong Kong, China	2017	ng/g dw	<LOD - 286	$C_{14-17}Cl_{5-10}$		(Zeng et al., 2017)
Tokyo Bay. Japan	2017	ng/g dw	3.2 - 56.8	$C_{14-17}Cl_{5-10}$		(Zeng et al., 2017)
Liaocheng, China	2017	ng/g dw	<1.51 - 188	$C_{14-17}Cl_{5-10}$	A total of 31 sampling sites were designated to collect samples of surface farmland soil.	(Chen et al., 2021c)[1]

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Beijing, China	2017	ng/L	35 - 217	$C_{10-27}Cl_{5-14}$	24 suspended particle/sediment samples were taken from the inflows and outflows of the different units in the wetland system.	(Wang et al., 2021a)[1]
Yellow River, China	2016	ng/g dw	44.8	$C_{14-17}Cl_{5-10}$		(Qiao et al., 2016)
Haungpu River and its main tributaries (Shanghai)	2016	ng/g	10.1 - 10800	$C_{14-17}Cl_{5-10}$	A total of 74 sampling locations were selected from Huangpu River and its main tributaries. CA:C14-17 were detected in all sediment samples.	(Wang et al., 2019c)[1]
Yunnan, China	2016	ng/g	20 - 1206	$C_{14-17}Cl_{5-10}$	In total, 22 pooled surface soil samples were collected in Yunnan. CA:C14-17 were detected in all samples.	(Wang et al., 2020a)[1]
Longtang Town, China	2015	ng/g dry weight	57 - 390	$C_{14-17}Cl_{5-10}$	Soil samples, collected in 2015 - 2016	(Liu et al., 2020c)[1]
Longtang Town, China	2015	ng/g dry weight	430 - 600	$C_{14-17}Cl_{5-10}$	Grass samples, collected in 2015 - 2016	(Liu et al., 2020c)[1]
Africa	2015	ng/g	< MDL - 1400 (Agbogbloshie site) < MDL - 1300 (Kingtom site)	Relates to C_{14-17}	Soil samples collected from diferent sites: the Agbogbloshie e-waste site (n=15) and the Kingtom domestic dumpsite (n=10).	(Moeckel et al., 2020)[1]
Persian Gulf, Iran	2015	ng/g	22.7 - 71.1	Relates to C_{10-17}	50 surface seawater samples were collected from the coral reef fields.	(Ranjbar Jafarabadi et al., 2021)[1]
Dongguan, China	2011	ng/g	104 - 630	$C_{14-17}Cl_{5-10}$	3 topsoil samples (SO1–SO3) were collected in Dongguan, Guangdong province.	(Wu et al., 2020b)[1]
Dongguan, China	2011	ng/g	49.4 - 110	$C_{14-15}Cl_{5-10}$; $C_{16-17}Cl_{6-10}$	4 sediment samples (SD1–SD4) were collected in Dongguan, Guangdong province.	(Wu et al., 2020b)[1]
Dongguan, China	2011	ng/g	23.9 - 2427	Relates to C_{14-17}	49 surface soil samples (SO1-49) were collected from Dongguan City, South China. CA:C14-17 were detected in all soil samples	(Wu et al., 2020b)[1]

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Dongguan, China	2011	ng/g	14.0 - 1581	Relates to C_{14-17}	17 sediment samples (SD1-17) were collected from Dongguan City, South China. CA:C14-17 were detected in all sediment samples	(Wu et al., 2020b)[1]
Tibetan Plateu, Asia	2010	µg/g TOC	0.8 - 3.3	$C_{14-17}Cl_{5-10}$	Soil samples obtained from the region covering a range of 1843.5 km × 370.6 km at Ngari, Nyingchi, Namco, Shergyla Mountain, and Lhasa, in 2010 - 2016.	(Wu et al., 2020a)[1]
Laizhou Bay, China	2009	ng/g dw	6 - 63	$C_{14-17}Cl_{5-10}$		(Pan et al., 2018)
Rivers around Laizhou Bay, China	2009	ng/g dw	1.8 - 3200			(Pan et al., 2018)
China	2006	kg	0.29−21000	Relates to C_{14-17}	Sediment cores were collected from the central area of nine lakes from different regions of China. This study aimed to estimate the amount of CA:C14-17 present in lakes before 2006.	(Zhang et al., 2019)[1]
Sediment core, Lake St. Francois, St. Lawrence River	1995	µg/kg dry wt.	700			(Muir et al., 2002)
Sediment core, Lake St. Francois, St. Lawrence River	1990	µg/kg dry wt.	400			(Muir et al., 2002)
Sediment core, Lake St. Francois, St. Lawrence River	1986	µg/kg dry wt.	750			(Muir et al., 2002)
Sediment core, Lake St. Francois, St. Lawrence River	1981	µg/kg dry wt.	700			(Muir et al., 2002)
Sediment core, Lake St. Francois, St. Lawrence River	1976	µg/kg dry wt.	1 000			(Muir et al., 2002)
Sediment core, Lake St. Francois, St. Lawrence River	1972	µg/kg dry wt.	1 200			(Muir et al., 2002)
Japan	1980	µg/kg	500 - 8 500			(Environment Agency Japan, 1991)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Japan	1979	µg/kg	600 - 10 000			(Environment Agency Japan, 1991)
Jiaojiang River, China		ng/g dry weight	507 - 4.40×10^6	Relates to C_{14-17}	9 surface soil samples were collected.	(Xu et al., 2019b)[1]
Jiaojiang River, China		ng/g dry weight	271 - 2.72×10^4	Relates to C_{14-17}	21 surface sediment samples were collected from the lower reaches.	(Xu et al., 2019b)[1]
Hebei Province, China		ng/g	<10 - 385	$C_{14-17}Cl_{5-10}$	130 soil samples were collected and combined to form 26 pooled samples.	(Wang et al., 2022)[1]
River Banwy, Llangadfan		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Lea, Batford		µg/kg	1 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Clwyd, Ruthin		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Dee, Corwen		µg/kg	300	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Wnion, Merioneth		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Five drinking water reservoirs, Manchester area		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Aire, Leeds		µg/kg	10 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Ouse, Goole		µg/kg	2 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Trent, West Bromwich		µg/kg	6 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Trent, Walton-upon-Trent		µg/kg	1 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
River Trent, Swarkestone		µg/kg	14 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Trent, Newark		µg/kg	8 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Trent, Gainsborough		µg/kg	3 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Humber Estuary, Hull		µg/kg	2 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Humber Estuary, Stone Creek		µg/kg	2 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Mersey Estuary, New Brighton		µg/kg	3 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Mersey Estuary, Liverpool Pier Head		µg/kg	8 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Thames, Sanford		µg/kg	1 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Wyre Estuary		µg/kg	not detected - 1 600	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Mersey Estuary, 14 sediment samples		µg/kg	not detected	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Tees, Low Dinsdale		µg/kg	300	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Tees, North Gare breakwater		µg/kg	50	Relates to C_{10-20}		(Campbell and McConnell, 1980)
River Tees, Middlesbrough		µg/kg	15 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)
Downstream of production site, US		µg/kg dry wt.	6.8 - 8.2			(Murray et al., 1987a, Murray et al., 1987b)

Location	Year of the study	Units		Concentration	Detected congeners (if reported)	Comment	Reference
Forth estuary		µg/kg wt.	dry	3.3		Mean levels of total chlorinated paraffins - predominantly LCCP (only traces of CA:C14-17 present)	(van Zeijl, 1997)
Humber estuary		µg/kg wt.	dry	1.2		Mean levels of total chlorinated paraffins - predominantly LCCP (only traces of CA:C14-17 present)	(van Zeijl, 1997)
St. Lawrence River, Canada, downstream of a chlorinated paraffin manufacturing plant		µg/kg wt.	dry	<3 500			(Tomy et al., 1998)
Industrial areas of the UK		µg/kg wt.	dry	65 000		A total of 77 samples from 1998. Highest concentration, downstream of a lubricant blending/metalworking site.	(Cefas, 1999)
Close to chlorinated paraffin manufacturing site, Australia		µg/kg weight	dry	1 108		Sample I	(Kemmlein et al., 2002)
Close to chlorinated paraffin manufacturing site, Australia		µg/kg weight	dry	1 168		Sample II	(Kemmlein et al., 2002)
Close to chlorinated paraffin manufacturing site, Australia		µg/kg weight	dry	3 108		Sample II	(Kemmlein et al., 2002)
Close to chlorinated paraffin manufacturing site, Australia		µg/kg weight	dry	16 403		Sample IV	(Kemmlein et al., 2002)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Lake Thun, Switzerland		µg/kg dry weight	26	$C_{14}Cl_{5-10}$; $C_{15-17}Cl_{5-9}$	Sediment core, surface layer corresponding to around 2004	(Iozza et al., 2008)
Pearl River Delta, South China		µg/kg dry weight	880 to 38 000	$C_{14-17}Cl_{5-10}$	Range	(Chen et al., 2011)
Pearl River Delta, South China. Pond sediments in the vicinity of an electronic waste recycling area		µg/kg dry weight	21 000		Mean	(Chen et al., 2011)
Pearl River Delta, South China. River sediments from industrialised areas.		µg/kg dry weight	3 900		Mean	(Chen et al., 2011)
Firth of Clyde, Scotland			detected		CA:C14-17 detected but not quantified	(Hussy et al., 2012)
Chongming Island, China		ng/g	Minimum = 2.56		Soil	(Sun et al., 2013)
Chongming Island, China		ng/g	Maximum = 96.3		Soil	(Sun et al., 2013)
Chongming Island, China		ng/g	Median = 7.32		Soil	(Sun et al., 2013)
Dongjiang River, China		ng/g	59.3	$C_{14-17}Cl_{6-10}$	Top soils (0−5 cm) at 60 sites	(Wang et al., 2013)
Pearl River Delta, South China		ng/g	Minimum = 1.95		Soil	(Wang et al., 2014)
Pearl River Delta, South China		ng/g	Maximum = 188		Soil	(Wang et al., 2014)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Pearl River Delta, South China		ng/g	Median = 7.98	ΣCl_5: 0.378-26.0 ng/g; ΣCl_6: 0.287-30.5 ng/g; ΣCl_7: 0.404-47.3 ng/g; ΣCl_8:0.367-45.0 ng/g; ΣCl_9: 0.296-26.4 ng/g; ΣCl_{10}: 0.147-12.6 ng/g	Soil	(Wang et al., 2014)
Switzerland		ng/g	5.1 – 160		Soil	(Bogdal et al., 2015)
Yellow River, China		ng/g dw	20.5 – 93.7	$C_{14}Cl_{5\text{-}11}$; $C_{15}Cl_{5\text{-}10}$; $C_{16}Cl_{6\text{-}10}$; $C_{17}Cl_{5\text{-}9}$	Sediment samples from the middle reaches of the Yellow River	(Xia et al., 2016)
China		ng/g dry weight	3481.8	$C_{14\text{-}17}Cl_{5\text{-}10}$	In-plant coniferous leaves and soil, 2016 (average)	(Xu et al., 2016)
Yangtze River, China		ng/g dw	Not detected to 14.6 ng/g dw	$C_{14}Cl_{6\text{-}10}$; $C_{15}Cl_{6\text{-}10}$; $C_{16}Cl_{6\text{-}9}$; $C_{17}Cl_{6\text{-}9}$	Sediments from the middle reaches of the Yangtze River	(Qiao et al., 2017)
Shanghai, China		ng/g dry weight	ND – 666	ΣCl_5: 0.01-67.5 ng/g ΣCl_6: 0.01-96.8 ng/g ΣCl_7: 0.04-168 ng/g ΣCl_8: 0.02-180 ng/g ΣCl_9: 0.11-117 ng/g ΣCl_{10}: 0.01-52.6 ng/g	Suburb soils, 2017	(Wang et al., 2017b)

Location	Year of the study	Units	Concentration	Detected congeners (if reported)	Comment	Reference
Jiaojiang River, China		ng/g dw	507 to 4.40×10^6	$C_{14\text{-}17}Cl_{5\text{-}10}$	Soil samples within 5 km of the e-waste dismantling centres	(Xu et al., 2019b)
Jiaojiang River, China		ng/g dw	271 – 2.72×10^4	$C_{14\text{-}17}Cl_{5\text{-}10}$	Sediment samples from the surrounding area	(Xu et al., 2019b)
China		ng/g dw	127 – 1969	$C_{14\text{-}17}Cl_{5\text{-}10}$	Core soils from Chinese nation-wide agricultural lands	(Aamir et al., 2019b)

Note: [1] new studies which were not reported in the SVHC support document (ECHA, 2021d)

B.5.5.4. Monitoring data of CA:C14-17 in biota (and some foodstuffs)

Table 84: Summary of levels of CA:C14-17 in biota in the EU. Detected congeners are presented only for biota samples from 2016 onwards.

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Germany	2018	Herring gull (egg)	*Larus argentatus*	ng/g lipid	48 - 61	Relates to $C_{14\text{-}17}$	A total of 72 samples were analysed. The sampling sites covered coastal, terrestrial, and freshwater ecosystems.	(Yuan et al., 2022)[1]
Germany	2018	Eelpout (musculature)	*Zoarces viviparus*	ng/g lipid	59 (median)	Relates to $C_{14\text{-}17}$		(Yuan et al., 2022)[1]
Germany	2018	Blue mussel (soft tissue)	*Mytilus edulis complex*	ng/g lipid	1800 (median)	Relates to $C_{14\text{-}17}$		(Yuan et al., 2022)[1]
Germany	2017 - 2018	Spruce (shoots)	*Picea abies*	ng/g lipid	<MDL - 150	Relates to $C_{14\text{-}17}$		(Yuan et al., 2022)[1]
Germany	2018	Pine (shoots)	*Pinus sylvestris*	ng/g lipid	140 (median)	Relates to $C_{14\text{-}17}$		(Yuan et al., 2022)[1]
Germany	2018	Lombardy poplar (leaves)	*Populus nigra*	ng/g lipid	810 - 1000	Relates to $C_{14\text{-}17}$		(Yuan et al., 2022)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Germany	2017 - 2018	Beech (leaves)	*Fagus sylvatica*	ng/g lipid	220 - 1500	Relates to C_{14-17}		(Yuan et al., 2022)[1]
Germany	2018 - 2018	Oe deer, one-year-old (liver)	*Capreolus capreolus*	ng/g lipid	33 - 64	Relates to C_{14-17}		(Yuan et al., 2022)[1]
Germany	2017	earthworm (worms content without gut)	*Aporrectodea longa*	ng/g lipid	67	Relates to C_{14-17}		(Yuan et al., 2022)[1]
Germany	2017	earthworm (droppings)	*Aporrectodea longa*	ng/g dw	11	Relates to C_{14-17}		(Yuan et al., 2022)[1]
Germany	2017 - 2018	earthworm (worms content without gut)	*Lumbricus terrestris*	ng/g lipid	130 - 260	$C_{14}Cl_{3-11}$ $C_{15}Cl_{2-11}$ $C_{16}Cl_{3-12}$ $C_{17}Cl_{4-12}$		(Yuan et al., 2022)[1]
Germany	2017 - 2018	earthworm (droppings)	*Lumbricus terrestris*	ng/g dw	10 - 1000	$C_{14}Cl_{3-13}$ $C_{15-16}Cl_{4-12}$ $C_{17}Cl_{4-13}$		(Yuan et al., 2022)[1]
Germany	1995 - 2019	Bream (musculature)	*Abramis brama*	ng/g lipid	100 - 4000	$C_{14-15}Cl_{2-12}$ $C_{16}Cl_{3-12}$ $C_{17}Cl_{4-12}$		(Yuan et al., 2022)[1]
Germany	2018	Barbell (musculature)	*Barbus barbus*	ng/g lipid	160	Relates to C_{14-17}		(Yuan et al., 2022)[1]
Germany	2018	Zebra mussel (soft tissue)	*Dreissena polymorpha*	ng/g lipid	84 - 740	Relates to C_{14-17}		(Yuan et al., 2022)[1]
Germany	2018	Quagga mussel (soft tissue)	*Dreissena rostriformis*	ng/g lipid	2400	Relates to C_{14-17}		(Yuan et al., 2022)[1]
Oslofjord, Norway Søndre Skjælholmen, Norway	2017	Herring gulls blood	*Larus argentatus*	ng/g dw	6.00 - 200	Relates to C_{14-17}	30 samples of herring gull blood and 30 samples of herring gulls eggs.	(Knudtzon et al., 2021)[1]
Oslofjord, Norway Søndre Skjælholmen,	2017	Herring gulls eggs	*Larus argentatus*	ng/g dw	3.00 - 630	Relates to C_{14-17}	30 samples of herring gull blood and 30 samples of herring gulls eggs.	(Knudtzon et al., 2021)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Norway								
Germany	2019 - 2020	Fresh fish	n.a.	ng/g ww	1.3 - 410	$C_{14\text{-}16}Cl_{6\text{-}10}$, $C_{17}Cl_{7\text{-}9}$	25 fresh fish samples from different bodies of water in Germany.	(Tien et al., 2021)[1]
Greenland	2018	Narwhal (muscle)	*Monodon monoceros*	ng/g lipid	<44	Relates to $C_{14\text{-}17}$	Cetacean samples were collected between 2016 and 2018 from around Greenland and the Swedish west coast. Bivalves, as sentinel organisms in coastal pollution monitoring, were collected from Greenland in 2018 and 2020. Greenland sharks were accidentally caught in trawls or entangled in long lines around Iceland in 2001 and 2002. The killer whale and harbor porpoises from Sweden were stranded and were also sampled.	(Yuan et al., 2021)[1]
Greenland	2018	Narwhal (blubber)	*Monodon monoceros*	ng/g lipid	<10	Relates to $C_{14\text{-}17}$	(as above)	(Yuan et al., 2021)[1]
Greenland; Sweden	2016 -2018	Harbor porpoise (blubber)	*Phocoena phocoena*	ng/g lipid	<9.8 - 18	$C_{14}Cl_{4\text{-}11}$ $C_{15\text{-}17}Cl_{4\text{-}10}$	(as above)	(Yuan et al., 2021)[1]
Greenland	2020	Blue mussel (soft tissue)	*Mytilus edulis*	ng/g lipid	87 - 250	$C_{14\text{-}17}Cl_{4\text{-}10}$	(as above)	(Yuan et al., 2021)[1]
Greenland	2018	Iceland scallop (soft tissue)	*Chlamys islandica*	ng/g lipid	120	Relates to $C_{14\text{-}17}$	(as above)	(Yuan et al., 2021)[1]
Greenland; Sweden	2016 - 2018	Killer whale (muscle)	*Orcinus orca*	ng/g lipid	35 - 270	$C_{14\text{-}15}Cl_{4\text{-}10}$ $C_{16}Cl_{4\text{-}9}$ $C_{17}Cl_{5\text{-}11}$	(as above)	(Yuan et al., 2021)[1]
Greenland; Sweden	2017 - 2018	Killer whale (blubber)	*Orcinus orca*	ng/g lipid	<14 - 74	$C_{14}Cl_{4\text{-}10}$ $C_{15\text{-}16}Cl_{4\text{-}9}$ $C_{17}Cl_{5\text{-}9}$	(as above)	(Yuan et al., 2021)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Greenland	2017	Minke whale (muscle)	*Balaenoptera acutorostrata*	ng/g lipid	19	$C_{14}Cl_{4-8}$ $C_{15-16}Cl_{5-8}$ $C_{17}Cl_{6-8}$	(as above)	(Yuan et al., 2021)[1]
Greenland	2018	Pilot whale (muscle)	*Globicephala melas*	ng/g lipid	20 -50	Relates to C_{14-17}	(as above)	(Yuan et al., 2021)[1]
Greenland	2018	Pilot whale (blubber)	*Globicephala melas*	ng/g lipid	<8.6–17	Relates to C_{14-17}	(as above)	(Yuan et al., 2021)[1]
Iceland	2001 - 2003	Greenland shark (liver)	*Somniosus microcephalus*	ng/g lipid	5.0 - 5.1	$C_{14-15}Cl_{4-9}$ $C_{16}Cl_{5-9}$ $C_{17}Cl_{5-8}$	(as above)	(Yuan et al., 2021)[1]
Baltic sea (Darsser Ort, Arkona Basin)	2015	Blue mussel		ng/g lw	210	$C_{14}Cl_{4-10}$ $C_{15}Cl_{3-11}$ $C_{16}Cl_{4-11}$ $C_{17}Cl_{3-12}$	Mean concentration of CA:C14-17 in soft body; n=100	(de Wit et al., 2020)
Baltic sea (Darsser Ort, Arkona Basin)	2015	Viviparous eelpout		ng/g lw	130	$C_{14}Cl_{3-10}$ $C_{15}Cl_{4-10}$ $C_{16}Cl_{3-11}$ $C_{17}Cl_{3-11}$	Mean concentration of CA:C14-17 in the muscle; females and males 2 years; n=47	(de Wit et al., 2020)
Baltic sea (Byxelkrok, Western Gotland Basin)	2014 and 2016	Atlantic herring		ng/g lw	130	$C_{14}Cl_{4-8}$ $C_{15}Cl_{5-10}$ $C_{16}Cl_{3-11}$ $C_{17}Cl_{8-11}$	Mean concentration of CA:C14-17 in muscle; females and males 7–13 years, n=40; females and males 6–12 years, n=38	(de Wit et al., 2020)
Baltic sea (Byxelkrok, Western Gotland Basin)	2014 and 2016	Atlantic herring		ng/g lw	160	$C_{14}Cl_{4-8,10}$ $C_{15}Cl_{4-10}$ $C_{16}Cl_{3-10}$ $C_{17}Cl_{5-8}$	Mean concentration of CA:C14-17 in liver; females and males 7–13 years, n=40; females and males 6–12 years, n=38	(de Wit et al., 2020)
Baltic sea (Western Gotland Basin, Åland Sea, Northern Baltic Proper)	2006–2009 and 2009–2010	Grey seal		ng/g lw	n.a.		Mean concentration of CA:C14-17 in muscle; 2 females and 3 males juveniles 0–1 year, n=5; adult males 8–11 years, n=4	(de Wit et al., 2020)
Baltic sea (Western Gotland Basin, Åland Sea, Northern Baltic Proper)	2006–2009 and 2009–2010	Grey seal		ng/g lw	57	$C_{14}Cl_{3-11}$ $C_{15}Cl_{5-8,10}$ $C_{16}Cl_{4-10}$ $C_{17}Cl_{4-11}$	Mean concentration of CA:C14-17 in blubber; 2 females and 3 males juveniles 0–1 year, n=5; adult males 8–11 years, n=4	(de Wit et al., 2020)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Baltic sea (Western Gotland Basin, Åland Sea, Northern Baltic Proper)	2006–2009 and 2009–2010	Grey seal		ng/g lw	220	$C_{14}Cl_{3-9}$ $C_{15}Cl_{3-10}$ $C_{16}Cl_{5-9,12}$ $C_{17}Cl_{3-11}$	Mean concentration of CA:C14-17 in liver; 2 females and 3 males (juveniles 0–1 year), n=5; adult males 8–11 years, n=4	(de Wit et al., 2020)
Baltic sea (Western Gotland Basin, Eastern Gotland Basin)	2014–2015 and 2012–2016	Harbor seal		ng/g lw	n.a.		Mean concentration of CA:C14-17 in muscle; juvenile males, n=5; adults, n=4	(de Wit et al., 2020)
Baltic sea (Western Gotland Basin, Eastern Gotland Basin)	2014–2015 and 2012–2016	Harbor seal		ng/g lw	82	$C_{14}Cl_{3-11}$ $C_{15}Cl_{4-11}$ $C_{16}Cl_{5-10}$ $C_{17}Cl_{5-9}$	Mean concentration of CA:C14-17 in blubber; juvenile males, n=5; adults, n=4	(de Wit et al., 2020)
Baltic sea (Western Gotland Basin, Eastern Gotland Basin)	2014–2015 and 2012–2016	Harbor seal		ng/g lw	390	$C_{14}Cl_{4-9}$ $C_{15}Cl_{3-9}$ $C_{16}Cl_{5-6}$ $C_{17}Cl_{6-12}$	Mean concentration of CA:C14-17 in liver; juvenile males, n=5; adults, n=4	(de Wit et al., 2020)
Baltic sea (Eastern Gotland Basin)	2008 and 2006–2012	Harbor porpoise		ng/g lw	n.a.		Mean concentration of CA:C14-17 in muscle; 1 female and 1 male (juveniles), n=2; 3 females and 1 male (adults), n=4	(de Wit et al., 2020)
Baltic sea (Eastern Gotland Basin)	2008 and 2006–2012	Harbor porpoise		ng/g lw	48	$C_{14}Cl_{4-10}$ $C_{15}Cl_{4-9,11}$ $C_{16}Cl_{4-10}$ $C_{17}Cl_{5-9}$	Mean concentration of CA:C14-17 in blubber; 1 female and 1 male (juveniles), n=2; 3 females and 1 male (adults), n=4	(de Wit et al., 2020)
Baltic sea (Eastern Gotland Basin)	2008 and 2006–2012	Harbor porpoise		ng/g lw	290	$C_{14}Cl_{3-12}$ $C_{15}Cl_{3-11}$ $C_{16}Cl_{3-11}$ $C_{17}Cl_{3-9}$	Mean concentration of CA:C14-17 in liver; 1 female and 1 male (juveniles), n=2; 3 females and 1 male (adults), n=4	(de Wit et al., 2020)
Baltic sea (Christiansø, Bornholm Basin)	2015	Common eider		ng/g lw	170	$C_{14}Cl_{4-11}$ $C_{15}Cl_{4-11}$ $C_{16}Cl_{5-10}$ $C_{17}Cl_{3-11}$	Mean concentration of CA:C14-17 in eggs; female adults, n=5/5	(de Wit et al., 2020)
Baltic sea (Christiansø, Bornholm Basin)	2015	Common eider		ng/g lw	370	$C_{14}Cl_{4-12}$ $C_{15}Cl_{3-11}$ $C_{16}Cl_{4-9}$ $C_{17}Cl_{6-9}$	Mean concentration of CA:C14-17 in liver; female adults, n=5/5	(de Wit et al., 2020)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Baltic sea (St. Karlsö, Western Gotland Basin)	2016	Common guillemot		ng/g lw	62	$C_{14}Cl_{3-11}$ $C_{15}Cl_{3-8,11}$ $C_{16}Cl_{3-9}$ $C_{17}Cl_{2-9}$	Mean concentration of CA:C14-17 in eggs; n=4/5	(de Wit et al., 2020)
Baltic sea (Kalmar/Blekinge Counties, Stockholm/Uppsala Counties)	2015	White-tailed eagle		ng/g lw	200	$C_{14}Cl_{3-11}$ $C_{15}Cl_{2-11}$ $C_{16}Cl_{3-10}$ $C_{17}Cl_{3-11}$	Mean concentration of CA:C14-17 in eggs; n=4/5	(de Wit et al., 2020)
Chéran River (mean)	2019	Common Barbel	*Barbus barbus*	µg/kg lipid weight	7 123			(Labadie et al., 2019)
Usses River (mean)	2019	Common Barbel	*Barbus barbus*	µg/kg lipid weight	4 615			(Labadie et al., 2019)
Combeauté River (mean)	2019	Common Barbel	*Barbus barbus*	µg/kg lipid weight	5 423	$C_{14}Cl_{5-10}$ $C_{15}Cl_{6-10}$ $C_{16}Cl_{6-10}$ $C_{17}Cl_{7-10}$		(Labadie et al., 2019)
Rhône River (mean)	2019	Common Barbel	*Barbus barbus*	µg/kg lipid weight	904	$C_{14}Cl_{5-10}$ $C_{15}Cl_{6-10}$ $C_{16}Cl_{7-10}$ $C_{17}Cl_{7-10}$		(Labadie et al., 2019)
Morge Canal (mean)	2019	Common Barbel	*Barbus barbus*	µg/kg lipid weight	3 292			(Labadie et al., 2019)
Gressholmen, Inner Oslofjord, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD:2.81±4 Min.: 2.76 Max.:9.52			(Green et al., 2019)
Tjøme, Outer Oslofjord, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD: 34.4±10 Min.: 30.2 Max.:49.7			(Green et al., 2019)
Singlekalven, Hvaler, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD: 7.21±12 Min.: 7.16 Max.:27.6			(Green et al., 2019)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Sylterøya, Langesundfjord, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD: 42.4±1119 Min.: 3.27 Max.:1960			(Green et al., 2019)
Nordnes, Bergen harbour, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD: 87.1±13 Min.: 67.3 Max.:91.4			(Green et al., 2019)
Vågsvåg, Outer Nordfjord, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD: 11.5±3 Min.: 10.9 Max.:16.1			(Green et al., 2019)
Ålesund harbour area, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD: 21.7±4 Min.: 19.7 Max.:26.8			(Green et al., 2019)
Ørland area, Outer Trondheimsfjord, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD: 28.1±4 Min.: 23.5 Max.:31.5			(Green et al., 2019)
Bodø harbour, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD: 170±644 Min.: 33.3 Max.:1210			(Green et al., 2019)
Mjelle, Bodø area, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD: 7.61±1 Min.: 6.04 Max.:7.9			(Green et al., 2019)
Svolvær airport area, Norway	2018	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median±SD: 53.1±30 Min.: 48.2 Max.:103			(Green et al., 2019)
Inner Oslofjord, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 105.5±25 Min.: 66.8 Max.:146		liver	(Green et al., 2019)
Tjøme, Outer Oslofjord, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 65.9±117.7 Min.: 50.5		liver	(Green et al., 2019)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
					Max.:474			
Kirkøy, Hvaler, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 60.95±82 Min.: 57.3 Max.:224		liver	(Green et al., 2019)
Stathelle area, Langesundfjord, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 108±66 Min.: 70.2 Max.:266		liver	(Green et al., 2019)
Kristiansand harbour area, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 77.8±35 Min.: 65.6 Max.:171		liver	(Green et al., 2019)
Inner Sørfjord, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 99.6±79 Min.: 52.7 Max.:331		liver	(Green et al., 2019)
Bømlo, Outer Selbjørnfjord, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 69.5±28 Min.: 49.5 Max.:131		liver	(Green et al., 2019)
Bergen harbour area, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 80.8±516 Min.: 58.5 Max.:1830		liver	(Green et al., 2019)
Ålesund harbour area, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 114±225 Min.: 50 Max.:957		liver	(Green et al., 2019)
Trondheim harbour, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 107±62 Min.: 62.3 Max.:288		liver	(Green et al., 2019)
Austnesfjord, Lofoten, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 124.5±72 Min.: 68.4 Max.:320		liver	(Green et al., 2019)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Tromsø harbour area, Norway	2018	Atlantic Cod	*Gadus morhua*	µg/kg ww	Median±SD: 77±1373 Min.: 50 Max.:5390		liver	(Green et al., 2019)
Gressholmen, Inner Oslofjord, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 11.9			(Green et al., 2019)
Færder, Outer Oslofjord, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 9.89			(Green et al., 2019)
Singlekalven, Hvaler, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 5.82			(Green et al., 2019)
Bjørkøya, Langesundfjord, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 22.7			(Green et al., 2019)
Sylterøya, Langesundfjord, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 10.5			(Green et al., 2019)
Nordnes, Bergen harbour, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 44.9			(Green et al., 2019)
Vågsvåg, Outer Nordfjord, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 27.3			(Green et al., 2019)
Ålesund harbour, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 41.6			(Green et al., 2019)
Ørland area, Outer Trondheimsfjord, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 4.46			(Green et al., 2019)
Bodø harbour, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 52.4			(Green et al., 2019)
Mjelle, Bodø area, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 17.3			(Green et al., 2019)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Svolvær airport area, Norway	2017	Blue Mussel	*Mytilus edulis*	µg/kg ww	Median: 22.2			(Green et al., 2019)
Scandinavia	2011	Herring	*Clupea harengus*	µg/kg lipid	44		female 4–6 years, muscle	(Yuan et al., 2019b)
Scandinavia	2014	Herring	*Clupea harengus*	µg/kg lipid	30		female 4–5 years, muscle	(Yuan et al., 2019b)
Scandinavia	2017	Herring	*Clupea harengus*	µg/kg lipid	51	$C_{14}Cl_{3-10}$ $C_{15}Cl_{3-10}$ $C_{16}Cl_{3-9}$ $C_{17}Cl_{4-11}$	female 3–5 years, muscle	(Yuan et al., 2019b)
Scandinavia	2014	Herring	*Clupea harengus*	µg/kg lipid	140		female and male 7 – 13 years, liver	(Yuan et al., 2019b)
Scandinavia	2014	Herring	*Clupea harengus*	µg/kg lipid	120		female and male, 7–13 years, muscle	(Yuan et al., 2019b)
Scandinavia	2016	Herring	*Clupea harengus*	µg/kg lipid	170		female and male, 6 – 12 years, liver	(Yuan et al., 2019b)
Scandinavia	2016	Herring	*Clupea harengus*	µg/kg lipid	140		female and male 6 – 12 years, muscle	(Yuan et al., 2019b)
Scandinavia	2015	Herring	*Clupea harengus*	µg/kg lipid	440		female adults, liver	(Yuan et al., 2019b)
Scandinavia	2015	Common Eider	*Somateria mollissima*	µg/kg lipid	140-200	$C_{14-15}Cl_{4-11}$ $C_{16}Cl_{5-10}$ $C_{17}Cl_{3-12}$	egg	(Yuan et al., 2019b)
Scandinavia	2015	Common Eider	*Somateria mollissima*	µg/kg lipid	290		female adults, liver	(Yuan et al., 2019b)
Scandinavia	2016	Common Guillemot	*Uria aalge*	µg/kg lipid	58-67	$C_{14-15}Cl_{3-11}$ $C_{16}Cl_{3-9}$ $C_{17}Cl_{2-9}$	egg	(Yuan et al., 2019b)
Scandinavia	2015	White-tailed Sea-eagle	*Haliaeetus albicilla*	µg/kg lipid	140-250	$C_{14}Cl_{3-11}$ $C_{15}Cl_{2-11}$ $C_{16}Cl_{3-10}$	egg	(Yuan et al., 2019b)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
						$C_{17}Cl_{3\text{-}11}$		
Scandinavia	2006 – 2008	Grey Seal	*Halichoerus grypus*	µg/kg lipid	210 (liver)		males juveniles (0 – 1 year), sampled 2006 – 2008	(Yuan et al., 2019b)
Scandinavia	2006 – 2008	Grey Seal	*Halichoerus grypus*	µg/kg lipid	83 (blubber)		males juveniles (0 – 1 year), 2006 – 2008	(Yuan et al., 2019b)
Scandinavia	2009 – 2010	Grey Seal	*Halichoerus grypus*	µg/kg lipid	230 (liver)	$C_{14}Cl_{3\text{-}9}$ $C_{15}Cl_{3,5\text{-}10}$ $C_{16}Cl_{5\text{-}9,12}$ $C_{17}Cl_{3\text{-}9,11}$	males adults (8 – 11 year), sampled 2009-2010	(Yuan et al., 2019b)
Scandinavia	2014 – 2015	Grey Seal	*Halichoerus grypus*		32 (blubber)		sampled 2014 – 2015	(Yuan et al., 2019b)
Scandinavia	2014 – 2015	Grey Seal	*Halichoerus grypus*	µg/kg lipid	540 (liver)		juveniles, sampled 2014 – 2015	(Yuan et al., 2019b)
Scandinavia	2014 – 2015	Harbour Seal	*Phoca vitulina*	µg/kg lipid	100		juveniles, blubber, sampled 2014 – 2015	(Yuan et al., 2019b)
Scandinavia	2012 – 2016	Harbour Seal	*Phoca vitulina*	µg/kg lipid	230 (liver)	$C_{14}Cl_{3\text{-}9}$ $C_{15}Cl_{3\text{-}9}$ $C_{16}Cl_{4\text{-}9}$ $C_{17}Cl_{3\text{-}8,11,12}$	adults, sampled 2012-2016	(Yuan et al., 2019b)
Scandinavia	2012 – 2016	Harbour Seal	*Phoca vitulina*	µg/kg lipid	64 (blubber)		adults, sampled 2012-2016	(Yuan et al., 2019b)
Scandinavia	2006 – 2012	Harbour Seal	*Phoca vitulina*	µg/kg lipid	140 (liver)		3 females and 1 male adults, liver	(Yuan et al., 2019b)
Scandinavia	2006 – 2012	Harbour Porpoise	*Phocoena phocoena*	µg/kg lipid	36 (blubber)		3 females and 1 male adults	(Yuan et al., 2019b)
Scandinavia	2008	Harbour Porpoise	*Phocoena phocoena*	µg/kg lipid	440 (liver)	$C_{14}Cl_{3\text{-}12}$ $C_{15}Cl_{3\text{-}12}$ $C_{16}Cl_{3\text{-}12}$ $C_{17}Cl_{3\text{-}9}$	1 female and 1 male adults	(Yuan et al., 2019b)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Scandinavia	2008	Harbour Porpoise	*Phocoena phocoena*	µg/kg lipid	59 (blubber)	$C_{14}Cl_{4\text{-}10}$ $C_{15}Cl_{4\text{-}11}$ $C_{16}Cl_{4\text{-}10}$ $C_{17}Cl_{5\text{-}9}$	1 female and 1 male adults	(Yuan et al., 2019b)
Scandinavia	2012 – 2015	Moose	*Alces alces*	µg/kg lipid	1 600	$C_{14\text{-}15}Cl_{3\text{-}11}$ $C_{16}Cl_{3\text{-}10}$ $C_{17}Cl_{4\text{-}10}$	female and male adults, muscle	(Yuan et al., 2019b)
Scandinavia	2014	Bank Vole	*Myodes glareolus*	µg/kg lipid	370	$C_{14}Cl_{3\text{-}10}$ $C_{15}Cl_{3\text{-}11}$ $C_{16}Cl_{3\text{-}10}$ $C_{17}Cl_{3\text{-}12}$	female and male adults, muscle	(Yuan et al., 2019b)
Scandinavia	2012 – 2016	Eurasian Lynx	*Lynx lynx*	µg/kg lipid	750	$C_{14}Cl_{3\text{-}10}$ $C_{15}Cl_{3\text{-}10}$ $C_{16}Cl_{3\text{-}11}$ $C_{17}Cl_{4\text{-}11}$	female and male adults, muscle	(Yuan et al., 2019b)
Scandinavia	2012 – 2016	Grey Wolf	Canis lupus	µg/kg lipid	830	$C_{14}Cl_{3\text{-}11}$ $C_{15}Cl_{3\text{-}10}$ $C_{16}Cl_{4\text{-}12}$ $C_{17}Cl_{4\text{-}11}$	female and male adults, muscle	(Yuan et al., 2019b)
Scandinavia	2012 – 2015	Starling	Sturnus vulgaris	µg/kg lipid	310		female and male fledgings, muscle	(Yuan et al., 2019b)
Scandinavia	2014	Common Kestrel	*Falco tinnunculus*	µg/kg lipid	85	$C_{14}Cl_{3\text{-}11}$ $C_{15}Cl_{3\text{-}10}$ $C_{16}Cl_{3\text{-}11}$ $C_{17}Cl_{4\text{-}9}$	egg	(Yuan et al., 2019b)
Scandinavia	2014	Tawny Owl	*Strix aluco*	µg/kg lipid	87		egg	(Yuan et al., 2019b)
Scandinavia	2013 – 2017	Eagle Owl	*Bubo bubo*	µg/kg lipid	720	$C_{14\text{-}16}Cl_{3\text{-}11}$ $C_{17}Cl_{3\text{-}12}$	female and male adults, muscle	(Yuan et al., 2019b)
Scandinavia	2012 – 2015	Marsh Harrier	Circus aeruginosus	µg/kg lipid	180	$C_{14}Cl_{3\text{-}12}$ $C_{15\text{-}17}Cl_{3\text{-}11}$	female and male adults, muscle	(Yuan et al., 2019b)
Scandinavia	2012 – 2016	Golden Eagle	*Aquila chrysaetos*	µg/kg lipid	360		female and male adults, muscle	(Yuan et al., 2019b)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Scandinavia	2012 – 2016	Peregrine Falcon	*Falco peregrinus*	µg/kg lipid	410	$C_{14}Cl_{3\text{-}11}$ $C_{15}Cl_{3\text{-}11}$ $C_{16}Cl_{3\text{-}11}$ $C_{17}Cl_{4\text{-}11}$	female and male adults, muscle	(Yuan et al., 2019b)
Southern Germany	2014 - 2017	Salmon		µg/kg ww	1.1 - 79		122 farmed and 11 wild salmon samples	(Krätschmer et al., 2019)
Inner Oslofjord, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 498.0		liver	(Green et al., 2018)
Tjøme, Outer Oslofjord, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 35.15		liver	(Green et al., 2018)
Kirkøy, Hvaler, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 77.2		liver	(Green et al., 2018)
Stathelle area, Langesundfjord, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 143.0		liver	(Green et al., 2018)
Kristiansand harbour area, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 226.5		liver	(Green et al., 2018)
Inner Sørfjord, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 100.0		liver	(Green et al., 2018)
Bømlo, Outer Selbjørnfjord, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 74.6		liver	(Green et al., 2018)
Bergen harbour area, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 310.0		liver	(Green et al., 2018)
Ålesund harbour area, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 842.0		liver	(Green et al., 2018)
Trondheim harbour, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 102.0		liver	(Green et al., 2018)
Austnesfjord, Lofoten, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 71.6		liver	(Green et al., 2018)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Tromsø harbour area, Norway	2017	Altlantic cod	*Gadus morhua*	µg/kg ww	Median: 123.0		liver	(Green et al., 2018)
Islands of Sommarøy and Hillerøy, in Troms County, Norway	2013	Mink	Neovison vison	ng/g ww	Average: 13 Min. — Max.: 1.1—32		liver; n=10 samples; detection frequency = 100 %, sampled 2013 and 2014	(Schlabach et al., 2018)
Tromsøya island, Tromsø, Norway	2017	Common gull	*Larus canus*	ng/g ww	Average: 40 Min. — Max.: 9.4—87		eggs; n=5 eggs; detection frequency = 100 %	(Schlabach et al., 2018)
Inner Oslofjord		Polychaetes		µg/kg ww	Average: 12	$C_{15}Cl_{6\text{-}9}$	3 pooled samples (whole individuals)	(Ruus et al., 2018)
Inner Oslofjord		Blue Mussel	*Mytilus edulis*	µg/kg ww	Average: 10	$C_{16}Cl_{5\text{-}9}$	3 pooled samples (soft tissue)	(Ruus et al., 2018)
Inner Oslofjord		Krill	*Euphausiacea*	µg/kg ww	60	$C_{17}Cl_{5,8,9}$	3 pooled samples (whole individuals)	(Ruus et al., 2018)
Inner Oslofjord		Prawn	*Pandalus borealis*	µg/kg ww	2		3 pooled samples (tail soft tissue)	(Ruus et al., 2018)
Inner Oslofjord		Herring	*Clupea harengus*	µg/kg ww	Average: 17		3 pooled samples (muscle)	(Ruus et al., 2018)
Inner Oslofjord		Atlantic Cod	*Gadus morhua*	µg/kg ww	Arithmetic mean 216 (range: 51-1050)		Liver (detected in all 15 samples)	(Ruus et al., 2018)
Inner Oslofjord		Herring Gull	*Larus argentatus*	µg/kg ww	Arithmetic mean 28.23 (range: 8.2-76)		Blood (detected in all 15 samples)	(Ruus et al., 2018)
Outer Oslofjord		Herring Gull	*Larus argentatus*	µg/kg ww	Arithmetic mean 38.87 (range: 5.8-200)		Blood (detected in all 15 samples)	(Ruus et al., 2018)
Inner Oslofjord		Herring Gull	*Larus argentatus*	µg/kg ww	Arithmetic mean 29.14 (range: 6.1-68)		Egg (detected in all 15 samples)	(Ruus et al., 2018)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Outer Oslofjord		Herring Gull	*Larus argentatus*	µg/kg ww	Arithmetic mean 69.58 (range: 3.1-630)		Egg (detected in all 15 samples)	(Ruus et al., 2018)
Oslo, Norway	2017	Earthworms		µg/kg ww	Mean: 37 Median: 39 Minimum: 25 Maximum: 46			(Heimstad et al., 2018)
Oslo, Norway	2017	Eurasian Sparrowhawk	*Accipter nisus*	µg/kg ww	Mean: 12.2 Median: <LOD Minimum: <LOD Maximum: 74.0		eggs	(Heimstad et al., 2018)
Oslo, Norway	2017	Tawny Owl	*Strix aluco*	µg/kg ww	Mean: <LOD Median: <LOD Minimum: <LOD Maximum: <LOD		eggs	(Heimstad et al., 2018)
Oslo, Norway	2017	Rat	*Rattus norvegicus*	µg/kg ww	Mean: 183 Median: 177 Minimum: 81.0 Maximum: 327		liver	(Heimstad et al., 2018)
Oslo, Norway	2017	Red Fox	*Vulpes vulpes*	µg/kg ww	Mean: 68.1 Median: 61 Minimum: 23 Maximum: 130		liver	(Heimstad et al., 2018)
Oslo, Norway	2017	Badger	*Meles meles*	µg/kg ww	Mean: 43 Median: 41 Minimum: 37 Maximum: 51		liver	(Heimstad et al., 2018)
The Alps	2004	Spruce needles		µg/kg	5.2 - 95		Eight samples collected in October 2004. Concentrations refer to CA:C14-17.	(Iozza et al., 2009a)
The Alps	2004	Spruce needles		µg/kg	26 - 450		Samples from various altitudes from 7 locations collected in Autumn 2004. Concentrations refer to total chlorinated paraffins	(Iozza et al., 2009b)
North and Baltic Sea		Dab, cod and flounder		µg/kg	260 (liver)		Highest	(Reth et al., 2005)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Industrial areas of the United Kingdom	1998	Fish		µg/kg	2 800 (pike liver)		Highest concentration - tentatively identified as CA:C14-17	(Cefas, 1999)
		Mackerel		µg/kg lipid	46			(Greenpeace, 1995)
		Common Porpoise	Phocoena phocoena	µg/kg lipid	3 - 7			(Greenpeace, 1995)
		Fin Whale	Balaenoptera physalus	µg/kg lipid	144			(Greenpeace, 1995)
Revingehed, Skåne, Sweden	1986	Rabbit	*Oryctolagus cuniculus*	µg/kg lipid	2 900 (muscle)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)
Grimsö, Västtmanland, Sweden	1985-1986	Moose	*Alces alces*	µg/kg lipid	4 400 (muscle)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)
Ottsjö, Jämtland, Sweden	1986	Reindeer	*Rangifer tarandus*	µg/kg lipid	140 (suet)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)
Sweden	1982-1986	Osprey	*Pandion haliaetus*	µg/kg lipid	530 (muscle)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)
Lake Vättern, Central Sweden	1987	Arctic Char	*Salvelinus alpinus*	µg/kg lipid	570 (muscle)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Lake Storvindeln, Lapland,	1986	Whitefish	*Coregonus sp.*	µg/kg lipid	1 000 (muscle)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)
Bothnian Sea, Sweden	1986	Herring	*Clupea harengus*	µg/kg lipid	1 400 (muscle)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)
Baltic proper, Sweden	1987	Herring	*Clupea harengus*	µg/kg lipid	1 500 (muscle)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)
Skagerrak, Sweden	1987	Herring	*Clupea harengus*	µg/kg lipid	1 600 (muscle)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)
Kongsfjorden, Svalbard	1981	Ringed Seal	*Pusa hispida*	µg/kg lipid	130 (blubber)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)
Baltic Sea, Sweden	1979-1985	Grey Seal	*Halichoerus grypus*	µg/kg lipid	280 (blubber)	Unspecified chain length, with 6-16 chlorine atoms/molecule		(Jansson et al., 1993)
		Mussel		µg/kg	<7 - 170			(Murray et al., 1987a)
United Kingdom		Mussel		µg/kg	3 250	Mean concentration – relates to C_{10-20}		(Campbell and McConnell, 1980)
United Kingdom		Pouting	*Trisopterus luscus*	µg/kg	100	Mean concentration – relates to C_{10-20}		(Campbell and McConnell, 1980)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
United Kingdom		Pike	*Esox lucius*	µg/kg	25	Mean concentration – relates to C_{10-20}		(Campbell and McConnell, 1980)
United Kingdom		Grey Seal	*Halichoerus grypus*	µg/kg	75 (liver and blubber)	Mean concentration – relates to C_{10-20}		(Campbell and McConnell, 1980)
United Kingdom		Grey Heron	*Ardea cinerea*	µg/kg	100 - 1 200 (liver)	Relates to C_{10-20}		(Campbell and McConnell, 1980)
United Kingdom		Common Guillemot	*Uria aalge*	µg/kg	100 - 1 100 (liver)	Relates to C_{10-20}		(Campbell and McConnell, 1980)
United Kingdom		Herring Gull	*Larus argentatus*	µg/kg	200 – 900 (liver)	Relates to C_{10-20}		(Campbell and McConnell, 1980)
United Kingdom		Seabirds' eggs		µg/kg	up to 2 000	Relates to C_{10-20}		(Campbell and McConnell, 1980)

Note: [1] new studies which were not reported in the SVHC support document (ECHA, 2021d)

Table 85. Summary of levels of CA:C14-17 in biota outside the EU. Detected congeners are presented only for biota samples from 2016 onwards.

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
South China Sea	2020	Mussels tissue	n.a.	ng/g dw	14.5-15.8	$C_{14-18}Cl_{4-11}$		(Lyu et al., 2023)
South China Sea	2020	Mussels shell	n.a.	ng/g dw	1.9-3.3	$C_{14-18}Cl_{4-11}$	Average detected value	(Lyu et al., 2023)
South Korea	2012 - 2018	Black-tailed gull (eggs)	*Larus crassirostris*	ng/g lw	694 - 2023	$C_{14-17}Cl_{5-10}$	Egg samples from 2 different sites in South Korea.	(Choo et al., 2022)[1]
Yangtze River, China	2019	Chinese mitten crab	n.a.	ng/g lw	Not detected - 680	Relates to C_{14-17}	59 samples were collected from 17 crab farms in river basins along the Yangtze River.	(Dong et al., 2021)[1]
Beijing, China	2017	Plants	n.a.	ng/g dw	21 - 785	$C_{10-27}Cl_{5-14}$	A total of 11 different plant species were collected along with the water and sediment samples during sampling campaigns.	(Wang et al., 2020b)[1]
South China Sea	2014	Corals	*Porites lutea; Favia speciose; Goniastrea aspera; Acropora brueggemanni; Acropora humilis; Acropora hyacinthus; Pocillopora damicornis; Acropora pulchra; Acropora formosa; Montipora digitate*	ng/g dw	73 - 712	$C_{14-17}Cl_{5-10}$	A total of 55 coral samples collected from two sampling locations (Luhuitou and Dongjiao). CA:C14-17 were detected in all ten coral species.	(Chen et al., 2021b)[1]
Persian Gulf, Iran	2015	Coral tissue	*Porites lutea; Acropora robusta; Acropora valida; Favia favus; Favia speciose; Platygyra daedalea; Sinularia*	ng/g dw	15.5 - 136	$C_{14-17}Cl_{8-10}$	Coral fragments were collected by scuba diving in July 2015. The presence of CA:C14-17 were studied in coral tissues, coral sketelons and in zooxanthellae.	(Ranjbar Jafarabadi et al., 2021)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
			compressa; Sarcophyton trocheliophorum					
Persian Gulf, Iran	2015	Coral skeleton	*Porites lutea; Acropora robusta; Acropora valida; Favia favus; Favia speciose; Platygyra daedalea; Sinularia compressa; Sarcophyton trocheliophorum*	ng/g dw	1.5 - 58.6	$C_{14\text{-}17}Cl_{8\text{-}10}$	Coral fragments were collected by scuba diving in July 2015. The presence of CA:C14-17 were studied in coral tissues, coral sketelons and in zooxanthellae.	(Ranjbar Jafarabadi et al., 2021)[1]
Persian Gulf, Iran	2015	Zooxanthellae	*Porites lutea; Acropora robusta; Acropora valida; Favia favus; Favia speciose; Platygyra daedalea; Sinularia compressa; Sarcophyton trocheliophorum*	ng/g dw	19.4 - 113	$C_{14\text{-}17}Cl_{8\text{-}10}$	Coral fragments were collected by scuba diving in July 2015. The presence of CA:C14-17 were studied in coral tissues, coral sketelons and in zooxanthellae.	(Ranjbar Jafarabadi et al., 2021)[1]
Chinese Bohai Sea, China	2011 - 2018	Mollusks	*Neverita didyma Rapana venosa Chlamys farreri Scapharca subcrenata Meretrix meretrix Mytilus edulis Crassostrea talienwhanensis*	ng/g dw	Not detected - 4342	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 308 composite mollusk samples were collected from nine coastal cities along the Chinese Bohai Sea coast.	(Wang et al., 2020b)[1]
China	2017	Tree bark	*Salix matsudana; Cedrus brevifolia*	ng/g lipid weight	195 - $2.18x10^4$	$C_{14\text{-}17}Cl_{5,7,9}$	Tree bark samples were collected in at 33 sites in the vicinity of Zhengzhou City and an industrial park containing several CP-	(Niu et al., 2021)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
							producing plants that was located 31 km northwest of the city center. CA:C14-17 were detected at quantifiable concentrations in all tree bark samples.	
Paddy fields in the Yangtze River Delta, China	2011	Red-backed Rat Snake	*Elaphe rufodorsata*	ng/g lw	1 500±970 (<LOQ–3 500)	$C_{14\text{-}16}Cl_{3\text{-}10}$ $C_{17}Cl_{3\text{-}9}$	mean±SD (min-max) values in liver; October 2011, N=9; Relates to CA:C14-17 with 53.1±0.4 Cl wt (mean value).	(Du et al., 2020)
Paddy fields in the Yangtze River Delta, China	2011	Red-backed Rat Snake	*Elaphe rufodorsata*	ng/g lw	5 500±3 500 (2 100 – 11 000)	$C_{14\text{-}17}Cl_{3\text{-}10}$	mean±SD (min-max) values in muscle; October 2011, N=9; Relates to MCCP with 52.3±0.4 Cl wt (mean value).	(Du et al., 2020)
Paddy fields in the Yangtze River Delta, China	2011	Red-backed Rat Snake	*Elaphe rufodorsata*	ng/g lw	230±420 (<LOQ – 1 300)	$C_{14,17}Cl_{3\text{-}12}$ $C_{15\text{-}16}Cl_{3\text{-}11}$	mean±SD (min-max) values in adipose tissues; October 2011, N=9; Relates to CA:C14-17 with 54.4±1.4 Cl wt (mean value).	(Du et al., 2020)
Paddy fields in the Yangtze River Delta, China	2011	Short-tailed Mamushi	*Gloydius brevicaudus*	ng/g lw	1 800±1 800 (<LOQ–5 100)	$C_{14\text{-}17}Cl_{3\text{-}10}$	mean±SD (min-max) values in liver; October 2011, N=7; Relates to CA:C14-17 with 54.0±0.7 Cl wt (mean value).	(Du et al., 2020)
Paddy fields in the Yangtze River Delta, China	2011	Short-tailed Mamushi	*Gloydius brevicaudus*	ng/g lw	14 000±5 700 (7 400–22 000)	$C_{14\text{-}16}Cl_{3\text{-}11}$ $C_{17}Cl_{3\text{-}12}$	mean±SD (min-max) values in muscle; October 2011, N=7; Relates to CA:C14-17 with 57.0±0.2 Cl wt (mean value).	(Du et al., 2020)
Paddy fields in the Yangtze River Delta, China	2011	Short-tailed Mamushi	*Gloydius brevicaudus*	ng/g lw	170±110 (44–290)	$C_{14}Cl_{3\text{-}12}$ $C_{15\text{-}16}Cl_{3\text{-}11}$ $C_{17}Cl_{4\text{-}12}$	mean±SD (min-max) values in adipose tissues; October 2011, N=7; Relates to CA:C14-17 with 54.7±0.9 Cl wt (mean value).	(Du et al., 2020)
Longtang Town, China	2016	Chinese watersnake (muscle)	*Enhydris chinensis*	µg/g	37 - 200	$C_{14\text{-}17}Cl_{5\text{-}10}$	Aquatic organisms collected from the pond: 7 watersnake, 4 small fish (common carp), 4 prawn and 6 waterbird eggs (white-breasted waterhen).	(Guan et al., 2020)[1]
Longtang Town, China	2016	Chinese watersnake (eggs)	*Enhydris chinensis*	µg/g	8.2 - 23	$C_{14\text{-}17}Cl_{5\text{-}10}$	Aquatic organisms collected from the pond: 7 watersnake, 4 small fish (common carp), 4 prawn and 6 waterbird eggs (white-breasted waterhen).	(Guan et al., 2020)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Longtang Town, China	2016	Common carp	*Cyprinus carpio*	μg/g	32 - 58	$C_{14\text{-}17}Cl_{5\text{-}10}$	Aquatic organisms collected from the pond: 7 watersnake, 4 small fish (common carp), 4 prawn and 6 waterbird eggs (white-breasted waterhen).	(Guan et al., 2020)[1]
Longtang Town, China	2016	Oriental river prawn	*Macrobrachium nipponense*	μg/g	2.8 - 7.0	$C_{14\text{-}17}Cl_{5\text{-}10}$	Aquatic organisms collected from the pond: 7 watersnake, 4 small fish (common carp), 4 prawn and 6 waterbird eggs (white-breasted waterhen).	(Guan et al., 2020)[1]
Longtang Town, China	2016	Waterbird eggs	*Anaurornis phoenicurus*	μg/g	2.3 - 5.0	$C_{14\text{-}17}Cl_{5\text{-}10}$	Aquatic organisms collected from the pond: 7 watersnake, 4 small fish (common carp), 4 prawn and 6 waterbird eggs (white-breasted waterhen).	(Guan et al., 2020)[1]
Longtang Town, China	2015 - 2016	Beetle	*Anomala corpulenta*	ng/g dw	7.7 - 87	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Grasshopper larva	n.a.	ng/g dw	360 - 390	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Grasshopper adult	*Oxya chinensis*	ng/g dw	370 - 410	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Cricket	*Gryllulus chinensis*	ng/g dw	300 - 930	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Mole-cricket	*Gryllotalpa orientalis*	ng/g dw	460 - 740	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Mantis	*Tenodera sinensls*	ng/g dw	460 - 740	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Dragonfly larva in ditch	n.a.	ng/g dw	87 - 240	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Dragonfly larva in pond	n.a.	ng/g dw	180 - 1500	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Longtang Town, China	2015 - 2016	Dragonfly adult-1	*Aeshnidae rambur*	ng/g dw	250 - 640	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Dragonfly adult-2	*Libellulidae rambur*	ng/g dw	1700 - 2900	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Tadpole	n.a.	ng/g dw	560 - 720	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Frog	*Kaloula pulchra*	ng/g dw	320 - 2200	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Toad	*Duttaphrynus melanostictus*	ng/g dw	580 - 1400	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Lizard	*Calotes versicolor)*	ng/g dw	180 - 900	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Oriental magpie robin	*Copsychus saularis*	ng/g dw	370 - 1200	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Long-tailed shrike	*Lanius schach*	ng/g dw	100, 130	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Eurasian blackbird	*Turdus merula*	ng/g dw	620	$C_{14\text{-}17}Cl_{5\text{-}10}$	A total of 73 biotic samples of insects and predators were collected.	(Liu et al., 2020c)[1]
Longtang Town, China	2015 - 2016	Guava	n.a.	ng/g dw	380 - 650	Relates to $C_{14\text{-}17}$	Fruit samples.	(Liu et al., 2020c)[1]
Tibetan Plateau, Asia	2010 - 2016	Tree bark	n.a.	µg/g lw	1.8 - 5.7	Relates to $C_{14\text{-}17}$	17 bark, 18 needle, 26 lichen, and 92 moss samples, were obtained from the region covering a range of 1843.5 km × 370.6 km at Ngari, Nyingchi, Namco, Shergyla Mountain, and Lhasa.	(Wu et al., 2020a)[1]
Tibetan Plateau, Asia	2010 - 2016	Needle	*Usnea longissima Ach*	µg/g lw	1.6 - 5.0	Relates to $C_{14\text{-}17}$	18 bark, 18 needle, 26 lichen, and 92 moss samples, were obtained from the region covering a range of 1843.5 km × 370.6 km at Ngari,	(Wu et al., 2020a)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
							Nyingchi, Namco, Shergyla Mountain, and Lhasa.	
Tibetan Plateau, Asia	2010 - 2016	Lichen	*Usnea longissima Ach*	µg/g lw	0.7 - 4.0	$C_{14\text{-}17}Cl_{5\text{-}10}$	19 bark, 18 needle, 26 lichen, and 92 moss samples, were obtained from the region covering a range of 1843.5 km × 370.6 km at Ngari, Nyingchi, Namco, Shergyla Mountain, and Lhasa.	(Wu et al., 2020a)[1]
Tibetan Plateau, Asia	2010 - 2016	Moss	n.a.	µg/g lw	0.9 - 4.0	$C_{14\text{-}17}Cl_{5\text{-}10}$	20 bark, 18 needle, 26 lichen, and 92 moss samples, were obtained from the region covering a range of 1843.5 km × 370.6 km at Ngari, Nyingchi, Namco, Shergyla Mountain, and Lhasa.	(Wu et al., 2020a)[1]
Taihu Lake, China	2011 - 2018	Silver carp	n.a.	ng/g ww	3.4 - $1.56x10^3$	$C_{14\text{-}17}Cl_{5\text{-}10}$	Fish samples were collected by local commercial fishermen. A total of 203 samples were analysed: included topmouth culter (n=41), crucian carp (n=40), silver carp (n =40), bighead carp (n=41), and large icefish (n=41).	(Ma et al., 2020)[1]
Taihu Lake, China	2011 - 2018	Bighead carp	n.a.	ng/g ww	4.2 - $1.04x10^3$	$C_{14\text{-}17}Cl_{5\text{-}10}$	Fish samples were collected by local commercial fishermen. A total of 203 samples were analysed: included topmouth culter (n=41), crucian carp (n=40), silver carp (n =40), bighead carp (n=41), and large icefish (n=41).	(Ma et al., 2020)[1]
Taihu Lake, China	2011 - 2018	Crucian carp	n.a.	ng/g ww	9.1 - 482	$C_{14\text{-}17}Cl_{5\text{-}10}$	Fish samples were collected by local commercial fishermen. A total of 203 samples were analysed: included topmouth culter (n=41), crucian carp (n=40), silver carp (n =40), bighead carp (n=41), and large icefish (n=41).	(Ma et al., 2020)[1]
Taihu Lake, China	2011 - 2018	Topmouth culter	n.a.	ng/g ww	5.1 - 982	$C_{14\text{-}17}Cl_{5\text{-}10}$	Fish samples were collected by local commercial fishermen. A total of 203 samples were analysed: included	(Ma et al., 2020)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
							topmouth culter (n=41), crucian carp (n=40), silver carp (n =40), bighead carp (n=41), and large icefish (n=41).	
Taihu Lake, China	2011 - 2018	Large icefish	n.a.	ng/g ww	3.4 - 1.10x10^3	$C_{14\text{-}17}Cl_{5\text{-}10}$	Fish samples were collected by local commercial fishermen. A total of 203 samples were analysed: included topmouth culter (n=41), crucian carp (n=40), silver carp (n =40), bighead carp (n=41), and large icefish (n=41).	(Ma et al., 2020)[1]
Paddy fields in the Yangtze River Delta, China	2011	Black-spotted Frogs	*Pelophylax nigromaculatus*	ng/g ww	69±47 (31–190)	$C_{14\text{-}15}Cl_{2\text{-}10}$; $C_{16\text{-}17}Cl_{3\text{-}10}$	mean±SD (min-max) values in liver; 2011; females N=12; Relates to CA:C14-17 with 53.5±0.2 Cl wt	(Du et al., 2019)
Paddy fields in the Yangtze River Delta, China	2011	Black-spotted Frogs	*Pelophylax nigromaculatus*	ng/g ww	68±59 (5.5–180)	$C_{14\text{-}15}Cl_{2\text{-}10}$; $C_{16\text{-}17}Cl_{3\text{-}10}$	mean±SD (min-max) values in liver; 2011; males N=12; Relates to CA:C14-17 with 53.6±0.4 Cl wt	(Du et al., 2019)
Paddy fields in the Yangtze River Delta, China	2011	Black-spotted Frogs	*Pelophylax nigromaculatus*	ng/g ww	16±14 (<LOQ–52)	$C_{14\text{-}17}Cl_{3\text{-}10}$	mean±SD (min-max) values in eggs; 2011; N=12; Relates to CA:C14-17 with 53.9±0.6 Cl wt	(Du et al., 2019)
Paddy fields in the Yangtze River Delta, China	2011	Black-spotted Frogs	*Pelophylax nigromaculatus*	ng/g ww	5±3	$C_{14\text{-}15}Cl_{2\text{-}10}$; $C_{16\text{-}17}Cl_{3\text{-}10}$	mean±SD (min-max) values in muscle; 2011; females N=3 pool samples; Relates to CA:C14-17 with 52.8±0.6 Cl wt	(Du et al., 2019)
Paddy fields in the Yangtze River Delta, China	2011	Black-spotted Frogs	*Pelophylax nigromaculatus*	ng/g ww	25±50	$C_{14\text{-}15}Cl_{2\text{-}10}$; $C_{16\text{-}17}Cl_{3\text{-}10}$	mean±SD (min-max) values in muscle; 2011; males N=2 pool samples; Relates to CA:C14-17 with 52.2–52.4 Cl wt	(Du et al., 2019)
Australia	2007 - 2015	Humpback whale (blubber)	*Megaptera novaeangliae*	ng/g absolute mass	>33	Relates to $C_{14\text{-}17}$	Blubber samples were obtained from 9 humpback whale specimens. CA:C14-17 were detected above detection limits (MDL= 33 ng absolute mass) in 3 of the 9 samples.	(Casà et al., 2019)[1]
Yangtze River Delta, China	n.a.	Grass carp (freshwater ecosystem fish)	*Ctenopharyngodon idella*	ng/g lw	340	Relates to $C_{14\text{-}17}$	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples	(Zhou et al., 2019)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
							from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	
Yangtze River Delta, China	n.a.	Predatory carp (freshwater ecosystem fish)	*Erythroculter ilishaeformis*	ng/g lw	610 - 3100	Relates to C_{14-17}	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	(Zhou et al., 2019)[1]
Yangtze River Delta, China	n.a.	Bigmouth grenadier anchovy (freshwater ecosystem fish)	*Coilia ectenes*	ng/g lw	270 - 440	Relates to C_{14-17}	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	(Zhou et al., 2019)[1]
Yangtze River Delta, China	n.a.	Snakehead (freshwater ecosystem fish)	*Channa argus*	ng/g lw	500	Relates to C_{14-17}	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	(Zhou et al., 2019)[1]
Yangtze River Delta, China	n.a.	Yellow catfish (freshwater ecosystem fish)	*Pelteobagrus fulvidraco*	ng/g lw	760 - 2800	$C_{14}Cl_{3-10}$; $C_{15}Cl_{3-9}$; $C_{16-17}Cl_{4-9}$	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from	(Zhou et al., 2019)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
							a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	
Yangtze River Delta, China	n.a.	Crucian carp (freshwater ecosystem fish)	*Carassius auratus*	ng/g lw	1200	Relates to C_{14-17}	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	(Zhou et al., 2019)[1]
Yangtze River Delta, China	n.a.	Common carp (freshwater ecosystem fish)	*Cyprinus carpio*	ng/g lw	2000	Relates to C_{14-17}	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	(Zhou et al., 2019)[1]
Yangtze River Delta, China	n.a.	Clam (freshwater ecosystem bivalve)	*Corbicula aurea Heude*	ng/g lw	770 - 2200	$C_{14}Cl_{3-10}$; $C_{15}Cl_{4-10}$; $C_{16}Cl_{4-9}$; $C_{17}Cl_{7-8}$	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	(Zhou et al., 2019)[1]
Yangtze River Delta, China	n.a.	Snail (freshwater ecosystem gastropod)	*Bellamya aeruginosa*	ng/g lw	210 - 5500		Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	(Zhou et al., 2019)[1]

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Yangtze River Delta, China	n.a.	Duck egg	*Anas platyrhynchos*	ng/g lw	120	$C_{14\text{-}15}Cl_{3\text{-}11}$; $C_{16}Cl_{2,4\text{-}11}$; $C_{17}Cl_{4\text{-}12}$	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 3 species (1 chicken egg, 1 duck egg and 1 chinese pond heron).	(Zhou et al., 2019)[1]
Yangtze River Delta, China	n.a.	Chinese pond heron	*Ardeola bacchus*	ng/g lw	290 - 4600	$C_{14\text{-}15}Cl_{3\text{-}12}$; $C_{16}Cl_{2\text{-}11}$; $C_{17}Cl_{3\text{-}11}$	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	(Zhou et al., 2019)[1]
Paddy fields in the Yangtze River Delta, China	2011	Pond Loach	Misgurnus anguillicaudatus	µg/kg lw	2 500 (1 400 – 2 600)	$C_{14\text{-}17}Cl_{3\text{-}10}$; $C_{16\text{-}17}Cl_{4\text{-}10}$	Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Pond Loach	Misgurnus anguillicaudatus	µg/kg dw	270 (170 – 430)		Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Rice Field Eel	Monopterus albus	µg/kg lw	2 600 (820 – 3 700)	$C_{14\text{-}16}Cl_{3\text{-}10}$; $C_{17}Cl_{4\text{-}10}$	Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Rice Field Eel	Monopterus albus	µg/kg dw	140 (50 – 270)		Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Red-backed Rat Snake	Elaphe rufodorsata	µg/kg lw	3 800 (2 100 – 7 900)	$C_{14\text{-}16}Cl_{3\text{-}10}$; $C_{17}Cl_{4\text{-}10}$	Median (min-max)	(Du et al., 2018)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Paddy fields in the Yangtze River Delta, China	2011	Red-backed Rat Snake	Elaphe rufodorsata	µg/kg dw	170 (100 – 330)		Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Red-banded Snake	Dinodon rufozonatum	µg/kg lw	13 000	$C_{14}Cl_{3-9}$; $C_{15-16}Cl_{3-10}$; $C_{17}Cl_{4-11}$	Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Red-banded Snake	Dinodon rufozonatum	µg/kg dw	570		Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Short-tailed Mamushi	Gloydius brevicaudus	µg/kg lw	17 000 (7 400 – 19 000)	$C_{14}Cl_{3-10}$; $C_{15}Cl_{4-11}$; $C_{16}Cl_{5-11}$; $C_{17}Cl_{4-12}$	Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Short-tailed Mamushi	Gloydius brevicaudus	µg/kg dw	990 (450 – 1 300)		Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Yellow Weasel	Mustela sibirica	µg/kg lw	12 000 (6 700 – 33 000)	$C_{14}Cl_{4-10}$; $C_{15}Cl_{4-11}$; $C_{16}Cl_{5-11}$; $C_{17}Cl_{6-12}$	Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Yellow Weasel	*Mustela sibirica*	µg/kg dw	990 (640 – 2 900)		Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Peregrine Falcon	*Falco peregrinus*	µg/kg lw	2 100 (1 300 – 29 000)	$C_{14-17}Cl_{3-10}$	Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Peregrine Falcon	*Falco peregrinus*	µg/kg dw	260 (190 – 4 700)		Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta,	2011	Collared Scops-owl	*Otus lettia*	µg/kg lw	270 (96 – 440)	$C_{14-15}Cl_{3-10}$; $C_{16-17}Cl_{4-10}$	Median (min-max)	(Du et al., 2018)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
China								
Paddy fields in the Yangtze River Delta, China	2011	Collared Scops-owl	*Otus lettia*	µg/kg dw	74 (39 – 110)		Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Common Cuckoo	*Cuculus canorus*	µg/kg lw	200 (<170 – 1 400)	$C_{14\text{-}15}Cl_{3\text{-}10}$; $C_{16}Cl_{3\text{-}9}$; $C_{17}Cl_{4\text{-}10}$	Median (min-max)	(Du et al., 2018)
Paddy fields in the Yangtze River Delta, China	2011	Common Cuckoo	*Cuculus canorus*	µg/kg dw	25 (<12 – 92)		Median (min-max)	(Du et al., 2018)
Liaodong Bay, North China	2017	Bastard halibut		µg/kg lipid weight	706.5 ± 240.2	$C_{14\text{-}17}Cl_{6\text{-}10}$		(Huang et al., 2017)
Liaodong Bay, North China	2017	Turbot		µg/kg lipid weight	5 097 ± 2 242	$C_{14\text{-}17}Cl_{6\text{-}10}$		(Huang et al., 2017)
Liaodong Bay, North China	2017	Ray		µg/kg lipid weight	109.0 ± 44.6			(Huang et al., 2017)
Liaodong Bay, North China	2017	*Navodon septentrionalis*	*Navodon septentrionalis*	µg/kg lipid weight	375.9 ± 120.2	$C_{14\text{-}17}Cl_{5\text{-}10}$		(Huang et al., 2017)
Liaodong Bay, North China	2017	Yellow croaker		µg/kg lipid weight	55.19 ± 23.73	$C_{14\text{-}17}Cl_{5\text{-}10}$		(Huang et al., 2017)
Liaodong Bay, North China	2017	Bass		µg/kg lipid weight	24.57 ± 10.31	$C_{14\text{-}17}Cl_{5\text{-}10}$		(Huang et al., 2017)
Liaodong Bay, North China	2017	Capelin		µg/kg lipid weight	30.26 ± 11.49	$C_{14\text{-}17}Cl_{5\text{-}10}$		(Huang et al., 2017)
Liaodong Bay, North China	2017	Spanish Mackerel		µg/kg lipid weight	53.92 ± 22.64	$C_{14\text{-}17}Cl_{6\text{-}10}$		(Huang et al., 2017)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Liaodong Bay, North China	2017	Abalone		µg/kg lipid weight	63.48 ± 24.75	$C_{14\text{-}17}Cl_{5\text{-}10}$		(Huang et al., 2017)
Liaodong Bay, North China	2017	Cod		µg/kg lipid weight	22.37 ± 9.17	$C_{14\text{-}17}Cl_{5\text{-}10}$		(Huang et al., 2017)
Shanghai, China	2016	Masson pine needles		µg/kg	12.4 – 33 500	$C_{14\text{-}17}Cl_{5\text{-}10}$		(Wang et al., 2016)
Great Lakes Basin		"Biota"		µg/kg	21		Mean concentration based on an analysis of published studies	(Klecka et al., 2010)
Lake Ontario	1998	Lake Trout	*Salvelinus namaycush Diporeia*	µg/kg	25			(Ismail et al., 2009)
Lake Ontario	2004	Lake Trout	*Salvelinus namaycush Diporeia*	µg/kg	8			(Ismail et al., 2009)
Lake Ontario	1999 - 2004	Plankton	*Mysis*	µg/kg	not detected		Mean concentration. Sampled 1999 - 2004	(Houde et al., 2008)
Lake Michigan	1999 - 2004	Plankton	*Mysis*	µg/kg	not detected		Mean concentration. Sampled 1999 - 2004	(Houde et al., 2008)
Lake Ontario	1999 - 2004	Plankton	*Diporeia*	µg/kg	4.2		Mean concentration. Sampled 1999 - 2004	(Houde et al., 2008)
Lake Michigan	1999 - 2004	Plankton	*Diporeia*	µg/kg	not detected		Mean concentration. Sampled 1999 - 2004	(Houde et al., 2008)
Lake Ontario	1999 - 2004	Rainbow Smelt	*Osmerus mordax*	µg/kg	109		Mean concentration. Sampled 1999 - 2005	(Houde et al., 2008)
Lake Michigan	1999 - 2004	Rainbow Smelt	*Osmerus mordax*	µg/kg	not detected		Mean concentration. Sampled 1999 - 2006	(Houde et al., 2008)
Lake Ontario	1999 - 2004	Slimy Sculpin	*Cottus cognatus*	µg/kg	108		Mean concentration. Sampled 1999 - 2007	(Houde et al., 2008)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
Lake Michigan	1999 - 2004	Slimy Sculpin	*Cottus cognatus*	µg/kg	2.9		Mean concentration. Sampled 1999 - 2008	(Houde et al., 2008)
Lake Ontario	1999 - 2004	Alewife	*Alosa pseudoharengus*	µg/kg	35		Mean concentration. Sampled 1999 - 2009	(Houde et al., 2008)
Lake Michigan	1999 - 2004	Alewife	*Alosa pseudoharengus*	µg/kg	5.6		Mean concentration. Sampled 1999 - 2010	(Houde et al., 2008)
Lake Ontario	1999 - 2004	Lake Trout	*Salvelinus namaycush*	µg/kg	24		Mean concentration. Sampled 1999 - 2011	(Houde et al., 2008)
Lake Michigan	1999 - 2004	Lake Trout	*Salvelinus namaycush*	µg/kg	5.6		Mean concentration. Sampled 1999 - 2012	(Houde et al., 2008)
Close to a chlorinated paraffin manufacturing plant in Australia		Mussel		µg/kg lipid	23 200			(Kemmlein et al., 2002)
Close to a chlorinated paraffin manufacturing plant in Australia		Crabs		µg/kg lipid	30 500			(Kemmlein et al., 2002)
Lake Ontario	2001	Lake Trout	*Salvelinus namaycush Diporeia*	µg/kg	12		Mean concentration	(Muir et al., 2002)
Lake Ontario	2001	Rainbow Smelt	*Osmerus mordax*	µg/kg	109		Mean concentration	(Muir et al., 2002)
Lake Ontario	2001	Slimy Sculpin	*Cottus cognatus*	µg/kg	108		Mean concentration	(Muir et al., 2002)
Lake Ontario	2001	Alewife	*Alosa pseudoharengus*	µg/kg	35		Mean concentration	(Muir et al., 2002)
Lake Ontario	2001	Lake Trout	*Salvelinus namaycush*	µg/kg	15		Mean concentration	(Muir et al., 2002)

Location	Year of the study	Sample	Latin name	Units	Level	Detected congeners (if reported)	Comment	Reference
St. Lawrence River, Canada		Beluga Whale	*Delphinapterus leucas*	µg/kg ww	79 000 (max.)		Blubber samples from 15 females	(Bennie et al., 2000)
St. Lawrence River, Canada		Beluga Whale	*Delphinapterus leucas*	µg/kg ww	80 000 (max.)		Blubber samples from 10 males	(Bennie et al., 2000)
St. Lawrence River, Canada		Beluga Whale	*Delphinapterus leucas*	µg/kg ww	20 900 (max.)		Liver samples from 3 females	(Bennie et al., 2000)
St. Lawrence River, Canada		Beluga Whale	*Delphinapterus leucas*	µg/kg ww	5 820 (max.)		Liver samples from 3 males	(Bennie et al., 2000)
Lake Ontario, Canada		Carp		µg/kg ww	563 (max.)		Whole body homogenates from 3 individuals	(Bennie et al., 2000)
Lake Ontario, Canada		Trout		µg/kg ww	4 390 (max.)		Whole body homogenates from 10 individuals	(Bennie et al., 2000)

Note: [1] new studies which were not reported in the SVHC support document (ECHA, 2021d)

Table 86: Summary of levels of CA:C14-17 in human samples and some foodstuff in the EU.

Location	Year of the study	Sample	Units	Level	Comment	Reference
Bavaria		Human breast milk	µg/kg lipid	9.6 - 903 [median 115.4]	60 Samples. CA:C14-17 detected in 58 % of the samples. Range reflects the quantified levels.	(Hilger et al., 2011)
Lancaster and London, UK		Human milk	µg/kg lipid	127.5	95th percentile	(Thomas et al., 2003)
Lancaster and London, UK		Human milk	µg/kg lipid	61	Highest concentration	(Thomas and Jones, 2002)
		Human milk	µg/kg lipid	7		(Greenpeace, 1995)

Location	Year of the study	Sample	Units	Level	Comment	Reference
Norway	2007-2009; 2019	Human serum	µg/L ww	0.15 (2007-2009) 0.36 (2019)	A total of 100 blood samples from women were analysed in diferent periods: 2007-2009 and 2019.	(Xu et al., 2022)[1]
Czech Republic	n.a.	Human blood serum	ng/g lw	<200 - 2110	27 serum samples obtained from Czech adults were analysed.	(Tomasko et al., 2021b)[1]
China; Sweden; Norway	2010 - 2016	Human milk	ng/g fat	< Limit of detection - 1260	Human milk samples were collected from Shanghai (n=10), Jiaxing (n=13), and Shaoxing (n=13), located in the Yangtze River Delta (YRD), China. The other two sampling cities are located in Scandinavia, Stockholm (Sweden) (n=10+9) and Bodø (Norway) (n=8).	(Zhou et al., 2020b)[1]
Europe	2018 - 2020	Biscuits, wafers and crisps	ng/g ww	2.4 - 39.2	86 baby food samples were collected representing producers from 22 European countries. The collected samples were categorized as follows: 9 biscuits, wafers and crisps; 6 yoghurt or yoghurt-related; 11 pureed desserts (e.g. pudding, custard); 2 infant and follow-on formula; 23 fruit or vegetable puree; 8 ready to eat cereal and porridge; 19 dry cereal and porridge; 8 meat or fish based meals.	(Perkons et al., 2021)[1]
Europe	2018 - 2020	Yoghurt or yoghurt-related	ng/g ww	1.1 - 9.2	(as above)	(Perkons et al., 2021)[1]
Europe	2018 - 2020	Pureed dessert	ng/g ww	1.2 - 7.1	(as above)	(Perkons et al., 2021)[1]
Europe	2018 - 2020	Infant formula	ng/g ww	3.2 - 17.9	(as above)	(Perkons et al., 2021)[1]
Europe	2018 - 2020	Fruit or vegetable puree	ng/g ww	0.1 - 5.7	(as above)	(Perkons et al., 2021)[1]
Europe	2018 - 2020	Ready to eat cereal and porridge	ng/g ww	0.4 - 1.7	(as above)	(Perkons et al., 2021)[1]
Europe	2018 - 2020	Dry cereal and porridge	ng/g ww	0.9 - 16.1	(as above)	(Perkons et al., 2021)[1]
Europe	2018 - 2020	Meat or fish based meal	ng/g ww	1.9 - 7.1	(as above)	(Perkons et al., 2021)[1]

Location	Year of the study	Sample	Units	Level	Comment	Reference
Germany	2019	Infant formula	ng/g lipid weight	Not detected - 26	21 samples of infant formula and 10 samples of baby cereal were analysed.	(Krätschmer et al., 2021a)[1]
Germany	2019	Baby cereal	ng/g lipid weight	Not detected - 32	21 samples of infant formula and 10 samples of baby cereal were analysed.	(Krätschmer et al., 2021a)[1]
Antwerp, Belgium	n.a.	Food	ng/g ww	1.3 - 12	Individual samples of fish (smoked salmon), meat (pork sausage), oil (extra-virgin olive oil), milk (whole-fat dehydrated cow's milk) and cereal (whole-wheat breakfast cereal) were analysed.	(McGrath et al., 2021b)[1]
Belgium	2020	Grains and grain-based products	ng/g ww	<LOQ - 250	A total of 211 food samples were purchased from Belgian retailers, including 26 grains and grain-based products; 18 vegetables and vegetable products; 10 starchy roots and tubers; 10 fruit and fruit products; 30 meat and meat products; 27 fish and other seafood; 25 milk and dairy products; 10 egg and egg products; 16 sugar and confectionary; 26 animal and vegetable fats and oils; 5 composite dishes; 5 seasoning, sauces and condiments; and 3 food supplements.	(McGrath et al., 2021a)[1]
Belgium	2020	Vegetables and vegetable products	ng/g ww	<LOQ - 23	(as above)	(McGrath et al., 2021a)[1]
Belgium	2020	Starchy roots and tubers	ng/g ww	<LOQ - 5.2	(as above)	(McGrath et al., 2021a)[1]
Belgium	2020	Fruit and fruit products	ng/g ww	<LOQ - 5.2	(as above)	(McGrath et al., 2021a)[1]
Belgium	2020	Meat and meat products	ng/g ww	<LOQ - 27	(as above)	(McGrath et al., 2021a)[1]
Belgium	2020	Fish and other seafood	ng/g ww	<LOQ - 73	(as above)	(McGrath et al., 2021a)[1]
Belgium	2020	Milk and dairy products	ng/g ww	<LOQ - 22	(as above)	(McGrath et al., 2021a)[1]
Belgium	2020	Egg and egg products	ng/g ww	3.3 - 16	(as above)	(McGrath et al., 2021a)[1]

Location	Year of the study	Sample	Units	Level	Comment	Reference
Belgium	2020	Sugar and confectionary	ng/g ww	<LOQ - 140	(as above)	(McGrath et al., 2021a)[1]
Belgium	2020	Animal and vegetable fats and oils	ng/g ww	<LOQ - 190	(as above)	(McGrath et al., 2021a)[1]
Belgium	2020	Composite dishes	ng/g ww	<LOQ - 16	(as above)	(McGrath et al., 2021a)[1]
Belgium	2020	Seasoning, sauces and condiments	ng/g ww	<LOQ - 51	(as above)	(McGrath et al., 2021a)[1]
Belgium	2020	Food supplements	ng/g ww	<LOQ - 20	(as above)	(McGrath et al., 2021a)[1]
Germany	2018 - 2019	Bread	ng/g ww	0.72 - 4.5	154 food samples were analysed, of which 10 were ready-made meal sample.	(Krätschmer et al., 2021b)[1]
Germany	2018 - 2019	Dairy products	ng/g ww	0.02 - 27	154 food samples were analysed, of which 10 were ready-made meal sample.	(Krätschmer et al., 2021b)[1]
Germany	2018 - 2019	Eggs	ng/g ww	0.04 - 25	154 food samples were analysed, of which 10 were ready-made meal sample.	(Krätschmer et al., 2021b)[1]
Germany	2018 - 2019	Fats and oils	ng/g ww	n.d - 1800	154 food samples were analysed, of which 10 were ready-made meal sample.	(Krätschmer et al., 2021b)[1]
Germany	2018 - 2019	Fish	ng/g ww	n.d - 48	154 food samples were analysed, of which 10 were ready-made meal sample.	(Krätschmer et al., 2021b)[1]
Germany	2018 - 2019	Meat	ng/g ww	0.06 - 13	154 food samples were analysed, of which 10 were ready-made meal sample.	(Krätschmer et al., 2021b)[1]
Germany	2018 - 2019	Ready-made meals	ng/g ww	0.59 - 2.7	154 food samples were analysed, of which 10 were ready-made meal sample.	(Krätschmer et al., 2021b)[1]
Latvia, Riga	n.a.	Pastry baked products	ng/g	No information regarding the concentration of CA:C14-17	38 samples of oven-baked pastry products (e.g. pies, buns, strudels, croissants, cinnamon rolls) and 15 dough samples (puff pastry, shortcrust pastry, pizza dough, and yeast dough) were acquired from local markets and confectioneries.	(Perkons et al., 2019)[1]

Location	Year of the study	Sample	Units	Level	Comment	Reference
Latvia, Riga	n.a.	Unprocessed pastry dough	ng/g	No information regarding the concentration of CA:C14-17	39 samples of oven-baked pastry products (e.g. pies, buns, strudels, croissants, cinnamon rolls) and 15 dough samples (puff pastry, shortcrust pastry, pizza dough, and yeast dough) were acquired from local markets and confectioneries.	(Perkons et al., 2019)[1]
Germany	n.a.	Oil from several dietary supplements	ng/g fat	<LOD - 151000	Dietary supplements capsules (n = 25) with high oil content were bought from online retailers: 14 vitamin E supplements, 7 marine oil supplements, and 4 other oil supplements samples were analysed.	(Sprengel et al., 2019)[1]
Oslo, Norway	2017	Fieldfare	µg/kg ww	Mean: 21 Median: 7.35 Minimum: 4.70 Maximum: 135	eggs	(Heimstad et al., 2018)
Lancaster, UK		Cows' milk	µg/kg lipid	63		(Thomas and Jones, 2002)
Denmark		Butter	µg/kg lipid	11		(Thomas and Jones, 2002)
Wales		Butter	µg/kg lipid	8.8		(Thomas and Jones, 2002)
Ireland		Butter	µg/kg lipid	52		(Thomas and Jones, 2002)
		Herring oil	µg/kg lipid	12		(Greenpeace, 1995)
		Margarine containing fish oil	µg/kg lipid	28		(Greenpeace, 1995)
		Pork	µg/kg lipid	11		(Greenpeace, 1995)
		Cow's milk	µg/kg lipid	16		(Greenpeace, 1995)
United Kingdom		Plaice	µg/kg	30		(Campbell and McConnell, 1980)

Location	Year of the study	Sample	Units	Level	Comment	Reference
United Kingdom		Dairy products	µg/kg	300		(Campbell and McConnell, 1980)
United Kingdom		Vegetable oils and derivatives	µg/kg	150		(Campbell and McConnell, 1980)
United Kingdom		Fruit and vegetables	µg/kg	5		(Campbell and McConnell, 1980)
United Kingdom		Beverages	µg/kg	Not detected		(Campbell and McConnell, 1980)
United Kingdom, remote from industry		Domestic Sheep	µg/kg	not detected in liver, brain kidney, mesenteric fat		(Campbell and McConnell, 1980)
United Kingdom, close to chlorinated paraffin production site		Domestic Sheep	µg/kg	200 (liver);		(Campbell and McConnell, 1980)
Upstream of chlorinated paraffin manufacturing plant		Domestic Sheep	µg/kg	50 (mesenteric fat);		(Campbell and McConnell, 1980)
Downstream of chlorinated paraffin manufacturing plant		Domestic Sheep	µg/kg	50 (kidney); not detected in heart, lung or perinephritic fat		(Campbell and McConnell, 1980)
Apartments in Stockholm, Sweden	2006-2007	Indoor dust	µg/g	3.2 - 18	44 indoor air and six dust samples from apartments in Stockholm, Sweden, were analyzed. The median concentration reproted gives the total CA:C10-13 and CA:C14-17, concentrations separately to CA:C14-17 not reported.	(Friden et al., 2011)

Note: [1] new studies which were not reported in the SVHC support document (ECHA, 2021d)

Table 87: Summary of levels of CA:C14-17 in foodstuff and human samples outside the EU.

Location	Year of the study	Sample	Units	Level	Comment	Reference
China	2007	Human breast milk	µg/kg lipid weight	60.4	Median value	(Xia et al., 2017)
China	2011	Human breast milk	µg/kg lipid weight	64.3	Median value	(Xia et al., 2017)
China	2017	Breast milk	ng/g lipid weight	211 - 1089	Individual breast milk samples (n=2020) were collected from 29 urban areas and 13 rural areas in 11 provinces.	(Xu et al., 2021)[1]
China	2018	Human hair	ng/g dw	16.9 - 893	CA:C14-17 were analysed in 62 pairs of human hair and nails from North China.	(Han et al., 2021b)[1]
China	2018	Human nails	ng/g dw	61.0 - 476	CA:C14-17 were analysed in 62 pairs of human hair and nails from North China.	(Han et al., 2021b)[1]
Jinan, China	2020	Human serum	ng/g ww	28.7 - 167	Serum donated by 435 male volunteers.	(Zhao et al., 2021)[1]
China	2018	Maternal serum	ng/mL	17.4 - 224.9	A total of four kinds of matched samples (maternal serum, cord serum, placenta, and breast milk) were collected from the Mianyang Maternal and Child Health-Care Hospital.	(Liu et al., 2020b)[1]
China	2018	Placenta	ng/g ww	9.1 - 54.3	(as above)	(Liu et al., 2020b)[1]
China	2018	Cord serum	ng/mL	11.9 - 67.8	(as above)	(Liu et al., 2020b)[1]
China	2018	Breast milk	ng/mL	11.0 - 163.7	(as above)	(Liu et al., 2020b)[1]
Jinan, China	2019	Human serum	ng/g ww	134	Serum samples from 145 residents aged from 50 to 84 were analysed.	(Ding et al., 2020)[1]
China	2016 - 2017	Maternal blood	ng/mL	1.26 - 4.20	32 pairs of maternal blood, cord blood, and placenta samples were collected from pregnant women in South China. The blood was further separated into plasma and red blood cells (RBCs) for blood partitioning study.	(Chen et al., 2020)[1]

Location	Year of the study	Sample	Units	Level	Comment	Reference
China	2016 - 2017	Placenta	ng/g	1.91 - 4.89	(as above)	(Chen et al., 2020)[1]
Hubei province, China	2016	Maternal serum	ng/ml	29.33 - 1006	A total of 31 matched samples of maternal serum, placenta, and umbilical cord serum were collected from pregnant mothers.	(Aamir et al., 2019a)[1]
Hubei province, China	2016	Cord serum	ng/ml	13.60 - 90.12	(as above)	(Aamir et al., 2019a)[1]
Hubei province, China	2016	Placenta	ng/g	24.8 - 642.3	(as above)	(Aamir et al., 2019a)[1]
China	2018	Human placenta	µg/kg lipid weight	80.8 - 954		(Wang et al., 2017c)
China	2017	Human blood	µg/kg lipid weight	130 - 3200		(Wang et al., 2017a)
Australia	2004 - 2015		ng/g lipid weight (lw)	<MDL - 520	Human male serum samples.	(van Mourik et al., 2020a)[1]
11 provinces, China	n.a.	Green tea	ng/g	2.55 - 543	107 commercial green tea samples originating from 11 different provinces, were collected to study the occurrence of CA:C14-17.	(Wang et al., 2021c)[1]
Beijing, China	n.a.	Noodles	ng/g ww	12 - $5.2x10^2$	Samples of all 9 common brands of cup instant noodles were purchased from four supermarkets. The presence of CA:C14-17 were analysed in the noodles, seasonings and soup.	(Wang et al., 2021b)[1]
Beijing, China	n.a.	Seasonings	ng/g ww	8 - $6.5x10^2$	(as above)	(Wang et al., 2021b)[1]
Beijing, China	n.a.	Soup	ng/L ww	1.9x10 - $1.5x10^3$	(as above)	(Wang et al., 2021b)[1]
Liaocheng, China	2017	Leaves of maize	ng/g dw	77.6 - 52930	Whole mature maize plants were sampled from five sampling sites which were located in different directions.	(Chen et al., 2021c)[1]
Guangzhou, China	n.a.	Infant formula	ng/g	1.67 - 20.9	A total of 26 brands of infant food samples (n = 56), including 16 brands of infant formula, 7 brands of infant cereal, and 3 brands of infant puree, were collected from different supermarkets.	(Han et al., 2021a)[1]

Location	Year of the study	Sample	Units	Level	Comment	Reference
Guangzhou, China	n.a.	Cereals	ng/g	1.21 - 8.24	(as above)	(Han et al., 2021a)[1]
Guangzhou, China	n.a.	Purees	ng/g	0.53 - 5.41	(as above)	(Han et al., 2021a)[1]
European Union (EU) countries; Tunisia; Sri Lanka; Philippines.	2015 - 2017	Vegetables oils	ng/g lw	<20 - 543	4 types of vegetable oils (n=27).	(Tomasko et al., 2021a)[1]
Scotland; Norway; Chile; Iceland	2017	Fresh Salmon Wild Salmon	ng/g lw	<20 - 163	Fresh and frozen salmon fillets from farms (n = 12) and 1 sample of wild salmon.	(Tomasko et al., 2021a)[1]
China	2020	Dairy products	ng/g wet weight	9.0 - 77	Foodstuff samples (551 pooled samples, 93 items) were analysed: cereal (6 items, 32 pooled samples), vegetable (31 items, 173 pooled samples), fruit (8 items, 47 pooled samples), legume (8 items, 54 pooled samples), egg (4 items, 30 pooled samples), dairy products (5 items, 28 pooled samples), meat (17 items, 104 pooled samples), and aquatic product (14 items, 83 pooled samples).	(Ding et al., 2021)[1]
China	2020	Aquatic products	ng/g wet weight	9.0 - 38.7	(as above)	(Ding et al., 2021)[1]
China	2020	Meats	ng/g wet weight	2.6 - 37.4	(as above)	(Ding et al., 2021)[1]
China	2020	Eggs	ng/g wet weight	8.8 - 30.3	(as above)	(Ding et al., 2021)[1]
China	2020	Cereals	ng/g wet weight	22.2- 116.8	(as above)	(Ding et al., 2021)[1]
China	2020	Legumes	ng/g wet weight	4.3 - 113.4	(as above)	(Ding et al., 2021)[1]
China	2020	Fruits	ng/g wet weight	2.9 - 19.8	(as above)	(Ding et al., 2021)[1]

Location	Year of the study	Sample	Units	Level	Comment	Reference
China	2020	Vegetables	ng/g wet weight	1.4 - 50.7	(as above)	(Ding et al., 2021)[1]
Pretoria, South Africa	n.a.	Cat hair	µg/g	0.6 - 6.5	Cat hair samples (n=10) were collected from Persian cats at a pet grooming service, representing six homes.	(Brits et al., 2020)[1]
South China	n.a.	Cereals	ng/g	Not detected - 21	Samples collected from 9 different provincies in South China. CA:C14-17 were detected in almost all cereal samples.	(Cui et al., 2020)[1]
South China	n.a.	Vegetables	ng/g	10.0 - 66	Samples collected from 9 different provincies in South China. CA:C14-17 were detected in all vegetable samples.	(Cui et al., 2020)[1]
South China	n.a.	Potatoes	ng/g	4.1 - 11	Samples collected from 9 different provincies in South China. CA:C14-17 were detected in all potatoe samples.	(Cui et al., 2020)[1]
South China	n.a.	Legumes	ng/g	4.7 - 36	Samples collected from 9 different provincies in South China. CA:C14-17 were detected in almost all legume samples.	(Cui et al., 2020)[1]
South China	n.a.	Eggs	ng/g	23 - 87	Samples collected from 9 different provincies in South China. CA:C14-17 were detected in all egg samples.	(Cui et al., 2020)[1]
South China	n.a.	Milk	ng/g	5.4 - 23	Samples collected from 9 different provincies in South China. CA:C14-17 were detected in all milk samples.	(Cui et al., 2020)[1]
South China	n.a.	Meats	ng/g	13 - $1.0x10^2$	Samples collected from 9 different provincies in South China. CA:C14-17 were detected in all meat samples.	(Cui et al., 2020)[1]
South China	n.a.	Aquatic food	ng/g	12.0 - 72	Samples collected from 9 different provincies in South China. CA:C14-17 were detected in all aquatic food samples.	(Cui et al., 2020)[1]
China	2018	Milk	ng/g lw	6.8–800	48 samples of raw dairy cow milk were collected from milk tanks on 48 dairy farms in selected industrial areas associated with the production and/or consumption of CPs in five Chinese provinces.	(Dong et al., 2020b)[1]
China	n.a.	Cooking oil	ng/g	Not detected - 11.612	176 cooking oil samples from 93 different companies and 19 oil containers collected from various markets in China.	(Gao et al., 2020)[1]
China	n.a.	Oil containers	ng/g	Not detected - 66	(as above)	(Gao et al., 2020)[1]

Location	Year of the study	Sample	Units	Level	Comment	Reference
China	n.a.	White wine	ng/mL	< Limit of detection - 153	14 white wines and 8 red wines were collected from the markets or home from the cooperators.	(Zhou et al., 2020a)[1]
China	n.a.	Red wine	ng/mL	< Limite of detection - 142	14 white wines and 8 red wines were collected from the markets or home from the cooperators.	(Zhou et al., 2020a)[1]
Beijing, China	2019	Dry cat and dog food	ng/g	3.8 - 52700	In total, 35 different imported commercial dry cat and dog food samples, representing six different brands, were collected from supermarkets.	(Dong et al., 2020c)[1]
China	2016 - 2017	Cord	ng/mL	1.13 - 2.15	32 pairs of maternal blood, cord blood, and placenta samples were collected from pregnant women in South China. The blood was further separated into plasma and red blood cells (RBCs) for blood partitioning study.	(Chen et al., 2020)[1]
19 Chinese provinces		Cereal	µg/kg ww	Mean: 213	1710 cereal samples giving 19 pooled samples	(Wang et al., 2019b)
19 Chinese provinces		Legume	µg/kg ww	Mean: 184	1710 legume samples giving 19 pooled samples	(Wang et al., 2019b)
Samples from China, Chile, Peru, United States; and others from uncertain location	2016	Animal feed materials	ng/g	6.4 - 260	16 feed material samples were collected. The samples included 6 types of feed materials of animal origin and three types of feed materials of plant origin.	(Dong et al., 2019)[1]
Yangtze River Delta, China	n.a.	Chicken egg	ng/g lw	370	Species from 2 different ecosystems were analysed: - Freshwater ecosystem: samples from a total of 9 species (7 fishes, 1 bivalve and 1 gastropod). -Wetland ecosystem: samples from a total of 12 species (2 fishes, 3 reptiles, 6 birds and 1 mammal).	(Zhou et al., 2019)[1]
Bohai Bay, China		Fish (no further information provided)	µg/kg dw	42.1 – 5 307	Range	(Xia et al., 2016)
China	2011	Meat	ng/g ww	0.3 - 23.8	20 meat samples and products were collected from 20 provinces in China. CA:C14-17 were detected in all samples.	(Huang et al., 2018)[1]

Location	Year of the study	Sample	Units	Level	Comment	Reference
China	n.a.	Aquatic food (freshwater fish, marine fish, shrimps and oysters)	ng/g ww	9 - 586	Aquatic food samples were collected from 18 Chinese provinces. A total of 1620 individual aquatic food samples were collected and combined to give 18 pooled samples. CA:C14-17 were detected in all samples.	(Wang et al., 2018b)[1]

Note: [1] new studies which were not reported in the SVHC support document (ECHA, 2021d)

B.6. Risk characterisation

Quantitative risk assessments of PBT and vPvB substances is not relevant, due to the uncertainties regarding long-term exposure and effects. Therefore, the risks related to PBT and vPvB substances, such as substances containing CA:C14-17, to the environment or to humans cannot be adequately addressed in a quantitative way. The overall aim of the risk management of PBT and vPvB substances is to minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses. (REACH Annex I, section 6.5).

B.7. Case-by-case approach for congeners with data lacking

During the SVHC identification process of 'MCCP'[34], the ECHA Member State Committee (MSC) concluded that CA:C14-17 with three or more chlorine atoms would meet the 'persistence' criterion (P) and the 'very persistent' criterion (vP) in accordance with Annex XIII of the REACH Regulation, and that the available information on bioaccumulation and toxicity allowed a conclusion as PBT and/or vPvB for some of these congeners (ECHA, 2021a).

The conclusions of the MSC are reproduced in Table 88.

Despite the fact that the MSC could not conclude on the PBT and/or vPvB properties of all congeners, there is no information available to conclude on the absence of these hazards but rather a lack of data for some of the congeners to assess the hazards against the vPvB/PBT criteria.

As demonstrated recently in restriction proposals for PFHxA (ECHA, 2021c) and intentionally-added microplastics (ECHA, 2020), high persistency may be concluded to pose a risk itself (where it is present in combination with other properties such as long-distance transport or toxicity) because continued emissions would result in an increasing pollution stock associated with increased exposure, and therefore a high likelihood that effect thresholds (known or unknown) for the environment and human health would be exceeded at some point in the future.

In this section the Dossier Submitter assesses whether some of the very persistent CA:C14-17 congener groups may also be of concern based on their persistence and that regulatory actions may also be justified for these congener groups. To do so the Dossier Submitter is proposing to use the case-by-case risk assessment approach, as described in REACH Annex I, paragraph 0.10, to assess the risk of these very persistent congeners.

Risk assessment of chemicals under REACH can be performed in several ways, depending on the hazard properties of the substances to be restricted:

[34] defined in the candidate list as 'UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17'

- 'Conventional' (eco)toxicological risk assessment based on the derivation of a predicted no-effect concentration (PNEC) and a quantitative risk characterisation (PEC/PNEC or RCR approach),
- PBT/vPvB assessment (non-threshold approach), and
- Case-by-case assessment according to paragraph 0.10 of Annex I to REACH[35].

The 'case-by-case' approach is very flexible, and according to REACH Annex I, paragraph 0.10, in relation to particular effects for which the procedures set out in Sections 1 to 6 of Annex I are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis.

Such 'case-by-case' approach to hazard and risk assessment has been applied in earlier restrictions in particular when high persistency of a substance, or group of substances, has been demonstrated (ECHA, 2022, ECHA, 2020, ECHA, 2021c).

[35] "In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in Sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and summarised in the safety data sheet."

Table 88: Congener groups concluded as PBT and/or vPvB (in black font) and only as P/vP and B (in red font) by MSC

Number of chlorine atoms

	Cl_1	Cl_2	Cl_3	Cl_4	Cl_5	Cl_6	Cl_7	Cl_8	Cl_9	Cl_{10}	Cl_{11}	Cl_{12}	Cl_{13}	Cl_{14}	Cl_{15}	Cl_{16}	Cl_{17}
C_{14}	-	-	**vPvB**	**vPvB PBT**	**vPvB PBT**	**vPvB PBT**	**vPvB PBT**	**vPvB**	**vPvB**	**vPvB**	**vPvB**	P/vP	P/vP	P/vP			
C_{15}	-	-	**vPvB**	**vPvB**	**vPvB PBT**	**PBT**	**PBT**	**PBT**	P/vP B	P/vP	P/vP	P/vP	P/vP	P/vP	P/vP		
C_{16}	-	- B/vB	**vPvB**	**vPvB**	**vPvB PBT**	**PBT**	**PBT**	**PBT**	P/vP B	P/vP	P/vP	P/vP	P/vP	P/vP	P/vP	P/vP	
C_{17}	-	-	P/vP	P/vP	P/vP B	**PBT**	**PBT**	**PBT**	**PBT**	P/vP	P/vP	P/vP	P/vP	P/vP	P/vP	P/vP	P/vP

Source: (ECHA, 2021d)

Note: the conclusions for P/vP and B are indicated additionally for substances which have no vPvB or PBT status (in red font). Dash indicates where conclusion on persistency was not possible to reach due to lack of data.

B.7.1. Persistency

It was concluded by MSC that all congeners of CA:C14-17 with three or more chlorine atoms (i.e. $C_{14}Cl_{3–14}$, $C_{15}Cl_{3-15}$, $C_{16}Cl_{3-16}$ and $C_{17}Cl_{3-17}$) would meet the 'persistence' criterion (P) and the 'very persistent' criterion (vP) in accordance with Annex XIII, points 1.1.1 and 1.2.1, of the REACH Regulation (ECHA, 2021a).

B.7.2. Bioaccumulation

It was concluded by MSC that the following congener groups of CA:C14-17 have B and/or vB properties (ECHA, 2021a):

- C14Cl3—11 congener groups
- C15Cl3—9 congener groups
- C16Cl2—9 congener groups
- C17Cl5—9 congener groups

For other congener groups, to the MSC could not conclude on their potential for bioaccumulation due to the lack of appropriate experimental data.

B.7.3. Toxicity

B.7.3.1. Conclusion by MSC

It was concluded by MSC that the following congener groups of CA:C14-17 meet the toxicity criterion (T) in accordance with Annex XIII, point 1.1.3 (a), of the REACH Regulation:

- C_{14} congeners having 4, 5, 6 and 7 chlorine atoms,
- C_{15} congeners having 5, 6, 7 and 8 chlorine atoms,
- C_{16} congeners having 5, 6, 7 and 8 chlorine atoms, and
- C_{17} congeners having 6, 7, 8 and 9 chlorine atoms.

The conclusion was based on chronic toxicity studies on *Daphnia magna*, 21d NOEC (reproduction) values range from ~ 4 - 15.6 µg/L. The most reliable result is 21d NOEC of 8.7 µg/L for the C14-17, 52 % Cl wt, which is expected to contain the above listed congeners (ECHA, 2021d). For a UVCB substance like CA:C14-17, the observed toxicity may represent toxicity of one or more of its constituents. As the test material used in the available toxicity studies contained several groups of congeners of CA:C14-17 and no testing and analysis was performed at the level of the congener groups, it was not possible to identify whether the congener groups present in the tested substance contributed differently to the observed toxicity.

The conclusion for T in the SVHC identification was based on the following assumptions:

- the following congeners were present in the test material: C_{14} with 4, 5, 6 and 7 chlorine atoms; C_{15-16} with 5, 6, 7 and 8 chlorine atoms; C_{17} with 6, 7, 8 and 9 chlorine atoms
- these congeners exert toxic effects by the same mode(s) of action because these congener groups are structurally very similar (they differ only in carbon chain

length and number of chlorine substituents)
- all congener groups present in the C_{14-17}, 52 % Cl wt. test substance contributed equivalently to the observed toxicity.

For other congeners, the MSC could not conclude for the T criteria due to lack of data.

B.7.3.2. Case-by-case assessment of congeners without concluded PBT and/or vPvB properties by the MSC

Since CA:C14-17 contains thousands of constituents, the influence of varying degrees of chlorination and chain length on reported toxicity endpoints is not known.

The current data allows an assessment of the toxicity of congeners specified under section B.7.3.1. However, there is a lack of congener specific chronic toxicity data that would provide information on the toxicity of congeners with chlorination degree above 7 (C14), above 8 (C15, C16) and above 9 (C17) chlorine atoms (or $C_{17}Cl_{3-5}$). Therefore, as an indirect measure, for the purposes of this restriction proposal the Dossier Submitter has assessed if congeners $C_{14}Cl_{12-14}$; $C_{15}Cl_{9-15}$; $C_{16}Cl_{9-16}$, $C_{17}Cl_{3-5}$ and $C_{17}Cl_{10-17}$ are also likely to induce toxic effects. The assessment was based on 1) predictions of toxicity using QSAR and 2) grouping and read-across which is supported by experimental and monitoring data comparing bioavailability across the congener groups. In combination with persistence, such a conclusion could justify risk management of these congener groups. As congener groups $C_{14}Cl_3$, $C_{14}Cl_{8-11}$, $C_{15-16}Cl_{3-4}$ were concluded as vPvB by the MSC (Table 81), they have not been included in this case-by-case assessment.

B.7.3.2.1. Quantitative structure–activity relationship (QSAR)

The Dossier Submitter used Quantitative Structure–Activity Relationship (QSAR) models to predict chronic toxicity of congeners $C_{14}Cl_{12-14}$; $C_{15}Cl_{9-15}$; $C_{16}Cl_{9-16}$, $C_{17}Cl_{3-5}$ and $C_{17}Cl_{10-17}$ to fish, daphnia and algae.

The ECOSAR (v. 2.0) neutral organics model was used to produce chronic toxicity predictions. The predictions for some of the congener groups were in the applicability domain of the model: $C_{14}Cl_{12-13}$; $C_{15}Cl_{9-12}$; $C_{16}Cl_{9-11}$, $C_{17}Cl_{4-5}$ and $C_{17}Cl_{10}$. For the rest of the congener groups the predictions were out of domain due to the log Kow being greater than the upper limit of the descriptor domain (log Kow 8). The log Kow values used as input for the toxicity predictions are reported in the SVHC support document (ECHA, 2021d). The log Kow values were predicted with the ACD Percepta logP methods instead of using the KOWWIN model of Episuite. As described in the SVHC support document, the KOWWIN model has been shown higher uncertainties in the log Kow predictions of chloroalkanes (ECHA, 2021d).

The predicted NOECs for chronic toxicity to fish and daphnids for the congeners that are within applicability domain ($C_{14}Cl_{12-13}$; $C_{15}Cl_{9-12}$; $C_{16}Cl_{9-11}$, $C_{17}Cl_{4-5}$ and $C_{17}Cl_{10}$ congeners) are below 10 µg/L (Table 89). There are uncertainties with the predictions related to the proximity of the upper limit of the parametric domain for log Kow (log Kow of 8). The Daphnid chronic model is believed to be more reliable than the Fish chronic model for this type of constituents because the training set contains substances that have higher log Kow when compared to the Fish chronic model.

The NOEC predictions for daphnids range from 0.4 – 2.2 µg/l for the $C_{14}Cl_{12-13}$; $C_{15}Cl_{9-12}$;

$C_{16}Cl_{9\text{-}11}$, $C_{17}Cl_{4\text{-}5}$ and $C_{17}Cl_{10}$ congeners. These predictions are relatively consistent with the experimental 21-day NOEC (reproduction) value for *Daphnia magna*; 8.7 µg/L (range from ~ 4 - 15.6 µg/L) for the commercial EC 287-477-0 product C14-17, 52 % Cl wt. The Dossier Submitter considers that the experimental and predicted values are in relatively good agreement, indicating on the reliability of the model to predict chronic daphnia toxicity.

Table 89: Aquatic chronic toxicity predictions from the neutral organics model of ECOSAR (only those which are in the applicability domain of the model are presented)

Structure	Input logKow	NOEC fish (mg/l)	NOEC Daphnia (mg/l)	NOEC Algae (mg/l)
C14Cl12	7.6	0.00059[1]	0.00127[1]	*0.016*[2]
C14Cl13	8	0.00029[1]	0.00071[1]	0.010[1]
C14Cl14	8.3			
C15Cl9	7.2	0.00113[1]	0.00219[1]	*0.025*[2]
C15Cl10	7.4	0.00078[1]	0.00170[1]	*0.020*[2]
C15Cl11	7.7	0.00047[1]	0.00106[1]	*0.014*[2]
C15Cl12	7.8	0.00041[1]	0.00092[1]	*0.013*[2]
C15Cl13	8.1			
C15Cl14	8.4			
C15Cl15	8.8			
C16Cl9	7.3	0.00092[1]	0.00191[1]	*0.022*[2]
C16Cl10	7.5	0.00071[1]	0.00141[1]	*0.018*[2]
C16Cl11	7.6	0.00059[1]	0.00127[1]	*0.016*[2]
C16Cl12	8.2			
C16Cl13	8.3			
C16Cl14	8.6			
C16Cl15	8.9			
C16Cl16	9.3			
C17Cl3	8.5			
C17Cl4	8	0.00016[1]	0.00037[1]	0.005[1]
C17Cl5	7.8	0.00028[1]	0.00062[1]	0.001[1]
C17Cl10	7.9	0.00032[1]	0.00078[1]	0.011[1][1]
C17Cl11	8.1			

Structure	Input logKow	NOEC fish (mg/l)	NOEC Daphnia (mg/l)	NOEC Algae (mg/l)
C17Cl12	8.1			
C17Cl13	8.6			
C17Cl14	8.9			
C17Cl15	9.1			
C17Cl16	9.4			
C17Cl17	9.8			

Note: [1] prediction within the applicability domain of the model (logKow ≤ 8)
[2]: toxicity above water solubility, thus no effects at water solubility

B.7.3.2.2. Grouping

The congeners of CA:C14-17 can be expected to exert toxic effects by the same mode(s) of action because these congener groups are structurally very similar (they differ only in carbon chain length and number of chlorine substituents)(ECHA, 2021d). Therefore, structural similarity forms a solid basis to group all CA:C14-17 congeners and may allow to predict toxicity amongst the congeners.

However, despite the high structural similarity, the toxicity of some congeners could still be limited by reduced bioavailability when the degree of chlorination (and logKow) increases. Therefore, to support the grouping, potential limitations in bioavailability with increasing number of chlorine atoms needs to be considered.

CA:C14-17 congener groups can have different physical-chemical properties and bioaccumulation potential due to the difference in carbon chain length and number of chlorine atoms. In addition, also structural isomers of the same congener group can have different physical-chemical properties and bioaccumulation potential due to the positioning of the chlorine atoms on the carbon chain (ECHA, 2021d). According to the modelling exercise that took place during the SVHC identification, the BCF predictions reflected low bioaccumulation potential (BCF values < log BCF 3.3) for the C_{14}-C_{16} congeners with a chlorine content > 65 % , as well as for all C_{17} congeners. This was a result of the log Kow values being relatively higher for these congeners, which in the BCF Baseline model reflects anticipated decreasing uptake due to increasing hydrophobicity. However, very hydrophobic substances such as Dechlorane Plus (estimated log Kow = 11.2 30) can also pass the gastro-intestinal tract and there seems to be no indication of a hydrophobicity or size cut-off in the bioconcentration of Dechlorane Plus (Larisch and Goss, 2018). Similar lack of size or hydrophobicity cut-off has been also indicated by experimental studies on chloroalkanes (Castro et al., 2019). This indicates that BCF predictions may have uncertainties related to estimating the bioaccumulation potential of very hydrophobic substances (Larisch and Goss, 2018).

For CA:C14-17 it has been proposed that the bioaccumulation potential may be also affected by the rate of metabolism (ECHA, 2021d). Metabolism has been shown to decrease with increasing chlorination content and carbon chain length. Further details on modelling and experimental studies are provided in the SVHC support document (ECHA,

2021d).

Below the Dossier Submitter assesses if uptake rate and internal concentrations of the congeners $C_{14}Cl_{12\text{-}14}$; $C_{15}Cl_{9\text{-}15}$; $C_{16}Cl_{9\text{-}16}$, $C_{17}Cl_{3\text{-}5}$ and $C_{17}Cl_{10\text{-}17}$ are likely to decrease significantly by these processes (potential decrease in bioavailability or rate of metabolism), and hence are not expected to cause effects on organisms.

Metabolism

As discussed in the ECHA (2021d), cytochrome P450-dependent oxidation (involving dehalogenation reaction) and glutathione (GSH)-dependent conjugation are the primary routes in the metabolism of haloalkanes. The rate of metabolism of the chloroalkanes is influenced by the chain length and the degree of chlorination: the proportion of unmetabolised chloroalkanes increases with its degree of chlorination. Therefore, the congeners $C_{17}Cl_{3\text{-}5}$ may be more susceptible to metabolism/degradation than the C17 congeners which have higher level of chlorination. This in turn may lead to a decrease in accumulation potential of $C_{17}Cl_{3\text{-}5}$ congeners. Reduced accumulation due to metabolism is also reflected in the BCF models as a mitigating factor for bioaccumulation potential (see details in ECHA (2021d), Table 38).

Metabolism of lower chlorinated alkanes has been indicated by a study investigating dietary accumulation of congeners $C_{12}Cl_6$, $C_{12}Cl_{10}$, $C_{16}Cl_3$ and $C_{16}Cl_{13}$ in rainbow trout (Fisk et al., 1996). Lower chlorinated alkanes, e.g. $C_{16}Cl_3$, had shorter half-lives in rainbow trout than highly chlorinated alkanes. Analysis of fish tissue extracts revealed that the chlorinated alkane mixtures were selectively biotransformed with certain unknown components persisting in tissues. Lower chlorinated alkanes had greater proportions of polar 14C, which implies greater metabolism of these compounds.

However, even though higher metabolism of the lower chlorinated congeners is expected, it is not assumed to significantly decrease the tendency of $C_{17}C_{3\text{-}5}$ congeners to accumulate in an organism. The biomagnification factors (BMFs) for the $C_{16}Cl_3$ was still 1.07 in this study indicating high potential to accumulate. Furthermore, all of the C_{14} to C_{16} congeners with chlorination levels from 3 to 5 are concluded as very bioaccumulative (ECHA, 2021d) and therefore they cannot be expected to be metabolised/eliminated to a large extent. It is unlikely that the C_{17} congeners with the same number of chlorine atoms would show any different trend in biotransformation and elimination.

Evidence that the low chlorinated C_{17} congeners (with 3-5 chlorine atoms) are not immediately metabolised and eliminated is provided by ((Castro et al., 2019)). As summarised in (ECHA, 2021d) the congeners $C_{17}Cl_{3\text{-}5}$ have been detected in both the test material Cereclor S45 and in Daphnia after aqueous exposure. Therefore they can accumulate in *D.magna*.

Furthermore Du et al. (2020) investigated the occurrence and biomagnification of chloroalkanes in the semi-aquatic red-backed rat snake (*Elaphe rufodorsata*) and its prey the black-spotted frog (*Pelophylax nigromaculatus*), in paddy fields in the Yangtze River Delta, China. The study and the BMF values are presented in detail in the SVHC Support Document (ECHA (2021d), Table 45). Based on the BMF values reported therein, the mean lipid normalised BMFs in muscle and liver of snakes-frogs are for $C_{17}Cl_4$: 0.91 (muscle) and 3.97 (liver), and for $C_{17}Cl_5$: 2.44 (muscle) and 2.71 (liver). As a comparison, the BMFs

for $C_{17}Cl_6$, $C_{17}Cl_7$, $C_{17}Cl_8$ and $C_{17}Cl_9$ – which are toxic – are 1.65, 1.63, 1.70 and 1.92 for muscle and 3.02, 3.56, 3.62 and 1.67 for liver. Similarity in the BMF values implies that congeners $C_{17}Cl_4$ and $C_{17}Cl_5$ – despite not being concluded as meeting the T criterion - would not be heavily metabolised nor less bioavailable, and thus can reach tissues and cause toxic effects if they build-up to a critical concentration.

Uptake/accumulation potential of congeners

As presented in the SVHC support document (ECHA, 2021d), all congeners of CA:C14-17 are potentially bioaccumulative (log Kow >4.5). The range of the predicted log Kow for $C_{14}Cl_{1\text{-}14}$ is 6.2-8.25, $C_{15}Cl_{1\text{-}15}$, is 6.63 – 8.76, $C_{16}Cl_{1\text{-}16}$ is 7.07-9.28 and $C_{17}Cl_{1\text{-}17}$ is 7.33 - 9.8 (see Table 90).

It was explained that the log Kow is relatively independent of chlorine content for a given carbon chain length up to a chlorine content of 55 % Cl wt. The log Kow of the lowest chlorination degrees ($C_{14}Cl_{1\text{-}2}$, $C_{15}Cl_1$, $C_{16}Cl_{1\text{-}2}$ and $C_{17}Cl_1$) are higher than for congeners with more chlorine atoms and the log Kow starts decreasing around three chlorine atoms. The lowest log Kow are predicted for congeners with approximately 55 % chlorine content ($C_{14}Cl_7$, $C_{15}Cl_8$, $C_{16}Cl_7$ and $C_{17}Cl_8$) and after that starts to rise again with increasing chlorine content.

Furthermore, the predicted log Kow varies for the structural isomers of the same congener group depending on the position of the chlorine atoms, for example the range for the congener group $C_{15}Cl_3$ is 7.22 - 8.92 (see Table 54 of Annex II in the ECHA (2021d)). It was observed that there is less variation in the log Kow for structural isomers of the congener groups with higher degree of chlorination. The position of the chlorine atoms on the hydrocarbon chain has an effect on the log Kow, and this effect might be greater for congeners with fewer chlorine atoms substituted at the hydrocarbon chain.

In general, the lipophilicity and molecular weights of the congeners are high and may limit uptake rate. The effect of high lipophilicity, large molecular size and steric hindrance on uptake and bioavailability of the CA:C14-17 congeners have been discussed in the SVHC report (ECHA, 2021d). While QSAR models predict BCFs below 2000 L/kg wet weight for the hydrophobic CA:C14-17 congeners with a chlorine content > 65 % , it was recognised that, in contrast, experimental data on CA:C14-17 indicates high uptake of these highly chlorinated congeners e.g. (Fisk et al., 1996, Fisk et al., 1998, Castro et al., 2018, Mézière et al., 2021, Wang et al., 2021a, Liu et al., 2020c, Castro et al., 2019).

A study from Castro et al. (2019) has indicated that large and hydrophobic congeners of chloroalkanes were found to bioaccumulate in *D. magna*. They propose that increasing chlorine content is a good explanatory variable for the increase of log BCF and log BAF of the tested chloroalkane technical substances ($p < 0.01$, Table S8 in Castro et al. (2019)), regardless of their carbon chain length. The study investigated five chlorinated alkane technical substances: Cereclor S45 (MCCP 45 % Cl; C14–C17; UK); Cereclor 50LV (SCCP 50 % Cl; C10–C13; UK); Huels 70C (SCCP 70 % Cl; C10–C13; Germany); CP-42 (LCCP 42 % Cl; C10–C17, C21–C31; UK); CP-52 (CP 52 % Cl; C9–C29; China). The chlorine content represents the average percentage of total chlorine of the total mass of the CP. The BCFs and BAFs were calculated based on total concentrations of chlorinated alkanes in the test material. The technical mixture CP-52 included also congeners with CA:C14-17

up to 10 chlorine atoms. These congeners have been detected in both the test material CP-52 and in Daphnia after aqueous exposure. Therefore they are bioavailableto *D.magna*.

In this study, the effect of chlorine content on accumulation in daphnids was assessed by comparing the BCF or BAF values of Cereclor 50LV and Huels 70C, which are chloroalkane substances with the same carbon chain length. Cereclor 50LV and Huels 70C have chain lengths of C10 to C14 but differ in chlorine content (50 and 70 % Cl, respectively). Similar log BAF (6.9 ± 0.21 and 7.0 ± 0.14 for Cereclor 50LV and Huels 70C, respectively) and log BCF (7.2 ± 0.11 and 7.4 ± 0.44 for Cereclor 50LV and Huels 70C, respectively) were reported in the study, and thus the higher chlorination level is not expected to affect accumulation significantly.

It is noted that this comparison was performed using C10 to C14 chloroalkanes and therefore high level of chlorination (as in Huels 70C) may not limit bioavailability of these smaller chloroalkenes to a same extent when compared to C14 to C17 congeners. However, the data from this study demonstrate that high molecular size congeners (including also long-chain chloroalkanes which are even larger molecules) are able to permeate cell membranes and be taken up from water (Figure 3 in Castro et al. (2019)). The congener pattern (using the goodness of fit) between the technical substance CP-42 and congener profile observed in *D. magna* after CP-42 aqueous exposure was >90 % . This indicates that not only the small molecular size congeners present in CP-42 (LCCP 42 % Cl; C10–C17, C21–C31) accumulate to *D.magna*, but equally the large chloroalkanes contribute to the high log BCF (6.7 ± 0.23) and log BAF (6.5 ± 0.13) values calculated for CP-42. Therefore, this study indicates that the increasing chlorine content does not limit bioavailability of the chloroalkane congeners.

Similar results have been observed in plants in a wetland ecosystem: the level of chlorination did not limit the accumulation of short-, medium- and long-chain chloroalkanes into emergent, floating and submerged plants (Wang et al., 2021a). A total of 11 different plant species were collected along with the water and sediment samples. After collection, the plants were gently shaken to remove large soil particles, and on the same day, the plant samples were carefully washed with distilled water to remove sediment attached to the roots, rhizomes, stems and leaves. This study indicates that there is a positive correlation between the log Kow of the congeners and BCF. This means that the congeners with high log Kow (such as highly chlorinated congeners) are expected to be bioavailable and accumulate in wetland plants even more than the less lipophilic congeners. The highest level of chlorination is Cl_{14} in this study. However, BSAF values may have been more relevant for many of these plants since submerged and emergent plants (and one of the floating plants *Nymphaea tetragona*) are rooted in the sediment.

A significant positive correlation between BMFs and the number of Cl atoms has been demonstrated also in the fish–watersnake food chain and fish–waterbird egg food chain (5-10 chlorine atoms)(Guan et al., 2020).

Accumulation of highly chlorinated CA:C14-17 to fish has been demonstrated by Fisk et al. (1996). They performed dietary exposures to four 14C-polychlorinated alkanes ($C_{12}Cl_6$, $C_{12}Cl_{10}$, $C_{16}Cl_3$, and $C_{16}Cl_{13}$) using juvenile rainbow trout (*Oncorhynchus mykiss*). Sampled fish were separated into liver, gastrointestinal (GI) tract and carcass (whole fish minus liver and GI tract). Each tissue was weighed and analysed separately for 14C radioactivity. The lipid corrected BMFs for the $C_{16}Cl_3$ and $C_{16}Cl_{13}$ were 1.07 and 0.72 in the low dose

groups. The depuration rates from this study are (in the low dose group): 0.014 day-1 ($C_{16}Cl_3$) and 0.012 day-1 ($C_{16}Cl_{13}$). When using these depuration rates to predict BCF values based on the work by (Brooke and Crookes, 2012) (which suggests that a depuration rate constant around 0.085 day-1 or less would indicate a BCF above 5 000 L/kg), both congeners $C_{16}Cl_3$ and $C_{16}Cl_{13}$ would have a BCF above 5 000 L/kg. This indicates that these congeners are taken up and have a tendency to accumulate in fish exposed via food.

Another study demonstrating a considerable biomagnification of congeners of CA:C14-17 has been conducted in the Lake Ontario food web (Houde et al., 2008). The lipid normalized biomagnification factors (BMFs) for sculpin indicate that the BMFs seem to increase with increasing level of chlorination (BMF of 3.1 for $C_{15}Cl_5$ and BMF of 25 for $C_{15}Cl_{10}$). However, the data on sculpin is only based on one value and this assessment carries some uncertainty. In the same study, Lake trout-Alewife BMFs indicate some decline of BMFs with higher level of chlorination ($C_{15}Cl_7$: BMF of 0.25, $C_{15}Cl_{10}$: BMF of 0.02). The measured levels of chlorination for CA:C14-17 were from 5 to 10 in this study.

Study by Fisk et al. (1998) confirms that a highly chlorinated congener $C_{16}Cl_{13}$ can be taken up also by *Lumbriculus variegatus*. The uptake rate constant (0.013 g/g/d) and kinetic BAF of 0.6 were measured. However, for the determination of concentrations in the worms, the organisms were not cleansed of gut contents prior to analysis so this may have led to a significant overestimation of the actual concentration in the organism and hence the actual uptake of the substances. While the study indicates that $C_{16}Cl_{13}$ congener can be taken up by *L. variegatus*, it provides only limited evidence to substantiate the bioavailability across the CA:C14-17 congeners due to reliability issue described above.

Trophic Magnification Factors (TMFs) determined from terrestrial ecosystem in Longtang Town (Guangdong Province, China) in 2015-2016 also indicates uptake and magnification of Cl_5 to Cl_{10} congeners in terrestrial food web (Liu et al., 2020c). Seven insect species, two amphibians, one lizard and several insectivorous birds were sampled. Congeners having 10−17 carbon atoms and 5−10 chlorine atoms were measured using a gas chromatograph−mass spectrometer (GC/MS, Agilent) with electron capture negative ionization (ECNI) in selective ion-monitoring (SIM) mode. The TMFs were estimated as linear regression analyses of logarithmically transformed lipid-normalised concentrations of short and medium chain chloroalkane congener groups versus trophic level. A TMF value above 1 indicates that the chemical is biomagnifying. Based on this study all $C_{14\text{-}17}Cl_{5\text{-}10}$ have TMFs above 1. There is however uncertainty related to the analytical methods, the derived TMF values because the sampling took place at different times, the numbers of amphibians and lizards sampled are low compared to the number of insects, BMFs were calculated from predator muscle tissue but insect whole body, and the range of trophic levels occupied by single predator species (1.7 to 3.8) was higher than expected (so birds were excluded from the TMF calculations). Therefore, this study may have only limited value to assess bioaccumulation potential. It however can still provide supporting information to compare uptake across CA:C14-17 congeners, to compare if the congeners without toxicity data potentially have limited bioavailability and do not magnify to tissues in higher trophic levels. In this regard, the TMFs increase with increasing level of chlorination, being the highest for Cl_{10} congeners. The authors hypothesise that the highly chlorinated congeners have a larger trophic magnification potential due to their higher log KOA in terrestrial species and low metabolic potential.

Biomagnification of CA:C14-17 is also demonstrated for fish (Huang et al., 2017). This study studied bioaccumulation and biomagnification CA:C14-17 in several fish species in Liaodong Bay, China. A number of uncertainties are related to this study to assess bioaccumulation potential, e.g. limited number of fish samples at the higher trophic level, absence of defined predator-prey relationships in the sampled biota, and the quality of the correlations for both substances. However, when using the study only to compare the relative magnification between congeners, the TMFs were relatively similar across the congener groups (see Table 90). However, the study provides low weight for the comparison because of the abovementioned uncertainties and the fact that none of the TMFs was statistically significant ($p < 0.05$) and all had very low r^2 values.

Du et al. (2020) has also observed an enrichment of longer chained and more highly chlorinated chloroalkanes from liver to muscle and adipose tissue. They investigated the occurrence and biomagnification of chloroalkanes in the semi-aquatic red-backed rat snake (*Elaphe rufodorsata*) and its prey the black-spotted frog (*Pelophylax nigromaculatus*), in paddy fields in the Yangtze River Delta, China. Short-, medium-, and long-chain chloroalkanes were analysed by APCI-QTOF-MS in liver, muscle and adipose tissues (abdominal fat) and the concentrations found in frog muscles and liver and red-backed rat snake muscles and liver were used for calculating BMF values for muscle and liver tissues. The study and the BMF values are presented in detail in the SVHC Support Document (Table 45 in ECHA (2021d)). Based on the BMF values reported therein, the increasing level of chlorination did not seem to limit the magnification from frog liver and muscle to snake liver and muscle tissues (up to $C_{14}Cl_{11}$-$C_{17}Cl_{10}$). The BMFs in muscle of snakes-frogs ranged from 1.36 ($C_{14}Cl_3$) to 2.33 ($C_{14}Cl_{11}$), from 1.89 ($C_{15}Cl_3$) to 2.86 ($C_{15}Cl_{11}$), from 1.81 ($C_{16}Cl_3$) to 1.83 ($C_{16}Cl_{11}$), and from 0.91 ($C_{17}Cl_4$) to 0.21 ($C_{17}Cl_{12}$). However the liver BMFs indicated a drop in the BMFs with increasing chlorination for some of the congeners (C14, C16 and C17 with 11 chlorine atoms)(see Table 90).

A study by Mézière et al. (2021) has shown that highly chlorinated congeners up to chlorination level Cl_{15} ($C_{14\text{-}15}$), Cl_{11} (C_{16}), Cl_{12} (C_{17}) accumulate in hen liver, serum, muscle and adipose tissue. 25-week old laying hens (Isa Brown) were fed with the corresponding feed (spiked or non-spiked) during 91 days. The target chloroalkane concentration of spiked feed was 200 ng/g for each of the five technical mixtures (Chlorowax™ 500C containing SCCPs low % Cl; Paroil™ 179–HV containing SCCPs high %Cl; Unichlor™ 40–90 containing LCCPs low %Cl; CPW–100 containing LCCPs high %Cl; MCCP technical standard). Liquid chromatography – high resolution mass spectrometry (HRMS) coupling fitted with an electrospray ionisation source was used to analyse the chloroalkane concentrations. Accumulation ratios (AR) of the homologues of chloroalkanes were calculated as the concentrations of the CP subcategories in the tissue (ng/g lw) divided by the spiked feed (ng/g ww). To calculate homologue-level accumulation ratios, the concentration of a homologue *n, x* can be expressed according to the exposure mixture concentration at which the same homologue *n, x* would have the same relative intensity (An,x/AIS) and the contribution of the homologue to this exposure mixture. As a result, the ARs for CA:C14-17 seem to be similar for the congeners with high level of chlorination (e.g. AR 0.33-0.46 for $C_{15}Cl_{10\text{-}15}$) when compared to those congeners with lower number of chlorine atoms (e.g. AR 0.19 for $C_{15}Cl_8$)(see Table 90). Interestingly, also the long-chain chlorinated paraffins seem to accumulate in liver – also with very high chlorination levels (up to Cl_{25}). This information confirms that also the congeners with high level of

chlorination permeated through membranes from the gastro-intestinal tract, were transferred into blood and reached the different tissues, in particular the liver. Considering that liver is one of the target organs for chloroalkanes (see below section *Type of toxic effects)*, accumulation to liver should not be disregarded.

Type of toxic effects

Aquatic invertebrates were shown to be the most sensitive to CA:C14-17 in comparison to fish and algae, and the T conclusion was based on chronic toxicity studies on *D. magna* (ECHA, 2021d). A 21-day NOEC for reproduction (number of live offspring/surviving parent) and length of parent organisms was identified at 8.7 µg/L and 21-day LC50 for parent mortality at 25 µg/L. In fish, no acute toxicity has been observed but mild to moderate hepatocyte necrosis and moderate to severe depletion of lycogen/lipids has been observed when exposed to $C_{14}Cl_{5.1}$ or $C_{14}Cl_{6.7}$ congeners (summarised by (Joint Research Centre, 2011a, EU Commission, 2005)). No lesions or abnormalities were seen in the thyroid after 21 days, although only the mid-dose group was investigated.

Effects in mammals have been previously reviewed in several documents (e.g. (CEPA, 2008, Joint Research Centre, 2011b, SCHER, 2008, Danish EPA, 2013)). The toxicity studies have been mostly performed on CA:C14-17 with the level of chlorination of 40 % or 52 %, so there is no information available how the degree of chlorination would affect the toxicological profile.

The liver (weight increase, enzyme induction, centrilobular hepatocyte hypertrophy, necrosis at higher dose levels), thyroid (follicular hypertrophy and hyperplasia, increased TSH levels, decreased T4 levels) and kidney (increased weight, chronic nephritis, tubular pigmentation) are target organs for repeated oral dose toxicity of CA:C14-17 in rodents (e.g.(SCHER, 2008)). Increased relative liver weight is observed at 500 ppm in females, relative kidney weight was increased at 5 000 ppm in both sexes and serum cholesterol was increased in the females in a dose-related manner starting at 50 ppm (Poon et al., 1995). At dose 222 mg/kg/day there were also slight decreases in plasma triglycerides and cholesterol levels (Joint Research Centre, 2011b). Detailed investigations on parameters related to CA:C14-17 induced liver, thyroid and kidney toxicity (hepatic T4-UDPGA glucuronyl transferase activity, hepatic peroxisome proliferation, free and total plasma T4, T3 and TSH levels, and renal and hepatic α2µglobulin levels) have been also performed.

The effects on thyroid have been considered to be attributable to stimulation of this organ arising from a negative feedback control (Joint Research Centre, 2011b). It was hypothesised that an increase in the liver enzyme UDPG-transferase is stimulated by treatment with CA:C14-17 resulting in increased glucuronidation and consequent excretion of T4, with a resultant reduction in plasma T4 levels. The pituitary responds to the decreased levels of T4 by releasing more TSH, which in turn leads to increased production of T4 by the thyroid. The continuous stimulation of the thyroid in response to the increased excretion of plasma T4 (seen in this 14-day study) is predicted to ultimately give rise to hypertrophy and hyperplasia in this organ. Thyroid effects were not considered to be of relevance to human health in (Joint Research Centre, 2011b) but some reviews also have considered that the relevance to humans cannot be excluded (Danish EPA, 2013). These findings also have not been discussed in relation to endocrine disruption in non-target

organisms. Recently also the potential of CA:C14-17 has been reported to perturb thyroxine (T4) binding to the transport protein transthyretin (TTR) when investigated using a non-standard in vitro assay (Sprengel et al., 2021).

Furthermore, severe effects (internal haemorrhaging and deaths) have been observed in newborn rats. The maternal NOAEL for this effect was 47 mg/kg/day. Several studies have investigated the mode of action for this effect and it seems to be due to a CA:C14-17 mediated deficiency of vitamin K in the dams´ milk and to effects of CA:C14-17 itself in the milk on the pups. Also in the dams, haemorrhages were found at parturition with a NOAEL of 100 mg/kg bw (SCHER, 2008). This effect has been considered to be repeated dose effect rather than a developmental effect (Joint Research Centre, 2011b, SCHER, 2008).

Substance EC 287-477-0 has harmonised classification as Effect on or via lactation (H362), in addition to the classification as Aquatic Acute and Chronic 1. Several CA:C14-17 substances have additionally the following self- or notified classifications (see Section 1.4 in the main report): Aquatic Acute and Chronic 1, Effect on or via lactation, STOT Single Exp. 3 (affected organs: central nervous system, Respiratory system), Skin Irrit. 2, Eye Irrit. 2, STOT Rep. Exp. 1 and 2 (affected organs: central nervous system, liver), Acute Tox. 4.

Conclusion for the grouping:

As described above, the mode of action of the congeners of CA:C14-17 is expected to be the same (ECHA, 2021d). Also the increasing level of chlorination does not seem to limit bioavailability of CA:C14-17 congeners, nor do the $C_{17}Cl_{3-5}$ congeners appear to have fast disappearance from organisms due to fast biotransformation. Therefore, these congeners also could reach the sites of toxic action (receptors, cell membranes, etc) and can induce effects if they build-up to a critical concentration. This forms the basis of a conclusion that congeners of CA:C14-17 which have not been demonstrated to exceed the T criterion can also be of concern.

There is no congener specific data to allow a comparison of toxicity or uptake potential in *D.magna* between the congeners which are agreed to meet the T criterion and those with no toxicity data. Castro et al. (2019) allowed a general conclusion on high bioconcentration of the technical mixtures and that the degree of chlorination would not limit bioaccumulation potential in *D.magna.* Data on other species (Table 90) support that bioavailability is not significantly prevented by increasing level of chlorination or that immediate excretion of $C_{17}Cl_{3-5}$ congener groups takes place due to rapid metabolism.

In addition, the mammalian toxicity studies have been mostly performed on CA:C14-17 with the level of chlorination of 40 % or 52 %. Effects on liver, kidneys and thyroid have been reported, and internal haemorrhaging and deaths of newborn pups (as described in the section *Type of toxic effects)*. The evidence on similar biomagnification potential across the congener groups (also higher chlorinated congeners) in snakes, birds, fish and other species (Table 90) implies that effects in liver, thyroid, kidneys can be expected if the exposure continues over longer time period.

Furthermore, confirmation of the bioavailability of a wide spectrum of congeners is also indicated by several monitoring studies (see section B.7.4.3). In particular the Cl_9 congeners was identified as one of the most abundant CA:C14-17 congeners in the

samples.

Table 90. Summary of the evidence supporting the grouping of CA:C14-17 congeners (using similar uptake and magnification potential) for the purpose of indicating a potential concern to induce effects in long-term exposures. The evidence collected indicates that bioavailability may not be limited by level of chlorination.

Evidence	Predicted logKow	BMFs (muscle of snakes-frogs)	BMFs (liver of snakes-frogs)	TMF (terrestrial food web)	BMF (rainbow trout)	BMF (sculpin-*Diporeia*)[2]	BMF (Lake trout-Alewife)	BAF *(L. variegatus)*	Accumulation ratio AR (hen liver)	TMF (invertebrates-fish)
Reference	(ECHA, 2021d)	Du et al. (2020), ECHA (2021d)	Du et al. (2020), ECHA (2021d)	(Liu et al., 2020c)[4]	(Fisk et al., 1996)	(Houde et al., 2008)	(Houde et al., 2008)	Fisk et al. (1998)	Mézière et al. (2021)	(Huang et al., 2017) [4]
C14 congeners										
$C_{14}Cl_7$ (PBT)	6.26-6.88	1.73	4.39	1.90		5.3	0.86		0.43	0.89
$C_{14}Cl_8$ (vPvB)	6.55-7.15	1.50	4.99	2.12		8.9	0.43		0.14	0.73
$C_{14}Cl_9$ (vPvB)	6.83-7.10	1.19	5.19	2.61		14	0.31		0.15	1.03
$C_{14}Cl_{10}$ (vPvB)	7.04-7.23	1.72	4.60	2.87		11	0.23		0.32	1.11
$C_{14}Cl_{11}$ (vPvB)	7.25-7.46	2.33	1.33						0.47	
$C_{14}Cl_{12}$[1]	7.57-7.78								0.37	
$C_{14}Cl_{13}$[1]	7.91-8.00								0.29	
$C_{14}Cl_{14}$	8.25								0.23	
C15 congeners										
$C_{15}Cl_8$ (PBT)	6.81-7.33	1.92	3.20	2.79					0.19	0.44
$C_{15}Cl_9$[1] (B)	7.19-7.97	1.99	2.20	3.06		43	0.03		0.32	0.33
$C_{15}Cl_{10}$[1]	7.19-7.47	2.78	1.70	3.62		25	0.02		0.46	0.23
$C_{15}Cl_{11}$[1]	7.49-7.65	2.86	3.50						0.46	
$C_{15}Cl_{12}$[1]	7.73-7.92								0.44	

Evidence	Predicted logKow	BMFs (muscle of snakes-frogs)	BMFs (liver of snakes-frogs)	TMF (terrestrial food web)	BMF (rainbow trout)	BMF (sculpin-*Diporeia*)[2]	BMF (Lake trout-Alewife)	BAF *(L. variegatus)*	Accumulation ratio AR (hen liver)	TMF (invertebrates-fish)
$C_{15}Cl_{13}$	8.07-8.16								0.44	
$C_{15}Cl_{14}$	8.40								0.44	
$C_{15}Cl_{15}$	8.76								0.33	
C16 congeners										
$C_{16}Cl_3$ (vPvB)	7.98-9.19	1.81	5.57		1.07			4.4		
$C_{16}Cl_8$ (PBT)	7.14-7.70	1.62	2.98	2.04					0.42	0.45
$C_{16}Cl_9$[1] (B)	7.27-7.65	1.54	1.83	2.86		35			0.46	0.25
$C_{16}Cl_{10}$[1]	7.46-7.74	2.41	1.58	3.13		8.8			0.75	0.42
$C_{16}Cl_{11}$[1]	7.63-7.99	1.83	<1[3]						0.77	
$C_{16}Cl_{12}$	7.98-8.16									
$C_{16}Cl_{13}$	8.26-8.42				0.72			0.6		
$C_{16}Cl_{14}$	8.57-8.66									
C17 congeners										
$C_{17}Cl_3$	8.51-8.94									
$C_{17}Cl_4$[1]	8.01-8.25	0.91	3.97							
$C_{17}Cl_5$[1] (B)	7.79-8.88	2.44	2.71	2.28					0.14	2.10
$C_{17}Cl_6$ (PBT)	7.50-8.44	1.65	3.02	2.29					0.22	0.78
$C_{17}Cl_9$ (PBT)	7.56-8.02	1.92	1.67	2.57					1.03	0.35
$C_{17}Cl_{10}$[1]	7.76-8.13	2.51	2.06	3.08					0.98	0.23
$C_{17}Cl_{11}$	7.88-8.14								1.00	
$C_{17}Cl_{12}$	8.14-8.52	0.21	<1[3]						1.05	

Note: [1] based on ECOSAR (v. 2.0) the predicted toxicity of C14Cl12-13, C15Cl9-12, C16Cl9-11, C17Cl4-5 and C17Cl10 would fall below the T criterion. Congeners C14Cl14, C15Cl13-15, C16Cl12-16, C17Cl3 and C17Cl11-17 are outside the applicability domain of the model.

[2] based on the detectable concentrations in one sample
[3] no concentration detected in the liver of snakes
[4] major uncertainties associated with the study to assess bioaccumulation potential (see in the text above).

B.7.4. Distribution in the environment and long-range transport potential

Environmental distribution and long-range transport potential of CA:C14-17 have been already assessed and described in the SVHC Support document (ECHA, 2021d), and the findings are summarised below. Following these general sections on distribution and long-range transport potential, a section on *Congener specific environmental monitoring data* presents congener specific environmental monitoring data which has not been presented in the SVHC support document.

B.7.4.1. Environmental distribution (a summary from SVHC Support document)

CA:C14-17 have a low solubility in water (maximum 0.027 mg/L) and high log Koc values (e.g. Koc 103,846 L/kg for the $C_{16}Cl_{3.3}$ and 175,333 L/kg for $C_{16}Cl_{13.4}$). The low solubility in water and the high log Koc values indicate that CA:C14-17 are likely to partition to suspended matter and sediment in aquatic environments. It is however also noted that CA:C14-17 congeners with low chlorine atom numbers (with < 4 chlorine atoms independently of the carbon chain lengths) will preferentially partition to the dissolved phase while the congeners with higher number of chlorine atoms will preferentially partition to the suspended particle phase in the water column.

In soil, almost all chloroalkanes (short-, medium- and long-chain) are expected to sorb completely to organic solids. Two transport processes affect the mobility of the CP constituents in soil: evaporation and particle erosion. CA:C14-17 with 3–5 chlorines have been predicted to be subject to both evaporation and erosion in soils. The congeners with more chlorines are more subject to erosion in soils. As the CP constituents are relatively hydrophobic, most are unlikely to be subject to leaching and reach groundwater.

Based upon their low vapour pressure values, CA:C14-17 have a low potential for volatilisation to the atmosphere. However, concentrations of CA:C14-17 found in air from remote regions indicate that atmospheric transport is occurring. Predicted vapour pressure using COSMOtherm indicate that vapour pressure is likely to decrease with increasing carbon chain length and chlorine content. This is seen also in their log Koa and log Kaw values. Predicted log Koa and log Kaw for CA:C14-17 are between 5.96 – 16.08 and -7.66 – 1.13, respectively. As the carbon chain length increased, the Koa values increased, i.e. the constituents are getting less volatile. However, the Kaw is relatively unchanged by an increasing carbon chain length, indicating that the water solubility and the vapour pressure of chloroalkanes changes to a similar extent. The Kaw decreases and Koa increases with increasing degree of halogenation. Constituents with more halogens favour the aqueous and organic phase relative to the gas phase. Relatively high Koa and low to moderate Kaw values for most chloroalkane constituents means that they can be expected to associate primarily with organic matter in soils and sediments.

Distribution modelling was conducted using Level III Fugacity Model (MCI method) and the STPWIN model of EPI Suite (v. 4.11) (US EPA, 2012), for the constituents $C_{14}Cl_6$ and $C_{16}Cl_7$ (one constituent per congener group). The model shows that CA:C14-17 will be distributed mainly to the soil and the sediment compartments once released to the

environment, and they will be mainly removed to sludge in a wastewater treatment plant given its high Koc and limited biodegradation potential.

Monitoring data for CA:C14-17 in surface water, sediment, soil, biota, sludge and air are presented in B.5.5. The available European monitoring data generally show widespread occurrence of CA:C14-17.

B.7.4.2. Long-range transport potential (a summary from SVHC Support document)

Based on their physical-chemical properties, some congeners of CA:C14-17 are predicted to have long-range transport potential (LRTP). Indeed, 'MCCP' have similar physical-chemical properties to legacy persistent organic pollutants (POPs).

Some congeners of CA:C14-17 can be enriched in mountains while others can accumulate in Polar Regions. The congeners of CA:C14-17 that become enriched in mountains tend to be less volatile than those that are preferentially accumulating in Polar Regions. The predicted atmospheric half-life will vary for the CA:C14-17 congeners according to degree of chlorination with the estimated half-lives increasing with increasing number of chlorine atoms in the structure. Atmospheric half-lives for vapour phase range between 0.6 to 7.1 days, thus indicating a potential for long-range transport for some congeners.

Predicted atmospheric half-lives of chloroalkanes increase with the degree of chlorination, whereas the chain length plays less of a role. The constituents with relatively low degree of chlorination have the lowest half-lives in air. The heavily halogenated chloroalkanes (CA:C14-17 with Cl~4–6+) are retained in soil or water compartments after particle deposition and would not effectively volatise and have repeated cycles of deposition and re-evaporation to higher latitudes. These constituents would need to undergo LRT without being deposited along the way in order to accumulate in remote locations like the Arctic. The congeners with longer carbon chain and higher degree of chlorination had higher affinity to atmospheric particulates. The mechanism of absorption into organic matter of the aerosol played a much important role on atmospheric partitioning and transferring of chloroalkanes in remote areas. Sorbed to aerosol they would be effectively scavenged from the atmosphere by dry and wet deposition. As such, their accumulation potential in the Arctic is quite low, approximately 0– 20 % of the maximum Arctic Contamination Potential (ACP) value.

The same authors predicted that CA:C14-17 with ~5–6 and ~6–7 chlorines, respectively, were identified to have the highest combined potential for LRT and bioaccumulation in humans (the so called Arctic contamination and bioaccumulation potential (AC-BAP)) and thus to have the potential to be persistent organic pollutants. Monitoring data tend to confirm this prediction as it has been found that $C_{14\text{-}15}$ with 4-9 chlorines were found in the Arctic (biota) and in the Antarctic (air).

CA:C14-17 have been detected in various media in the Arctic, including in air from Svalbard (concentrations in the range of <44-720 pg/m3), in marine sediments from the Barents Sea and the Norwegian Sea (concentrations in the range of n.d—2.8 mg/kg dw), in terrestrial, avian and marine biota samples from the Norwegian Arctic between 2001 and 2018, including in top predators such as Polar Bears. CA:C14-17 were also found in air samples from the Antarctic (concentrations in the range of <0.26-27.5 pg/m3) and in

the Tibetan Plateau (at Shergyla Mountain) at high altitude (1983 to 4553 m above sea level) with concentrations in the range of 50—690 pg/m3.

The presence of CA:C14-17 at sites remote from known point sources such as the Arctic and Antarctic therefore indicates long-range environmental transport. Furthermore, monitoring data indicate that the concentrations have increased during the last decades. The increase of concentrations was observed in blue mussels from the coast in Norway between 2017—2018 ((Green et al., 2019)) and in porpoise and dolphin samples from South China Sea between 2004—2014 (Zeng et al., 2015). A similar increase trend in concentrations of CA:C14-17 was observed in the Arctic air (from 2013 to 2019;(Bohlin-Nizzetto et al., 2020)) and in air samples from the Tibetan Plateau (from 2012 to 2015; (Wu et al., 2019)). The increase of concentrations was observed in blue mussels from the coast in Norway between 2017—2018 ((Green et al., 2019)) and in porpoise and dolphin samples from South China Sea between 2004—2014 (Zeng et al., 2015). A similar increase trend in concentrations of CA:C14-17 was observed in the Arctic air (from 2013 to 2019;(Bohlin-Nizzetto et al., 2020)) and in air samples from the Tibetan Plateau (from 2012 to 2015; (Wu et al., 2019)).

CA:C14-17 have also been included in recent measurement campaigns at the Arctic atmospheric monitoring stations of Alert, Zeppelin, Barrow, Storhoefði and Little Fox Lake, and show an increased from 23 to 750 pg/m3 from 2013 to 2020.

In addition, an increasing temporal trend was observed for chloroalkane (short and long chains) in the Antarctica according to Xie et al. (2022).

B.7.4.3. Congener specific environmental monitoring data

In this section the Dossier Submitter took a closer look at the congener patterns (in relation to level of chlorination) of the measured environmental concentrations of CA:C14-17. Due to limitations in accurate quantification of some analytical methods (see Section B.1.5), these congener specific data are presented generally as relative abundances of congeners with varying level of chlorination present in the samples. The Dossier Submitter therefore collected the presence (not the concentrations) of congeners in the publications where the relative abundances of these congeners have been determined (Sections B.5.5.1, B.5.5.2, B.5.5.3, B.5.5.4). The purpose is to provide indication about which congeners have been detected, because the relative abundances are dependent on the type of instrument applied and cannot be compared between studies which have applied different techniques (e.g. GC-ECNI-MS versus APCI-QToF-HRMS).

In majority of publications the analytical methods (e.g. GC/MS with electron capture negative ionisation, ECNI) allowed to separate congeners with chlorine atoms in the range 5–10 (e.g. (Li et al., 2018a, Qiao et al., 2016, Wang et al., 2019c, Wang et al., 2017b, Xu et al., 2016)). Therefore, the absence of other congeners (e.g. those with chlorine atoms below 5 and above 10) does not necessarily mean an absence of these congeners in the sample but rather that, if present below certain concentrations they may not be distinguished from the background noise with the analytical method used. Some of the recent publications however already have more sensitive analytical methods which allow a reliable identification of a wider spectrum of chlorination (e.g. APCI-qTOF-HRMS in Brandsma et al. (2017)and Yuan et al. (2019b); UPLC-APCI-Orbitrap-MS in Yuan et al.

(2022) and de Wit et al. (2020)).

The studies indicate that the congener patterns mostly reflect those of the commercial products. In general, the congeners with Cl_{7-8} are the most abundant in the environmental samples but also $C_{14-17}Cl_9$ have been shown to be almost equally abundant congener (e.g. (Yuan et al., 2022)). In some studies, the congeners with 9 and 10 chlorine atoms have been even the most abundant C14-17 congeners in fish tissues (e.g. Combeaute River (Labadie et al., 2019)). Several studies indicate a wide spectrum of congeners in environmental samples from chlorination level 3, up to 17 (e.g. (Yuan et al., 2022), see Sections B.5.5.1, B.5.5.2, B.5.5.3, B.5.5.4).

The CA:C14-17 congeners with chlorination levels of 5-10 have been also detected in remote regions: in soil, lichen and moss (Tibetan Plateau), as well as in air samples (King George Island, Antarctica). While the analytical methods used in these studies did not allow to confirm the presence of the most wider range of congeners, the results already can be used to indicate that the congeners up to (at least) chlorination level of 10 can be also subjects to long-distance transport.

B.7.5. Conclusions

The information available during the SVHC identification of 'MCCP' did not allow the MSC to conclude on the PBT and/or vPvB properties of $C_{14}Cl_{12-14}$, $C_{15}Cl_{9-15}$, $C_{16}Cl_{9-16}$, $C_{17}Cl_{3-5}$ and $C_{17}Cl_{10-17}$.

Nevertheless, the high persistency of these congeners can pose a risk because continued emissions could result in increasing exposures and, therefore, a high likelihood that effect thresholds (known or unknown) would be exceeded over time. Quantification of the exposure levels of these CA:C14-17 congeners is not straightforward, nor is the determination of the effect thresholds.

As explained in Section B.1.5, it is recognised that for all chloroalkanes the complexity of congeners in their composition may have created additional challenges in analytical measurements in the past, due to the presence of other chlorinated contaminants (such as pesticides). Furthermore, low-resolution methods, which are commonly available in laboratories, do not provide a sharp distinction of the congener groups and cannot be used to provide a quantification for individual carbon-chlorine congener groups. Therefore, the analytical methods used in several studies have not so far allowed to assess accurately the concentrations of different CA:C14-17 congeners with varying level of chlorination in the environment. There are some recent studies which have used more advanced analytical methods and the congener groups have been measured in water, air, sediment, soil and biota (Sections B.7.4 and B.5.5). These studies indicate a wide spectrum of congeners in environmental samples from chlorination level 3, up to 17.

Determination of the effect thresholds for different CA:C14-17 congeners faces also challenges. Toxicity of the CA:C14-17 has been investigated using technical mixtures available (mostly 52 % Cl wt). Such data does not allow assessment of toxicity of congeners directly and the observed toxicity may represent toxicity of one or more of its constituents, and the quantification of congeners present in the test solution is often lacking (see B.7.3.1). These factors present uncertainties in the assessment of toxicity within and beyond these technical mixtures and in particular when assessing toxicity of

specific congener groups.

As an indirect measure, the Dossier Submitter assessed the toxicity of $C_{14}Cl_{12\text{-}14}$, $C_{15}Cl_{9\text{-}15}$, $C_{16}Cl_{9\text{-}16}$, $C_{17}Cl_{3\text{-}5}$ and $C_{17}Cl_{10\text{-}17}$ using QSAR and grouping. The purpose was to find out whether there is a reason to assume that the CA:C14-17 congeners, beyond those present in the studied technical mixtures, would not carry a similar concern and hazard profile than those congeners which are present in C14-17 52 % Cl wt technical mixture. Firstly, all the CA:C14-17 congeners are expected to induce toxicity with the same mode of action because they are all structurally very similar and none has additional functional groups attached to the chlorinated alkane structure (see B.7.3.1). Secondly, accumulation and magnification of various CA:C14-17 congeners in different trophic levels (see B.7.3.2.2) implies that there is no clear cut off in bioavailability for the congeners. Therefore CA:C14-17 congeners regardless of their chlorine content, have the potential to induce toxic effects. This was supported by the QSAR analysis performed with ECOSAR v. 2.0 (Section B.7.3.2.1).

Considering that CA:C14-17 with 3 or more chlorine atoms are very persistent, their environmental concentrations will increase over time as a result from ongoing releases. Increasing concentrations has been confirmed by the monitoring data (see Section B.7.4.2). Because they are also bioavailable to organisms, they can build-up to critical concentrations over time and induce toxic effects in daphnia and in higher trophic levels. Immobilisation/mortality and reduced reproductive output observed in *Daphnia magna* lead to reduced population size. Considering that aquatic invertebrates are an important part of aquatic food chains, reduced population size of *D. magna* (or other aquatic invertebrates) may reduce food availability at higher levels of the food chain. Thus, populations at higher trophic levels can be affected, with potential community- and ecosystem level effects. In addition, as CA:C14-17 are persistent and magnify in food chains (as indicated in Sections B.7.1 and Table 90), the concern in higher trophic levels also arises directly from the exposure to the chemicals via food. The effects in higher trophic levels may be observed in liver, thyroid, kidney, internal haemorrhaging and deaths of new-born animals (as indicated by the data on rodents and fish).

CA:C14-17 congener groups with PBT and/or vPvB properties should be treated as non-threshold substances for the purpose of risk assessment. Considering the likelihood that the other persistent congeners ($C_{14}Cl_{12\text{-}14}$, $C_{15}Cl_{9\text{-}15}$, $C_{16}Cl_{9\text{-}16}$, $C_{17}Cl_{3\text{-}5}$ and $C_{17}Cl_{10\text{-}17}$) likely carry similar hazards, a case-by-case approach according to REACH Annex I, paragraph 0.10, applies for these additional CA:C14-17 congeners. The procedures set out in Sections 1 to 6 of Annex I are impracticable because data cannot be generated individually to thousands of congeners to establish that they are bioaccumulative and toxic. It should be also noted that so far the presence of these additional congeners in the environment is not addressed in all the monitoring programmes (most of the monitoring data are referring to ΣMCCP or ΣCA:C14-17) and therefore current monitoring results are expected to provide only a partial picture and possibly an underestimation of the overall exposures to these congeners.

A case-by-case approach for hazard and risk assessment has been applied in earlier restrictions ((ECHA, 2020, ECHA, 2022, ECHA, 2021c)). Also in the present case the persistency, ongoing releases, likelihood for long-range transport and toxicity, the non-threshold nature of the hazard and a possible regrettable substitution to these other persistent CA:C14-17 congener groups ($C_{14}Cl_{12\text{-}14}$, $C_{15}Cl_{9\text{-}15}$, $C_{16}Cl_{9\text{-}16}$, $C_{17}Cl_{3\text{-}5}$ and $C_{17}Cl_{10\text{-}}$

$_{17}$) would warrant a need for minimisation of the releases of all CA:C14-17 congener groups by the proposed restriction to ensure sufficient reduction of the risk arising from the use of CA:C14-17.

Appendix C: Justification for action on a Union-wide basis

Please refer to the main report.

Appendix D: Baseline

D.1. POP listing process and planning overview

Generic description of the POP listing process:

The Figure 8 below gives an overview of the POP listing process.

Figure 8: Process overview of the POP
Source: ECHA website- https://echa.europa.eu/proposals-for-new-pops

Any party to the Stockholm Convention can submit a proposal to add a new persistent organic pollutant to the annexes of the Convention (STEP 1).

The POP Review Committee (POPRC), an expert body under the Stockholm Convention, evaluates the submitted proposals against the criteria set in the Annex D to the Convention. If it concludes that screening criteria are met, it launches a global collection of information on further hazards, risks, uses and exposures (STEP 2). The POPRC uses this information to compile a risk profile as defined in Annex E to the Convention.

Based on the risk profile, the POPRC decides whether global action is warranted on the substance (STEP 4). If it decides to proceed with the proposal, the POPRC launches a global call for information related to potential risk management solutions, alternatives,

socio-economic considerations and existing risk management measures (STEP 5). This information is used by the POPRC to prepare the risk management evaluation as defined in Annex F to the Convention (STEP 6).

In the final step, the POPRC assesses the information and makes a recommendation to the Conference of the Parties (COP) on listing the substance under the Convention (STEP 7).

Any proposed amendments to the Convention must be adopted by consensus of all parties during the COP meeting. As a last resort, if no agreement is reached, a three-quarter's majority can adopt the amendments (STEP 8).

There are different options to regulate substances under POP:

- Annex A: Total elimination (no exemption at all),
- Annex B: Restriction (with potential exemptions), and
- Annex C: Unintentional production (measure to reduce or eliminate releases from unintentional production).

The provisions of the Stockholm Convention and the Aarhus Protocol are implemented in the European Union by the POPs Regulation (EC 2019/1021). Once the COP adopts a decision to amend the Annex(es) to the Stockholm Convention to list a new substance, the decision needs to be transposed in Union law by amending Annex I, II and/or III of the POPs Regulation. These amendments are done by delegated acts.

<u>UK proposal on chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥45 %:</u>

On 27 April 2021, the United Kingdom submitted a proposal (UK, 2021) for listing 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥45 % ' in the Annexes to the Stockholm Convention on Persistent Organic Pollutants (UNEP, 2021). The proposal was accepted for further processing under the Convention. Overall the assessment, discussions and listing adoption are likely to take four to five years.

Figure 9 presents the provisional planning for the listing of 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥45 % ' in the Annexes to the Stockholm Convention on Persistent Organic Pollutants. The provisional timing is assuming an adoption of the Risk Profile (RP) on 30 September 2022, the availability of the first draft Risk Management Evaluation (RME) by the beginning of 2023, and the RME adoption in September 2023. After RME adoption, the listing of the substances to Annex A, B and/or C to the Stockholm convention could be decided during the COP 2025 meeting[36].

In case the RP would not be adopted in September 2022, its adoption will be scheduled for September 2023. Then the first draft RME would be made available beginning of 2024 for adoption in September 2024. After RME adoption, the listing of the substances to Annex

[36] COP meeting are organised every two years. Next COP meetings are scheduled for May 2023, and 2025.

A, B and/or C to the Stockholm convention could still be decided during the COP 2025 meeting.

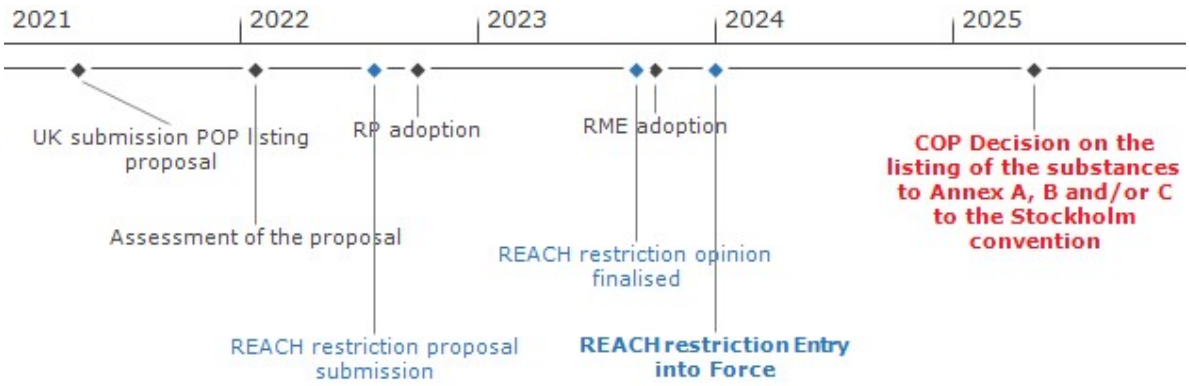


Figure 9: Provisional timing overview of the POP listing proposal ('chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥45 %)

Appendix E: Impact Assessment

E.1. Risk Management Options

E.1.1. Discarded options for substance identification

The restriction entries in Annex XVII to REACH are composed of two pieces of information. The conditions of the restriction are set in the right-hand side column of the restriction table entries, and the restricted substance is designated in the first column on the left as shown on Figure 10.

Figure 10: Example of an Annex XVII restriction entry

Column 1 Designation of the substance, of the group of substances to be restricted	Column 2 Conditions of restriction (EXAMPLE)
	1. Shall not (….) 2. Articles containing the substance(s) shall not …. 3. Etc.

When looking at the way to designate the restriction entry (column 1 on the left), and due to the UVCB nature of the substances to be restricted, the Dossier Submitter investigated various options:

(1) 'Use specific numerical identifiers (EC/CAS number)' – this is the most common practice for Annex XVII entries, or

(2) 'Use a description of the substances covered by the entry' – this is a recent practice relevant for grouping substances with the same intrinsic properties (e.g. microplastics, and PFAS arrowheads/related substances such as PFOA, PFHxS and C9-C14 PFCAs). Definitions have shown to be particularly efficient and effective where an exhaustive list of numerical identifiers cannot be established.

Each option to define the restricted substances was assessed against the following subset of REACH restriction criteria:

- Effectiveness (i.e. targeted to the risk, risk reduction)
- Practicality (i.e. implementable for industry and the supply chain)
- Enforceability

The options were discussed with Substance Identity Experts in ECHA and with Member State laboratories having robust experience on chloroalkanes identification in mixtures and articles (e.g. NILU in Norway).

The substance identity proposal of the Dossier Submitter is described in the main report. For the sake of transparency, this appendix is briefly presenting the discarded options for

the identification of the substances to be restricted.

E.1.1.1. Definition based on carbon chain length and a chlorination level (DISCARDED option)

Description

The substances to be restricted could be defined using a definition akin to the one proposed by the UK in the POP identification process.

While the UK are proposing to restrict under the Stockholm Convention 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥ 45 %', this definition could in theory be adapted to set a chlorination level cut-off in line with the SVHC identification agreement (cf. section B.4 and B.1.3), i.e.:

'Chloroalkanes with carbon chain lengths within the range from C14 to C17 and chlorine content ≥ X %' where X represents the average level of chlorination.

Effectiveness (i.e. targeted to the risk, risk reduction)

In its agreement on the SVHC identification of 'MCCP' (ECHA, 2021a) which is reproduced in section B.4, the MSC provided for each congener group with PBT and/or vPvB properties an indication of the theoretical chlorination level per CA:C14-17.

The proposed definition could therefore appear to be targeted to the identified risk, i.e. the presence of congeners with PBT and/or vPvB properties.

It should nevertheless be noted that among the suppliers of chloroalkanes, and within the supply chain, the chlorine content refers to the average degree of chlorination for the substance itself, and not to the degree of chlorination of the congener groups. A wider range of congener groups than those with a degree of chlorination above the average value X are therefore expected to be present and would in principle need to be taken into account when determining whether a product would fall within the scope of the restriction. By way of example, a chloroalkane consisting of C14 chlorinated alkanes with a degree of chlorination of 45 % by weight could contain $C_{14}H_{26}Cl_4$ (chlorine content: 42.3 % by weight) and $C_{14}H_{25}Cl_5$ (chlorine content: 47.9 % by weight) (example from ECHA (2021d)).

As the commercially available chloroalkanes generally include more than one carbon chain length and more than one congener group, a definition based on carbon chain length and a chlorination level should be specific to the congener groups and not to an entire substance in order to be effective and to target the risk of the PBT and/or vPvB constituents in substances, mixtures and articles.

Practicality (i.e. implementable for industry and the supply chain)

The chlorination level is a parameter which is controlled during the manufacturing process of chloroalkanes. As explained above the degree of chlorination is currently understood and applied by the supply chain as the 'chlorination level of the substance itself'. In some commercially available products such as CP52 (which contains a wide range of congeners

ranging from C10 to C20 carbon chain length), the chlorine content is also used without referring to the chain length.

This option may therefore create confusion if the definition is not clearly understood and applied to congener groups by all actors in the supply chain.

If the above elements are taken into consideration, then REACH registrants and manufacturer/importers of chloroalkanes (whatever the tonnage) could identify the substances that would fall in the scope of the restriction proposal using chlorination level.

If manufacturer/importers of chloroalkanes only indicate the chlorination degree of the substance, for downstream users analysing independently the average degree of chlorination of the chloroalkane precursor that contributes to the composition of their product is cumbersome and would potentially require the quantification of all the chloroalkanes congener groups. Furthermore, it is possible that, throughout the processing of the chloroalkane along the supply chain, the average value derived by a downstream user further down the supply chain will not match the value of the precursor.

Enforceability

Enforcement is feasible using the laboratory testing techniques described in section B.1.5. Depending on the nature of the product that is under scrutiny, the laboratory techniques may require the quantification of every CA:C14-17 congener group so that the average chlorination level can be derived. It is plausible that such analysis will lead to situations where the analysis will unveil the presence of congener groups with PBT and/or vPvB properties at ≥ 0.1 % whereas the average degree of chlorination of the chloroalkane remains below the threshold X.

Paper-based inspection could be possible as well but would require the thorough documentation of the chloroalkane average degree of chlorination across the entire supply chain.

Overall conclusion

Designating the substances to be restricted using chlorination level could only be at least as effective, practicable and enforceable as the proposed designation in the main report **IF** the communication of the chloroalkane average degree of chlorination along the supply chain would be thoroughly documented by each actor in the supply chain. Still the misalignment between congener groups having PBT and/or vPvB properties and average degree of chlorination making a chloroalkane having PBT / vPvB properties may raise concerns regarding the effectiveness of this approach, unless the chlorination level is applied on the congener groups.

E.1.2. Different options for the maximum concentration limit in mixtures and articles

Considering that the presence of CA:C14-17 in a mixture or an article may be due to the presence of a chloroalkane containing CA:C14-17 in this mixture or article, Table 91 below gives an overview of the maximum concentration of CA:C14-17 in a mixture or article,

depending on the dilution/concentration of chloroalkane (containing CA:C14-17) in this mixture or article. Each line in the table corresponds to a different theoretical dilution/concentration of chloroalkane between 1 and 100 %. Each column considers a potential concentration limit of CA:C14-17 of concerns that could be applied in the restriction proposal: 0.1 %, 0.01 %, 0.005 % and 0.001 %.

Based on these potential restriction limits, a theoretical max. concentration of CA:C14-17 is calculated in scenarios in which chloroalkanes (containing CA:C14-17) would be mixed with other substances to produce a mixture or an article.

Table 91 is particularly relevant to understand the consequences of the proposed concentration limit in mixtures and articles on imported mixtures and articles. Indeed, while all mixtures and articles produced in Europe would use chloroalkanes containing CA:C14-17 in concentration below 0.1 %, mixtures and articles produced outside Europe could be produced with chloroalkanes containing CA:C14-17 in concentration above 0.1 % and still fulfil the overall 0.1 % limit for mixtures and articles.

For example, according to Table 91, if the maximum concentration of CA:C14-17 with PBT and/or vPvB properties in mixtures or articles is set to 0.1 % (baseline scenario), this means that imported mixtures and articles may still have been produced outside the EU with chloroalkanes containing CA:C14-17 in concentration between 0.1 and 10 % (depending on the dilution level of the chloroalkanes in the mixture or in the article).

Similarly, if the maximum concentration of CA:C14-17 with PBT and/or vPvB properties in mixtures or articles is set to 0.01 % (scenario 1), imported mixtures and articles may still have been produced outside the EU with chloroalkanes containing CA:C14-17 in concentration between 0.01 and 1 %.

Various theoretical dilutions/concentrations of chloroalkanes between 1 and 100 % are presented in Table 91. According to the reported dilution ranges for all uses (cf. use description in the main report), dilutions between 3 and 70 % appear to be most realistic. This means that, in order to apply the same stringent conditions to both imported and EU-produced mixtures and articles, a concentration of CA:C14-17 in mixtures and articles could in theory be set to either 0.01 % or 0.005 % irrespective of the chloroalkane dilution/concentration in the mixture or article.

Table 91: Theoretical max. concentration of CA:C14-17 in chloroalkanes used to produce mixtures or articles outside Europe – impact of the restriction concentration limit

	If the maximum concentration of CA:C14-17 of concern in mixtures or articles is set to:			
Dilution/concentration of chloroalkane in the mixture or article	0.1 % (proposed restriction)	0.01 % (scenario 1)	0.005 % (scenario 2)	0.001 % (scenario 3)
	The chloroalkane used to produce the mixture or article can contain the following maximum concentration of CA:C14-17 of concern:			
1 %	10.00 %	1.00 %	0.50 %	0.10 %
2 %	5.00 %	0.50 %	0.25 %	0.05 %
3 %	3.33 %	0.33 %	0.17 %	0.03 %
4 %	2.50 %	0.25 %	0.13 %	0.03 %
5 %	2.00 %	0.20 %	0.10 %	0.02 %
6 %	1.67 %	0.17 %	0.08 %	0.02 %
7 %	1.43 %	0.14 %	0.07 %	0.01 %

Dilution/concentration of chloroalkane in the mixture or article	**If the maximum concentration of CA:C14-17 of concern in mixtures or articles is set to:** 0.1 % (proposed restriction)	0.01 % (scenario 1)	0.005 % (scenario 2)	0.001 % (scenario 3)
	The chloroalkane used to produce the mixture or article can contain the following maximum concentration of CA:C14-17 of concern:			
8 %	1.25 %	0.13 %	0.06 %	0.01 %
9 %	1.11 %	0.11 %	0.06 %	0.01 %
10 %	1.00 %	0.10 %	0.05 %	0.01 %
11 %	0.91 %	0.09 %	0.05 %	0.01 %
12 %	0.83 %	0.08 %	0.04 %	0.01 %
13 %	0.77 %	0.08 %	0.04 %	0.01 %
14 %	0.71 %	0.07 %	0.04 %	0.01 %
15 %	0.67 %	0.07 %	0.03 %	0.01 %
16 %	0.63 %	0.06 %	0.03 %	0.01 %
17 %	0.59 %	0.06 %	0.03 %	0.01 %
18 %	0.56 %	0.06 %	0.03 %	0.01 %
19 %	0.53 %	0.05 %	0.03 %	0.01 %
20 %	0.50 %	0.05 %	0.03 %	0.01 %
21 %	0.48 %	0.05 %	0.02 %	0.00 %
22 %	0.45 %	0.05 %	0.02 %	0.00 %
23 %	0.43 %	0.04 %	0.02 %	0.00 %
24 %	0.42 %	0.04 %	0.02 %	0.00 %
25 %	0.40 %	0.04 %	0.02 %	0.00 %
26 %	0.38 %	0.04 %	0.02 %	0.00 %
27 %	0.37 %	0.04 %	0.02 %	0.00 %
28 %	0.36 %	0.04 %	0.02 %	0.00 %
29 %	0.34 %	0.03 %	0.02 %	0.00 %
30 %	0.33 %	0.03 %	0.02 %	0.00 %
31 %	0.32 %	0.03 %	0.02 %	0.00 %
32 %	0.31 %	0.03 %	0.02 %	0.00 %
33 %	0.30 %	0.03 %	0.02 %	0.00 %
34 %	0.29 %	0.03 %	0.01 %	0.00 %
35 %	0.29 %	0.03 %	0.01 %	0.00 %
36 %	0.28 %	0.03 %	0.01 %	0.00 %
37 %	0.27 %	0.03 %	0.01 %	0.00 %
38 %	0.26 %	0.03 %	0.01 %	0.00 %
39 %	0.26 %	0.03 %	0.01 %	0.00 %
40 %	0.25 %	0.03 %	0.01 %	0.00 %
41 %	0.24 %	0.02 %	0.01 %	0.00 %
42 %	0.24 %	0.02 %	0.01 %	0.00 %
43 %	0.23 %	0.02 %	0.01 %	0.00 %
44 %	0.23 %	0.02 %	0.01 %	0.00 %
45 %	0.22 %	0.02 %	0.01 %	0.00 %
46 %	0.22 %	0.02 %	0.01 %	0.00 %
47 %	0.21 %	0.02 %	0.01 %	0.00 %
48 %	0.21 %	0.02 %	0.01 %	0.00 %
49 %	0.20 %	0.02 %	0.01 %	0.00 %
50 %	0.20 %	0.02 %	0.01 %	0.00 %
51 %	0.20 %	0.02 %	0.01 %	0.00 %
52 %	0.19 %	0.02 %	0.01 %	0.00 %
53 %	0.19 %	0.02 %	0.01 %	0.00 %
54 %	0.19 %	0.02 %	0.01 %	0.00 %
55 %	0.18 %	0.02 %	0.01 %	0.00 %
56 %	0.18 %	0.02 %	0.01 %	0.00 %
57 %	0.18 %	0.02 %	0.01 %	0.00 %
58 %	0.17 %	0.02 %	0.01 %	0.00 %
59 %	0.17 %	0.02 %	0.01 %	0.00 %
60 %	0.17 %	0.02 %	0.01 %	0.00 %
61 %	0.16 %	0.02 %	0.01 %	0.00 %
62 %	0.16 %	0.02 %	0.01 %	0.00 %
63 %	0.16 %	0.02 %	0.01 %	0.00 %
64 %	0.16 %	0.02 %	0.01 %	0.00 %
65 %	0.15 %	0.02 %	0.01 %	0.00 %

Dilution/concentration of chloroalkane in the mixture or article	**If the maximum concentration of CA:C14-17 of concern in mixtures or articles is set to:** 0.1 % (proposed restriction)	0.01 % (scenario 1)	0.005 % (scenario 2)	0.001 % (scenario 3)
	The chloroalkane used to produce the mixture or article can contain the following maximum concentration of CA:C14-17 of concern:			
66 %	0.15 %	0.02 %	0.01 %	0.00 %
67 %	0.15 %	0.01 %	0.01 %	0.00 %
68 %	0.15 %	0.01 %	0.01 %	0.00 %
69 %	0.14 %	0.01 %	0.01 %	0.00 %
70 %	0.14 %	0.01 %	0.01 %	0.00 %
71 %	0.14 %	0.01 %	0.01 %	0.00 %
72 %	0.14 %	0.01 %	0.01 %	0.00 %
73 %	0.14 %	0.01 %	0.01 %	0.00 %
74 %	0.14 %	0.01 %	0.01 %	0.00 %
75 %	0.13 %	0.01 %	0.01 %	0.00 %
76 %	0.13 %	0.01 %	0.01 %	0.00 %
77 %	0.13 %	0.01 %	0.01 %	0.00 %
78 %	0.13 %	0.01 %	0.01 %	0.00 %
79 %	0.13 %	0.01 %	0.01 %	0.00 %
80 %	0.13 %	0.01 %	0.01 %	0.00 %
81 %	0.12 %	0.01 %	0.01 %	0.00 %
82 %	0.12 %	0.01 %	0.01 %	0.00 %
83 %	0.12 %	0.01 %	0.01 %	0.00 %
84 %	0.12 %	0.01 %	0.01 %	0.00 %
85 %	0.12 %	0.01 %	0.01 %	0.00 %
86 %	0.12 %	0.01 %	0.01 %	0.00 %
87 %	0.11 %	0.01 %	0.01 %	0.00 %
88 %	0.11 %	0.01 %	0.01 %	0.00 %
89 %	0.11 %	0.01 %	0.01 %	0.00 %
90 %	0.11 %	0.01 %	0.01 %	0.00 %
91 %	0.11 %	0.01 %	0.01 %	0.00 %
92 %	0.11 %	0.01 %	0.01 %	0.00 %
93 %	0.11 %	0.01 %	0.01 %	0.00 %
94 %	0.11 %	0.01 %	0.01 %	0.00 %
95 %	0.11 %	0.01 %	0.01 %	0.00 %
96 %	0.10 %	0.01 %	0.01 %	0.00 %
97 %	0.10 %	0.01 %	0.01 %	0.00 %
98 %	0.10 %	0.01 %	0.01 %	0.00 %
99 %	0.10 %	0.01 %	0.01 %	0.00 %
100 %	0.10 %	0.01 %	0.01 %	0.001 %

E.1.3. Discarded restriction options

E.1.3.1. RO2 - Ban on placing on the market and use

Description of the RO

Under RO2, the placing on the market of substances, mixtures, or articles containing CA:C14-17 with PBT and/or vPvB properties above a concentration limit of 0.1 % (cf. section 2.2.4) would be banned after a transition period. A ban on placing on the market means that industrial and professional users as well as consumers will not be able to purchase on the EU market (including via Internet) substances, mixtures, or articles containing CA:C14-17 with PBT and/or vPvB properties.

RO2 includes also a ban on the use itself. This means that all industrial, professional or consumer uses of substances, mixtures or articles containing CA:C14-17 with PBT and/or

vPvB properties would also be banned after the transition period has expired.

Given the broad definition of 'use' under REACH, which includes storage, keeping, filling of containers and transfer from one container to another and other utilisations according to REACH Article 3(24), RO2 would in practice include a de facto ban on manufacturing.

Hence RO2 could be understood as a total ban.

Practicality (i.e. implementable for industry and the supply chain)

A ban on manufacturing or placing on the market would be as practicable as the other ROs (cf. main report). However, this option could be extremely costly for society and therefore non-proportionate to implement in practice.

Indeed, under RO2, uses at industrial and professional downstream users sites, but also uses by consumers would not be allowed anymore; the implementation of RO2 would therefore imply either (i) a recall from the market of all substances, mixtures and articles that have not been consumed or reached their end of life (for articles), and/or (ii) an early disposal of articles containing CA:C14-17 with PBT and/or vPvB properties.

Given the long lifespan of some articles and materials containing CA:C14-17, for example:

- Use#02: Average service life of rubber conveyor belts used for underground mining is about 12.5 years, while some manufacturers indicate even a 30 year service life (EU Commission, 2021a).
- Use#01: Buildings have a much longer lifetimes of 50±25 years, and some of the hazardous chemicals included in this study will be present in building and construction waste for many decades (Potrykus, 2015).
- Use#00: In the EEE sector it is more difficult to determine the average lifetime, as there are many different product categories to consider. Large electronic appliances such as washing machines, dishwashers, stove tops, fridges and freezers have an average lifespan of 14 years. Smaller appliances such as TV's, radios, microwaves, printers and electric tools have an average lifespan of 5-10 years; and appliances such as mobile phone, laptops, tablets and computers have an even shorter average lifespan of approximately 4.5 years (Prakash, 2020).
- Use#00: Petrol cars in Europe (which may use electrical cables containing CA:C14-17) have an average age of approximately 18 years before they are sent to an ELV treatment facility (ACEA, 2020).

a recall or an early disposal of articles or mixtures containing CA:C14-17 would be expensive for society and not implementable in practice. Such costs would be borne by industry (recall + early disposal) and consumers (early disposal). In practice, for many product categories (e.g. OCF or PVC cables used in buildings), an early disposal would be impossible because it would require the dismantling of the whole constructions.

Given the range of applications, no estimate of the societal costs that would be incurred under RO2 was made but they can be assumed to be very high considering the type of articles impacted and their average lifespans.

Enforceability

The ban on manufacturing or placing on the market is as enforceable as the other ROs (cf. main report).

The enforcement of the ban on use would have to be carried out on site, including at consumers' places. Consumers – for examples those that have already bought OCF sealants before the expiration of the transition period – would also see their private property rights directly affected by this condition. Moreover, REACH inspectors (and other enforcement authorities) are not in the position to ensure the respect of this restriction provision, which makes RO2 essentially unenforceable.

Effectiveness and risk reduction capacity

If the transition period proposed under RO2 is long enough to accommodate and take into consideration the long lifespan of some articles and materials containing CA:C14-17 (cf. list above) this would reduce in turn the effectiveness of RO2. Indeed, during the TP, releases to the environment would continue, which makes RO2 less effective than the other ROs.

If on the other hand a short transition was set, the costs to society would make this RO disproportionate.

Overall conclusion

A ban on use, and in particular a ban on using mixtures and articles containing CA:C14-17 with PBT and/or vPvB properties in RO2 is:

- Less effective to address the risks than the proposed ROs
- Not practicable for the actors in the supply chain
- Not enforceable

E.1.3.2. RO4c - RO4a conditional to the implementation of specific risk management measures

The Dossier Submitter investigated with the help of an external consultant industry's most likely response to, and socio-economic impacts of, Restriction Options (ROs) specific to metalworking fluids (MWF):

- Ban on placing on the market (and use) of CA:C14-17-based MWFs, with and without a transition period
- Ban on placing on the market (and use) of CA:C14-17-based MWFs unless 'justified derogations for specific applications and/or accompanied with RMM' (RO4c)

The consultancy work was conducted between December 2021 and April 2022 and allowed members of the metalworking industry to participate in a dedicated survey and in follow-up interviews (Appendix G). 76 stakeholders from the EU, US, UK, Japan were contacted including additive suppliers (3), formulators of MWFs (31), and Downstream users (42). The dedicated survey was complementing the responses received during the CfEs.

As part of the survey that was distributed to actors during the stakeholder consultation, companies were asked about the existing RMMs that they had in place to reduce release

and exposure of/to CA:C14-17 during metalworking activities. This includes RMMs commonly in place during metalworking, cleaning of machine and 'processed' metal containing residues of CA:C14-17-based fluids, and disposal of used CA:C14-17-based metalworking fluids. Furthermore, to better understand the socio-economic impacts of RO4c, companies were asked what additional RMMs (if any) they could implement to reduce release and exposure of/to CA:C14-17 to levels low enough to justify a derogation.

Existing RMMs

There was very little detailed information on operating conditions provided in the survey conducted by the consultants, with several DUs simply stating that they complied with the conditions stipulated in the Safety Data Sheets (SDSs) for the MWFs that they used. Waste oils and cleaning residues are reported to be treated as hazardous waste and disposed off-site according to national regulations, often but not always going for incineration. This level of details was already provided during the CfE (e.g. CfE1#1337, CfE2#1467, #1476, #1478, #1480).

One DU indicated that sites using MWF containing CA:C14-17 are individually responsible for risk management measures and disposal, guided by information on the safety data sheets (SDSs) for MWFs. This DU provided an SDS for one of their MWFs containing CA:C14-17; this focusses on occupational exposure and contained generic guidance on exposure controls and personal protection in terms of reducing worker exposure, with reference to appropriate OELs and DNELs. No specific guidance is provided in the SDS on the type of RMMs that should be employed, and it is simply stated that good general ventilation should be sufficient to control worker exposure to airborne contaminants. It is recommended that (unspecified) engineering controls be implemented as the first line of protection, with administrative controls and PPE being used in the absence of engineering controls, or as supplemental controls where engineering controls are insufficient. In terms of RMMs to minimise environmental exposure it is stated that emissions from ventilation equipment should be checked against local environmental regulations, with the recommendation that engineering modification or enhanced emission treatment may be necessary to reduce emissions to acceptable levels.

Potential additional RMMs

Very little information was gathered from stakeholders on potential additional RMMs that could be implemented by companies to demonstrate reduced exposure or releases. The majority of responses to questions on this topic were answered stating that current guidelines (set by the SDS) were being followed.

Key findings from the survey

Most stakeholders from the metalworking industry believed that current RMM standards are adequate for controlling risks, although one formulator and one DU noted that some improvements could be made to their RMMs if required. The cost for this would depend on what further RMM conditions are imposed under RO4c.

It is currently not possible based on the limited information available to tentatively estimate the risk reduction potential, nor the total costs of RO4c, since most respondents

believe they are already complying with the risk management set out in their SDS and they have therefore not indicated additional RMMs that they could implement to further reduce release and exposure. The most cost-effective option for this sector appears to be RO4a (a permanent derogation without additional RMMs). However, this would suggest that companies would then not switch away from CA:C14-C17 based MWFs (i.e. they will likely avoid the higher costs of using alternatives).

If instead, specific RMMs are required to be implemented as part of any derogation for RO4c, then it is likely that companies will incur further costs to implement additional RMMs. This will depend on how stringent any further RMMs will be compared to what is already stated in their SDS.

The requirement to use further RMMs would create additional incentives for companies to switch to a more expensive alternative MWF, as they compensate the marginal increment of production costs by avoiding the cost of implementing additional RMMs. This incentive will be high if the costs of further RMMs are higher than the costs of using an alternative MWF and will thus promote substitution, even when a derogation is in place.

Conclusions regarding RO4c

Due to the diversity and broadness of metalworking activities covered by the restriction proposal, it has not been possible for the Dossier Submitter to establish and prescribe specific risk management measures that would fit all uses of metalworking fluids containing CA:C14-17 with PBT and/or vPvB properties, nor to assess the related compliance costs.

Based on the outcome of the CfE and the dedicated survey on MWF, the Dossier Submitter cannot currently define in RO4c continued use of MWFs containing CA:C14-C17 for specific metalworking processes (e.g. limiting it to processes like heavy duty broaching, pressing and deep drawing), or how to limit their use under specific operating conditions or RMM.

It is therefore the responsibility of affected industries to be more forthcoming during the Annex XV consultation of the proposed restriction with information on (i) the precise niche products still requiring the use of MWFs containing CA:C14-C17, and (ii) defining RMMs that could be implemented to allow further consideration of RO4c during the opinion making phase.

If practical, enforceable and proportionate solutions are proposed and duly justified by the metalworking sector during the Annex XV consultation, then such additional information could be considered by ECHA’s scientific committees.

E.1.4. Other Union-wide risk management options than a REACH restriction

Table 92: Other Union-wide risk management options

Risk management option	Description of the option and reason for discarding the option
Non legislative measures	
Voluntary industry agreement to restrict the use of substances containing CA:C14-17 or reduce the presence of CA:C14-17 in chloroalkanes	Though some registrants indicated during the Registrants' survey that they are currently working on the feedstock specifications and sourcing to reduce the concentration of CA:C14-17 in the chloroalkanes placed on the market. These actions are limited to few companies and chloroalkanes listed in section B.1.2, and no voluntary industry agreements or initiative at EU level have been identified by the Dossier Submitter.
EU Ecolabel and other Ecolabel	The EU Ecolabel and other national Ecolabel are voluntary schemes awarded to the environmentally best products on the market. The presence of SVHC substances is for example prohibited in most Ecolabels. Nordic Swan Ecolabel has also developed criteria for textiles, hides/skins and leather[37], prohibiting the presence of 'halogenated organic compounds in general (including chloroalkane' in order to obtain the Nordic Swan Ecolabel (CFE #1479). Companies placing substances, mixtures and articles on the market may apply voluntarily for these Ecolabels. Nevertheless as this voluntary measure is limited to some uses, countries, and does not cover all the substances potentially containing CA:C14-17 with PBT and/or vPvB properties, this measure, on its own, cannot address the risks identified by the Dossier Submitter.
Legislation other than REACH	
POPs Regulation under the Stockholm Convention	Regulation (EU) 2019/1021 (the POPs regulation) implements the Stockholm Convention on POPs in the EU. UK proposed to list 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥ 45 % ' as a POP under the Stockholm Convention in 2019 and the overall process is not expected to finalise before 2025 (cf. section D.1). This means that the REACH restriction process will finalise earlier, and the conclusions from the REACH restriction process can be used to inform the Stockholm Convention process. If a substance is listed under the Stockholm Convention on POPs the practice is to implement this in EU

[37] https://www.ecolabel.dk/-/criteriadoc/5358

Risk management option	Description of the option and reason for discarding the option
	law by amending the POPs regulation and by removing the corresponding restriction from Annex XVII of REACH (EU Commission, 2014b).
RoSH Directive (2011/65/EU)	The RoHS Directive restricts (with exceptions) the use of listed hazardous substances in the manufacture of various types of electronic and electrical equipment (EEE). Some uses of CA:C14-17, and in particular Use#00 – PVC (cables) may fall within the scope of the RoHS Directive. Substances containing CA:C14-17 are currently not listed as a restricted substance under RoHS, nevertheless the inclusion of 287-477-0 in Annex II to the RoHS Directive was already initiated by the Commission in 2020 but not concluded at the time of the restriction proposal submission. The Dossier Submitter notes also that the RoHS Directive applies to some types of EEE that may contain CA:C14-17, such as large and small household appliances and monitoring and control instruments containing PVC cables. However, the Directive does not apply to other relevant sectors of use such as 'means of transport for persons or goods, excluding electric two wheeled vehicles which are not type approved.' Considering that both the automotive and aviation sectors could uses PVC cables containing CA:C14-17, the exemption of these two applications from the RoHS Directive indicate that this risk management option would not be effective in reducing emissions of CA:C14-17. Having said that, and in line with the Commission paper on the interface between RoHS and the REACH Regulation (EU Commission, 2014a), the Commission may decide ultimately to restrict the EEE relevant uses under RoHS rather than REACH.
Biocidal Products Regulation	Some uses of CA:C14-17, and in particular Use#04 – Use in paint and coating may fall within the scope of the Biocides products Regulation. Indeed some uses in anti-fooling (biocides) paint were identified by the Dossier Submitter: substances containing CA:C14-17 are used as 'co-formulant' in biocide products. Under the Biocides Regulation co-formulant substances which meet the criteria for PBT or vPvB and which are present in concentration above 0.1 % should be considered as 'substance of concern' (SOC) for the purpose of the Risk Assessment, and the risk assessment should be reviewed once new hazard information are available. This review mechanism is unfortunately not always triggered in practice as it remains under the initiative of the authorisation holder. In addition, considering that the uses in Biocides would be limited, this risk management option on its own would not be effective in reducing emissions of CA:C14-17.
Product Safety Directive EC 2001/95	This Directive addresses risks to consumers (termed health and safety of consumers) related to specific products and not risks related to a cumulated exposure from different products, or to risks posed to the environment. This measure would therefore not be appropriate

Risk management option	Description of the option and reason for discarding the option
Waste Directive	A mandatory destruction (incineration) scheme could be considered as a risk management option for the waste life-cycle stage. However, this option is not currently considered to be feasible because of the implementation challenges associated with harmonising waste management practices across the EU, the (non) availability of incineration facilities in all EU countries (Neuwahl et al., 2019), and the identification of the articles containing CA:C14-17.
Industrial Emission Directive (2010/75/EU)	The Industrial Emissions Directive – IED - (2010/75/EU) requires operators of industrial installations to obtain a permit from the national authorities to continue operating. Permits place a requirement for the use of Best Available Techniques (BAT) to reduce emissions and the impact on the environment as a whole. The IED has the potential to limit emissions from permitted sites. However, many downstream users, such as manufacturers of articles containing CA:C14-17, are unlikely to require a permit and be subject to IED. Additionally, IED only control parts of the lifecycle and will thus have no effect on the service life emissions or release from the waste stage of articles. On the basis that the provisions of the IED will not apply to all sites where CA:C14-17 may be used and released, and that the provisions do not apply to key life cycle stages that may create a substantial part of the emissions (cf. section B.5), the Dossier Submitter considers that the provisions of the IED will not achieve the goal of minimising all environmental releases from CA:C14-17.
Land and soil Regulations	As demonstrated in section B.5, CA:C14-17 may be released to soils from industrial, professional or consumer activities, from landfill of wastes, and the application to soil of sewage sludge. There is currently no legal EU framework that would be able to address all these releases. Unlike for other environmental compartments, there is indeed no dedicated European legislation on soil quality. For large industrial sites, there are provisions in the IED that relate to soil protection and remediation. More generally, the Environmental Liability Directive (Directive 2004/34/EC) establishes a framework for preventing and remedying environmental damage. Under the EU Green Deal strategy, the Zero Pollution Action Plan and the revision of the thematic strategy for soil protection could also provide a framework to address the concerns raised by the contamination of soils.
Other REACH processes	
REACH Authorisation process	Four substances among the 69 under scrutiny are explicitely identified as an SVHC and included on the Candidate List (even though the Candidate List entry covers more than four substances). So these substances could have been prioritised for Annex XIV inclusion. However, authorising the use of four substances only would not be an efficient measure as it is demonstrated in this dossier that CA:C14-17 with PBT and/or vPvB properties may

Risk management option	Description of the option and reason for discarding the option
	be present in many more substances which may be used as an alternative to the four substances in the Candidate List. In addition, REACH authorisation does not apply to imported articles. As a huge proportion of articles that may contain CA:C14-17 are imported, REACH Authorisation would not be appropriate to address the risks. Last but not least, this risk management option may lead to potential regulatory uncertainty in case of future nomination of 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥45 %' to the Stockholm Convention. The EU Commission document on interlink between REACH, the Stockholm Convention as well as the UNECE POP Protocol (EU Commission, 2014b) states indeed that if a substance is included in Annex XIV and subsequently banned under the Stockholm Convention, not only should all existing authorisations be withdrawn but all applications for authorisation should be refused. For all these reasons, authorisation is thus not considered an appropriate risk management option.

E.2. Alternatives

E.2.1. Description of the use and function of the restricted substance(s)

The following tables report on the potential alternatives that the Dossier Submitter has identified during the dossier preparation.

E.2.2. Identification of alternative substances and techniques fulfilling the function

Table 93: Potential alternatives to substances containing chloroalkanes with carbon chain lengths within the range from C14 to C17 (CA:C14-17) (Plasticisers and/or Flame retardants)

Name of the alternative substance	EC	CAS	SI	Production and import volume in the EU	Plasticiser	Flame retardant
Cytidine 5'-(trihydrogen diphosphate) (CDP)	200-557-1	63-38-7	SI	n/a	n/a	yes
Citrates, e.g. Acetyltri-n-butylcitrate(ATBC)	201-067-0	77-90-7	SI	Registered tonnage of 10 000 – 100 000 tonnes per annum	yes	no
Triethyl phosphate (TEP)	201-114-5	78-40-0	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum	yes	yes
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol	201-236-9	79-94-7	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum	yes	yes
Bis(2-ethylhexyl) adipate	203-090-1	103-23-1	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum	yes	n/a
1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-ene-2,3-dicarboxylic anhydride	204-077-3	115-27-5	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 100 to < 1 000 tonnes per annum.	n/a	yes

Name of the alternative substance	EC	CAS	SI	Production and import volume in the EU	Plasticiser	Flame retardant
Triphenyl phosphate (TPP)	204-112-2	115-86-6	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 tonnes per annum.	yes	yes
Oxydiethylene dibenzoate	204-407-6	120-55-8	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum.	yes	n/a
2,2,4-trimethylpentane-1,3-diol	205-619-1	144-19-4	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 100 to < 1 000 tonnes per annum	yes	n/a
2-ethylhexyl diphenylphosphate	214-987-2	1241-94-7	SI	Registered tonnage of 1 000 – 10 000 tonnes per annum	yes	yes
Magnesium hydroxide	215-170-3	1309-42-8	SI	Registered tonnage of 100 000 – 1 000 000 tonnes per annum	no	yes
Diantimony trioxide	215-175-0	1309-64-4	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 tonnes per annum.	no	yes
Tris(methylphenyl) phosphate	215-548-8	1330-78-5	SI	n/a	yes	yes
Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	222-020-0	3319-31-1	SI	Registered tonnage of 10 000 – 100 000 tonnes per annum	yes	no
Bis(2-ethylhexyl) terephthalate (DEHT)	229-176-9	6422-86-2	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 100 000 to < 1 000 000 tonnes per annum.	yes	n/a
1-isopropyl-2,2-dimethyltrimethylene diisobutyrate	229-934-9	6846-50-0	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum.	yes	n/a

Name of the alternative substance	EC	CAS	SI	Production and import volume in the EU	Plasticiser	Flame retardant
Phosphorus	231-768-7	7723-14-0	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum	yes	yes
Tris(2-chloro-1-methylethyl) phosphate (TCPP)	237-158-7	13674-84-5	SI	This substance is registered under the REACH Regulation but is not currently being manufactured in and / or imported to the European Economic Area	yes	yes
Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)	237-159-2	13674-87-8	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum	yes	yes
Aluminium hydroxide	244-492-7	21645-51-2	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 000 to < 10 000 000 tonnes per annum.	n/a	yes
1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]	244-617-5	21850-44-2	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum	n/a	yes
Trixylyl phosphate	246-677-8	25155-23-1	SI	Registered tonnage of 1 000 – 10 000 tonnes per annum	yes	yes
Cresyl diphenylphosphate	247-693-8	26444-49-5	SI	n/a	yes	yes
Oxydipropyl dibenzoate	248-258-5	27138-31-4	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum	yes	n/a
Benzyl isooctyl phthalate	248-335-3	27215-22-1	SI	n/a	yes	n/a
Isopropylphenyl diphenyl phosphate (IPPDPP)	248-848-2	28108-99-8	SI	n/a	yes	yes
Di-''isononyl'' phthalate(DINP)	249-079-5	28553-12-0	SI	Registered tonnage of 100 000-1 000 000 tonnes per annum	yes	no

Name of the alternative substance	EC	CAS	SI	Production and import volume in the EU	Plasticiser	Flame retardant
Isodecyl diphenylphosphate	249-828-6	29761-21-5	SI	Registered tonnage of 100 - 1 000 tonnes per annum	yes	yes
N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide)	251-118-6	32588-76-4	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 100 to < 1 000 tonnes per annum	n/a	yes
1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene]	253-692-3	37853-59-1	SI	n/a	n/a	yes
tert-butylphenyl diphenyl phosphate (TBPDPP)	260-391-0	56803-37-3	SI	n/a	yes	yes
RSS Tetraphenyl m-phenylene bis(phosphate)	260-830-6	57583-54-7	SI	n/a	n/a	yes
Terphenyl, hydrogenated	262-967-7	61788-32-7	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum	yes	no
Paraffin waxes and Hydrocarbon waxes, chloro (LCCPs)	264-150-0	63449-39-8	SI	Registered tonnage of 10 000-100 000 tonnes per annum	yes	yes
Ammonium polyphosphate	269-789-9	68333-79-9	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum.	n/a	yes
1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich(eg DIDP)	271-091-4	68515-49-1	SI	Registered tonnage of 100 000-1 000 000 tonnes per annum	yes	no
Phenol, isobutylenated, phosphate (3:1)	273-065-8	68937-40-6	SI	n/a	yes	yes
Phenol, isopropylated, phosphate (3:1)	273-066-3	68937-41-7	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum.	yes	yes

Name of the alternative substance	EC	CAS	SI	Production and import volume in the EU	Plasticiser	Flame retardant
1,1'-(ethane-1,2-diyl)bis[pentabromobenzene]	284-366-9	84852-53-9	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum.	n/a	yes
Sulfonic acids, C10-21-alkane, Ph esters	293-728-5	91082-17-6	SI	n/a	yes	n/a
Diisoundecyl phthalate	306-165-8	96507-86-7	SI	n/a	yes	yes
Zinc Hydroxystannate	404-410-4	12027-96-2	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 tonnes per annum.	n/a	yes
(1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate	425-220-8	5945-33-5	SI	Registered tonnage of ≥ 10 000 tonnes per annum	yes	yes
1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester (DINCH)	431-890-2	166412-78-8	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 tonnes per annum.	yes	n/a
Diphosphoric acid, compd. with piperazine (1:1)	457-330-7	66034-17-1	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 100 tonnes per annum.	n/a	yes
Butene, homopolymer (products derived from either/or But-1-ene/But-2-ene)	500-004-7	9003-29-6	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum.	yes	n/a
1,3,5-triazine-2,4,6-triamine monophosphate	n/a	218768-84-4	SI	n/a	n/a	yes
Phosphinic acid, P,P-diethyl-, aluminum salt (3:1)	n/a	225789-38-8	SI	n/a	n/a	yes
Benzene, ethenyl-,homopolymer, brominated	n/a	88497-56-7	SI	n/a	n/a	yes
Glycerides, castor-oil mono-, hydrogenated, acetates	n/a	736150-63-3	SI	n/a	yes	n/a

Name of the alternative substance	EC	CAS	SI	Production and import volume in the EU	Plasticiser	Flame retardant
Calcium sulfonates	n/a	64521-08-0	SI	n/a	n/a	yes
Zinc stannate	n/a	12036-37-2	SI	n/a	n/a	yes

Source: Annex XV dossier for SVHC identification, UK RMOA, German RMOA, Dechlorane Plus restriction Dossier, RoHS Annex II Dossier for EC 287-477-0 based on KEMI proposal, and ECHA market survey

Table 94: Potential alternatives (extreme pressure additives, EPs) to substances containing chloroalkanes with carbon chain lengths within the range from C14 to C17 (CA:C14-17)

Name of the alternative substance	EC	CAS	SI	Production and import volume in the EU
Tributyl phosphate	204-800-2	126-73-8	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 tonnes per annum.
Bis(2-ethylhexyl) hydrogen phosphate	206-056-4	298-07-7	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 100 to < 1 000 tonnes per annum
Dimethyl phosphonate	212-783-8	868-85-9	SI	n/a
molybdenum disulfide	215-263-9	1317-33-5	SI	n/a
Tris(methylphenyl) phosphate	215-548-8	1330-78-5	SI	n/a
Didodecyl phosphonate	244-325-8	21302-09-0	SI	n/a
Cresyl diphenyl phosphate	247-693-8	26444-49-5	SI	n/a
Isopropylphenyl diphenyl phosphate	248-848-2	28108-99-8	SI	n/a
tert-butylphenyl diphenyl phosphate	260-391-0	56803-37-3	SI	n/a
Paraffin waxes and Hydrocarbon waxes, chloro (LCCPs)	264-150-0	63449-39-8	SI	Registered tonnage 10 000-100 000 tpa
RSS Molybdenum,	270-180-5	68412-26-0	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 to < 100 tonnes per

Name of the alternative substance	EC	CAS	SI	Production and import volume in the EU
bis(dibutylcarbamodithioato)di-μ-oxodioxodi-, sulfurized				annum.
Polysulfides, di-tert-dodecyl	270-335-7	68425-15-0	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum.
Polysulfides, di-tert-nonyl	270-336-2	68425-16-1	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 to < 10 tonnes per annum.
Phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts	270-608-0	68457-79-4	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum.
Phenol, isobutylenated, phosphate (3:1)	273-065-8	68937-40-6	SI	n/a
Phenol, isopropylated, phosphate (3:1)	273-066-3	68937-41-7	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per annum.
Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts	283-392-8	84605-29-8	SI	This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum.
Oleyl alcohol, ethoxylate, phosphate	933-828-4	39464-69-2	SI	n/a
diallyl chlorendate	n/a	3232-62-0	n/a	n/a

Source: Annex XV dossier for SVHC identification, UK RMOA, German RMOA, Dechlorane Plus restriction Dossier, RoHS Annex II Dossier for EC 287-477-0 based on KEMI proposal and ECHA market survey

E.2.3. Hazard of alternatives

Table 95: Hazard Classification of alternatives and their regulatory status

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
Cytidine 5'-(trihydrogen diphosphate) (CDP)	200-557-1	63-38-7	-	n/a	n/a	-	-	link	n/a
Citrates, e.g. Acetyl tri-n-butylcitrate (ATBC)	201-067-0	77-90-7	-	Not Classified	Aquatic Chronic 3, Flam. Gas 1, Muta. 1B, Carc. 1B, Eye Irrit. 2, Skin Irrit. 2.	-	RMOA conducted by France in 2016. Concern: endocrine disruption. Conclusion: no action needed at that time.	link	link
Triethyl phosphate (TEP)	201-114-5	78-40-0	Acute Tox. 4	Acute Tox. 4, Eye Irrit. 2,	STOT SE 3	-	-	link	link
2,2',6,6'-tetrabromo-4,4'-isopropylidene diphenol	201-236-9	79-94-7	Aquatic Acute 1, Aquatic Chronic 1	Carc. 2, Aquatic Acute 1, Aquatic Chronic 1	-	Under assessment as PBT by Denmark.	SVHC dossier under preparation. Scope: Carcinogenic (Article 57a). Expected date of submission: August 2022. The substance is also under assessment as endocrine disrupting.	link	link
Adipates, e.g. Bis(2-ethylhexyl) adipate	203-090-1	103-23-1	-	Not Classified	Aquatic Acute 1, Aquatic Chronic 1, Skin Irrit. 2, Eye Irrit. 2	-	Substance evaluation completed by Finland. Conclusions: need for a follow-up regulatory action at EU level and harmonized classification	link	link

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
(DEHA, DOA)							and labelling for the reproductive toxicity endpoint.		
1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-ene-2,3-dicarboxylic anhydride	204-077-3	115-27-5	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3	Skin Irrit. 2, Skin Sens. 1, Eye Irrit. 2A, Carc. 2, STOT RE 2, Aquatic Chronic 3	Eye Irrit. 2, STOT SE 3, STOT RE 2,	Concluded as not PBT, not vPvB by France (23 June 2022)	Proposed regulatory action by ECHA (Assessment of Regulatory needs, ARN1): restriction	link	link
Triphenyl phosphate (TPP)	204-112-2	115-86-6	-	Aquatic Acute 1, Aquatic Chronic 1.	Aquatic Chronic 2, Aquatic Chronic 4	-	RMOA (ARN1) concluded by France in 2019. Concerns assessed: endocrine disruption and skin sensitiser. Conclusion: no action needed at that time.	link	link
Oxydiethylene dibenzoate	204-407-6	120-55-8	-	Not Classified	-	-	Substance evaluation completed by Latvia (2020). Concerns: suspected reprotoxic, wide dispersive use, exposure of environment and workers, high RCR, consumer use and high (aggregated) tonnage. Conclusion no need for regulatory follow up action.	link	link

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
Tributyl phosphate	204-800-2	126-73-8	Acute Tox. 4, Skin Irrit. 2, Carc. 2	Acute Tox. 4, Skin Irrit. 2, Carc. 2, Aquatic Chronic 3	Acute Tox. 4,	-	-	link	link
2,2,4-trimethylpentane-1,3-diol	205-619-1	144-19-4	-	Eye Irrit. 2	STOT SE 3, Acute Tox. 4, Skin Irrit. 2,	-	-	link	link
Bis(2-ethylhexyl) hydrogen phosphate	206-056-4	298-07-7	-	Acute Tox. 4, Skin Corr. 1C, Eye Dam. 1,	Skin Corr. 1B, Skin Irrit. 2	-	-	link	n/a
Dimethyl phosphonate	212-783-8	868-85-9	-	Skin Sens. 1, Muta. 2, Carc. 2, Aquatic Chronic 3.	Flam. Liq. 3, Skin Irrit. 2, Eye Irrit. 2, Acute Tox. 3,	-	Substance evaluated by the Netherlands in 2017. Assessed concerns: carcinogenicity, mutagenicity and reproduction toxicity (CMR), wide dispersive use, consumer use, high (aggregated) tonnage, high risk characterisation risk (RCR). Conclusion: no need for regulatory follow-up action at EU level.	link	link
2-ethylhexyl diphenyl phosphate	214-987-2	1241-94-7	-	Not Classified	Aquatic Acute 1, Aquatic Chronic 1, Aquatic Chronic 2, Acute Tox. 4	PBT assessment performed by UK in 2013. Conclusion: not PBT, not vPvB.	-	link	link

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
Magnesium hydroxide	215-170-3	1309-42-8	-	Not Classified	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3 (resp.), Acute Tox. 4, Eye Dam. 1	-	-	link	n/a
Antimony trioxide	215-175-0	1309-64-4	Carc. 2	Carc. 2, STOT RE 2, Aquatic Chronic 3, Repr. 1A, STOT RE 1	Acute Tox. 4, Aquatic Chronic 2	-	Substance is in the CoRAP, with Germany as evaluating Member State. Initial grounds for concern: carcinogenic, exposure of workers, high tonnage, high RCR, wide dispersive use. Status: information requested.	link	link
molybdenum disulfide	215-263-9	1317-33-5	-	n/a	Not Classified, Acute Tox. 4, Skin Irrit. 2,Eye Irrit. 2, STOT SE 3,	-	-	link	link
Tris(methylphenyl) phosphate	215-548-8	1330-78-5	-	n/a	Skin Sens. 1, Repr. 2 (testicular), STOT RE 2 (nervous system), Aquatic Acute 1, Aquatic Chronic 1, Acute Tox. 4, Skin Sens. 1B, Eye Irrit. 2	-	-	link	link

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	222-020-0	3319-31-1	-	Not Classified	Repr. 2, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3 , Aquatic Chronic 4	Under assessment as PBT	Proposed regulatory actions in ARN1: restriction combined with authorisation.	link	link
Bis(2-ethylhexyl) terephthalate (DEHT)	229-176-9	6422-86-2	-	Not Classified.	-	-	Substance assessed by ECHA under the group name: Isophthalates, Terephthalates and Trimellitates (ARN1, 2021). Conclusion: currently no need for EU regulatory risk management . Justification: no or unlikely hazard.	link	link
1-isopropyl-2,2-dimethyltrimethylene diisobutyrate	229-934-9	6846-50-0	-	Repr. 2, Aquatic Chronic 3	Not Classified, Eye Irrit. 2, STOT RE 2,	-	-	link	link
Phosphorus	231-768-7	7723-14-0	Flam. Sol. 1, Aquatic Chronic 3,	Flam. Sol. 1, Aquatic Chronic 3, Not Classified, Pyr. Sol. 1, Acute Tox. 2, Skin Corr. 1A, Acute Tox. 2, Aquatic Acute 1, Acute Tox. 1,	-	-	-	link	n/a

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
Tris(2-chloro-1-methylethyl) phosphate (TCPP)	237-158-7	13674-84-5	-	n/a	Acute Tox. 4, Aquatic Chronic 3,	-	Included in the Restriction Roadmap under Chemical Strategy for Sustainability (suspected carcinogen and reprotoxic).	link	link
Tris[2-chloro-1-(chloromethyl) ethyl] phosphate (TDCP)	237-159-2	13674-87-8	Carc. 2	Carc. 2, Aquatic Chronic 1	Aquatic Chronic 2, Skin Irrit. 2,	-	Included in the Restriction Roadmap under the Chemical Strategy for Sustainability (suspected carcinogen and reprotoxic). The substance is also included in CoRAP with Germany as evaluating Member State (ED suspicion)	link	link
Didodecyl phosphonate	244-325-8	21302-09-0	-	n/a	Not Classified, Skin Irrit. 2	-	-	link	n/a
Aluminium hydroxide	244-492-7	21645-51-2	-	Not Classified	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3,	-	-	link	n/a
1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-	244-617-5	21850-44-2	-	Not Classified	-	Substance evaluation concluded by Germany (2021). Conclusion: not PBT, vPvB	Under assessment as endocrine disrupting, with Germany as authority. Also proposed regulatory action by	link	link

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
dibromopropoxy)benzene]							ECHA (ARN1): restriction.		
Trixylyl phosphate	246-677-8	25155-23-1	Repr. 1B	Repr. 1B, STOT RE 2, Aquatic Acute 1, Aquatic Chronic 1	Eye Irrit. 2, Aquatic Chronic 2	The substance was evaluated by Italy. Outcome of the assessment: inconclusive.	Substance was included in the Authorisation list in 2020.	link	link
Cresyl diphenyl phosphate	247-693-8	26444-49-5	-	n/a	Acute Tox. 4, Aquatic Acute 1, Aquatic Chronic 1, Aquatic Chronic 3.	-	-	link	n/a
Oxydipropyl dibenzoate	248-258-5	27138-31-4	-	Aquatic Chronic 3	Not Classified, Aquatic Chronic 2, Eye Irrit. 2	-	Substance evaluation (SEv1) completed by Latvia (2020). Concerns: suspected reprotoxic, wide dispersive use, exposure of environment and workers, high RCR, consumer use and high (aggregated) tonnage. Conclusion no need for regulatory follow up action.	link	link
Benzyl isooctyl phthalate	248-335-3	27215-22-1	-	n/a	Eye Irrit. 2	-	-	link	n/a

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
Isopropylphenyl diphenyl phosphate (IPPDPP)	248-848-2	28108-99-8	-	n/a	Not Classified.	-	-	link	n/a
Di-''isononyl'' phthalate (DINP)	249-079-5	28553-12-0	-	Not Classified	-	-	-	link	link
Isodecyl diphenyl phosphate	249-828-6	29761-21-5	-	Not Classified	Aquatic Chronic 4,	PBT assessment performed by UK in 2013. Conclusion: not PBT, not vPvB.	-	link	link
N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide)	251-118-6	32588-76-4	-	Not classified	-	Under assessment as PBT, with Norway as Evaluating Member State. Status suspended.	Substance included in the Community Rolling Action Plan (CoRAP).	link	link
1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene]	253-692-3	37853-59-1	-	n/a	Not Classified	Spain to submit an SVHC dossier in August 2022. Scope: vPvB (Article 57e) and Endocrine disrupting properties (Article 57(f) – environment).	SVHC dossier under preparation. Scope: vPvB (Article 57e) and Endocrine disrupting properties (Article 57(f) – environment)	link	link

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
tert-butylphenyl diphenyl phosphate (TBPDPP)	260-391-0	56803-37-3	-	n/a	Not Classified, Acute Tox. 4, Aquatic Acute 1	-	-	link	n/a
RSS Tetraphenyl m-phenylene bis(phosphate)	260-830-6	57583-54-7	-	n/a	Aquatic Chronic 3, Aquatic Chronic 2, Not Classified.	-	RMOA performed by France (2018). Concern: endocrine disruption. Conclusion: need for follow-up regulatory action at EU level.	link	link
Terphenyl, hydrogenated	262-967-7	61788-32-7	-	Aquatic Chronic 2	Aquatic Chronic 4, Not Classified	Substance evaluation concluded by Finland. Conclusion: vPvB	Annex XV restriction report submitted by Italy in April 2022. Also it was identified as substance of very high concern (SVHC) and included in the Candidate List for authorisation.	link	link
Paraffin waxes and Hydrocarbon waxes, chloro (LCCPs)	264-150-0	63449-39-8	-	Not Classified	Eye Irrit. 2 , Lact., Aquatic Acute 1,	EC 264-150-0 could also be considered to meet the REACH Annex XIII criteria for a PBT or vPvB substance if CA:C14-17 with PBT and/or vPVB properties are present in a concentration ≥ 0.1 %	The substance may be subject to an updated assessment by the UK Environment Agency to evaluate its PBT and/or vPvB potential (UK, 2021).	link	link

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
Ammonium polyphosphate	269-789-9	68333-79-9	-	Acute Tox. 4, Eye Irrit. 2	Not Classified.	-	-	link	n/a
RSS Molybdenum, bis(dibutylcarbamodithioato) di-μ-oxodioxodi-, sulfurized	270-180-5	68412-26-0	-	Aquatic Chronic 4	Acute Tox. 2, Not Classified, Aquatic Chronic 3,	-	-	link	n/a
Polysulfides, di-tert-dodecyl	270-335-7	68425-15-0	-	Skin Sens. 1B	Aquatic Chronic 4	-	-	link	link
Polysulfides, di-tert-nonyl	270-336-2	68425-16-1	-	Not classified.	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Aquatic Chronic 4.	-	-	link	link
Phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts	270-608-0	68457-79-4	-	Skin Irrit. 2, Eye Dam. 1, Aquatic Chronic 2	Eye Irrit. 2	-	-	link	link
1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-	271-091-4	68515-49-1	-	Not Classified	-	Potential hazard for PBT/vPvB	Proposed regulatory actions in ARN1: authorisation and restriction. Also some uses are already	link	link

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
rich (eg DIDP)							restricted under Annex XVII to REACH.		
Phenol, isobutylenated, phosphate (3:1)	273-065-8	68937-40-6	-	n/a	Aquatic Acute 1, Aquatic Chronic 1,	-	Substance similar to EC 273-066-3	link	n/a
Phenol, isopropylated, phosphate (3:1)	273-066-3	68937-41-7	-	Repr. 2, STOT RE 2, Aquatic Chronic 1,	Skin Sens. 1, Aquatic Chronic 2, Aquatic Chronic 4	Substance undergoing PBT assessment by the Netherlands.	Substance on the CoRAP list. Suspicion of ED properties.	link	link
Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts	283-392-8	84605-29-8	-	Skin Irrit. 2, Eye Dam. 1, Aquatic Chronic 2.	-	Under assessment as PBT by ECHA.	-	link	link
1,1'-(ethane-1,2-diyl)bis[pentabromobenzene]	284-366-9	84852-53-9	-	Not classified	Aquatic Chronic 4	Under assessment as PBT, with Sweden as Evaluating Member State.	-	link	link
Sulfonic acids, C10-21-alkane, Ph esters	293-728-5	91082-17-6	-	n/a	not classified	-	-	link	link

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
Diisoundecyl phthalate	306-165-8	96507-86-7	-	n/a	not classified	-	Currently no EU RRM action needed (ARN1).	link	link
Zinc Hydroxystannate	404-410-4	12027-96-2	-	Not classified.	-	-	-	link	n/a
(1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate	425-220-8	5945-33-5	-	Not Classified	Aquatic Chronic 4	PBT hazard inconclusive (ARN1).	No hypothesis yet for regulatory risk management (ARN1).	link	link
1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester (DINCH)	431-890-2	166412-78-8	-	Not Classified	-	-	Substance assessed by ECHA under the group name: Esters from branched or non-aromatic cyclic dicarboxylic acids and aliphatic alcohols (ARN1, 2021). Conclusion: currently no EU action needed.	link	link
Diphosphoric acid, compd. with piperazine (1:1)	457-330-7	66034-17-1	-	Eye Irrit. 2, Aquatic Chronic 3	-	-	-	link	link

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
Butene, homopolymer (products derived from either/or But-1-ene/But-2-ene)	500-004-7	9003-29-6	-	Aquatic Chronic 4, Asp. Tox. 1, Skin Irrit. 2, Flam. Liq. 2	Not Classified, Eye Irrit. 2, Acute Tox. 3	-	-	link	link
Oleyl alcohol, ethoxylate, phosphate	933-828-4	39464-69-2	-	n/a	Skin Irrit. 2	-	-	link	n/a
1,3,5-triazine-2,4,6-triamine monophosphate	n/a	218768-84-4	-	n/a	Not Classified	-	-	link	n/a
Phosphinic acid, P,P-diethyl-, aluminum salt (3:1)	n/a	225789-38-8	-	n/a	Not Classified	-	-	link	link
Benzene, ethenyl-,homopolymer, brominated	n/a	88497-56-7	-	n/a	Eye Irrit. 2, Not Classified.	-	-	link	n/a
Glycerides, castor-oil mono-, hydrogenated, acetates	n/a	736150-63-3	-	n/a	Not Classified	-	-	link	n/a

Name of the alternative substance	EC	CAS	Harmonised classification in CLP	Classification in the lead registrations	Additional classifications notified (most frequent)	Planned or ongoing PBT assessment	Regulatory scrutiny	Link C&L inventory	PACT
Calcium sulfonates	n/a	64521-08-0	-	n/a	Skin Sens. 1, Aquatic Chronic 2	-	-	link	n/a
Zinc stannate	n/a	12036-37-2	-	n/a	Not classified.	-	-	link	n/a
diallyl chlorendate	n/a	3232-62-0	-	n/a	n/a	-	-	n/a	n/a

Source: ECHA dissemination website and ECHA brief profile consulted between October 2021 and June 2022

E.2.4. Price of alternatives

The following tables report the prices of substances which may contain CA:C14-17 and the prices of the identified alternatives.

Table 96: Price of substances which may contain CA:C14-17

Name of the substance	EC	CAS	Price[1]	Source (link or other)[2]
Paraffin waxes and Hydrocarbon waxes, chloro (also identified as LCCP)	264-150-0	63449-39-8	1.43 €/kg	ECHA market survey
Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated	269-145-7	68188-19-2	0.88 €/kg	link
Alkanes, C14-17, chloro	287-477-0	85535-85-9	0.95 €/kg	link
Alkanes, C18-28, chloro	287-478-6	85535-86-0	1.80 €/kg	ECHA market survey

Source: ECHA market survey

Note: [1] The table reports only substances for which it was possible to identify the price. Where price ranges were identified by the Dossier Submitter, the central estimate has been reported in the table. When prices were reported in USD, the conversion to EURO was made by applying the exchange rate of 0.88 €/USD (which is the average exchange rate from 1st November 2021 to 1st March 2022[38]).

[2] The content of some websites may have changed and so the price of the alternative might no longer be available.

Table 97: Prices of alternatives (for plasticisers and/or flame retardants applications)

Name of the alternative substance	EC	CAS	Price €/kg[1]	Source (link or other)[2]
Citrates, e.g. Acetyl tri-n-butylcitrate (ATBC)	201-067-0	77-90-7	2.70 €/kg	link
Triethyl phosphate	201-114-5	78-40-0	2.73 €/kg	link
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol	201-236-9	79-94-7	6.16 €/kg	link

[38] https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/eurofxref-graph-usd.en.html

Name of the alternative substance	EC	CAS	Price €/kg[1]	Source (link or other)[2]
Bis(2-ethylhexyl) adipate	203-090-1	103-23-1	3.00 €/kg	link
1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-ene-2,3-dicarboxylic anhydride	204-077-3	115-27-5	3.52 €/kg	link
Triphenyl phosphate (TPP)	204-112-2	115-86-6	3.31 €/kg	link
Oxydiethylene dibenzoate	204-407-6	120-55-8	1.67 €/kg	link
2,2,4-trimethylpentane-1,3-diol	205-619-1	144-19-4	8.80 €/kg	link
2-ethylhexyl diphenyl phosphate	214-987-2	1241-94-7	6.60 €/kg	link
Magnesium hydroxide	215-170-3	1309-42-8	4.84 €/kg	link
Diantimony trioxide	215-175-0	1309-64-4	5.00 €/kg	link
Tris(methylphenyl) phosphate	215-548-8	1330-78-5	3.84 €/kg	link
Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	222-020-0	3319-31-1	1.50 €/kg	link
Bis(2-ethylhexyl) terephthalate (DEHT)	229-176-9	6422-86-2	1.44 €/kg	link
1-isopropyl-2,2-dimethyltrimethylene diisobutyrate	229-934-9	6846-50-0	4.40 €/kg	link
Phosphorus	231-768-7	7723-14-0	4.40 €/kg	link
Tris(2-chloro-1-methylethyl) phosphate (TCPP)	237-158-7	13674-84-5	1.60 €/kg	link
Tris[2-chloro-1-(chloromethyl)ethyl] phosphate	237-159-2	13674-87-8	2.29 €/kg	link
Aluminium hydroxide	244-492-7	21645-51-2	1.33 €/kg	link

Name of the alternative substance	EC	CAS	Price €/kg[1]	Source (link or other)[2]
1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]	244-617-5	21850-44-2	6.03 €/kg	link
Trixylyl phosphate	246-677-8	25155-23-1	6.60 €/kg	link
Cresyl diphenyl phosphate	247-693-8	26444-49-5	4.84 €/kg	link
Oxydipropyl dibenzoate	248-258-5	27138-31-4	2.11 €/kg	link
Di-''isononyl'' phthalate (DINP)	249-079-5	28553-12-0	1.44 €/kg	link
Isodecyl diphenyl phosphate	249-828-6	29761-21-5	6.60 €/kg	link
N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide)	251-118-6	32588-76-4	6.60 €/kg	link
tert-butylphenyl diphenyl phosphate (TBPDPP)	260-391-0	56803-37-3	1.32 €/kg	link
RSS Tetraphenyl m-phenylene bis(phosphate)	260-830-6	57583-54-7	3.52 €/kg	link
Terphenyl, hydrogenated	262-967-7	61788-32-7	3.96 €/kg	link
Paraffin waxes and Hydrocarbon waxes, chloro (LCCPs)	264-150-0	63449-39-8	1.43 €/kg	ECHA market survey
Ammonium polyphosphate	269-789-9	68333-79-9	1.14 €/kg	link
1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (eg DIDP)	271-091-4	68515-49-1	2.40 €/kg	link
1,1'-(ethane-1,2-diyl)bis[pentabromobenzene]	284-366-9	84852-53-9	5.50 €/kg	link
Sulfonic acids, C10-21-alkane, Ph esters	293-728-5	91082-17-6	1.54 €/kg	link
Diisoundecyl phthalate	306-165-8	68515-49-1	1.14 €/kg	link

Name of the alternative substance	EC	CAS	Price €/kg[1]	Source (link or other)[2]
(1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate	425-220-8	5945-33-5	3.95 €/kg	link
1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester (DINCH)	431-890-2	166412-78-8	1.81 €/kg	link
Diphosphoric acid, compd. with piperazine (1:1)	457-330-7	66034-17-1	6.86 €/kg	link
1,3,5-triazine-2,4,6-triamine monophosphate	n/a	218768-84-4	4.53 €/kg	link
Phosphinic acid, P,P-diethyl-, aluminum salt (3:1)	n/a	225789-38-8	7.04 €/kg	link
Benzene, ethenyl-,homopolymer, brominated	n/a	88497-56-7	6.30 €/kg	link

Source: ECHA market survey

Note: [1] The table reports only substances for which it was possible to identify the price. Where price ranges were identified by the Dossier Submitter, the central estimate has been reported in the table. When prices were reported in USD, the conversion to EURO was made by applying the exchange rate of 0.88 €/USD (which is the average exchange rate from 1st November 2021 to 1st March 2022).

[2] The content of some websites may have changed and so the price of the alternative might no longer be available.

Table 98: Price of alternatives (for extreme pressure additives application)

Name of the alternative substance	EC	CAS	Price €/kg	Source (link or other)
Tributyl phosphate	204-800-2	126-73-8	5.28 €/kg	ECHA market survey
Molybdenum disulfide	215-263-9	1317-33-5	7.48 €/kg	link
Tris(methylphenyl) phosphate	215-548-8	1330-78-5	3.52 €/kg	link
Cresyl diphenylphosphate	247-693-8	26444-49-5	4.84 €/kg	link
Isopropyl phenyl diphenyl phosphate	248-848-2	28108-99-8	1.89 €/kg	link

Name of the alternative substance	EC	CAS	Price €/kg	Source (link or other)
Bis(2-ethylhexyl) hydrogen phosphate	206-056-4	298-07-7	1.32 €/kg	link
Tert-butylphenyl diphenyl phosphate	260-391-0	56803-37-3	1.76 €/kg	ECHA market survey
Paraffin waxes and Hydrocarbon waxes, chloro	264-150-0	63449-39-8	1.43 €/kg	ECHA market survey
RSS Molybdenum, bis(dibutylcarbamodithioato)di-μ-oxodioxodi-, sulfurized	270-180-5	68412-26-0	18.04 €/kg	link
Phenol, isopropylated, phosphate (3:1)	273-066-3	68937-41-7	3.43 €/kg	link
Dimethyl phosphonate	212-783-8	868-85-9	5.00 €/kg	link

Source: ECHA market survey

Note: The table reports only substances for which it was possible to identify the price. Where price ranges were identified by the Dossier Submitter, the central value has been reported in the table. When prices were reported in USD, the conversion to EURO was made by applying the exchange rate of 0.88 €/USD (which is the average exchange rate from 1st November 2021 to 1st March 2022).

E.3. Economic impacts

The following sections describe in detail the approach and the assumptions that the Dossier Submitter adopted in assessing the economic impacts of RO1, RO3[39], RO4a and RO4b. Additional restriction options that were considered, but finally discarded, are described qualitative in E.1.3.

E.3.1. Use in PVC (Use#00)

The Dossier Submitter estimated the compliance costs for the PVC sector as a close proxy for the social cost of the proposed restriction. The main remaining use seems to be in PVC compounds used for manufacturing PVC cables (ECHA market survey). It is therefore assumed that all volumes of substances containing CA:C14-17 are used in the production of PVC compounds for PVC cables.

Based on information collected from stakeholders (via the ECHA market survey), the PVC sector will incur both one-off costs (for reformulation and testing) and an increase in variable costs because of the restriction (under each of the ROs).

The one-off cost to reformulate PVC compounds as well as to test the finished cables was assumed to be approximately €300 000 per company. This amount includes 20 different tests[40] each of which has a cost of approximately of €10 000-15 000 (ECHA market survey).

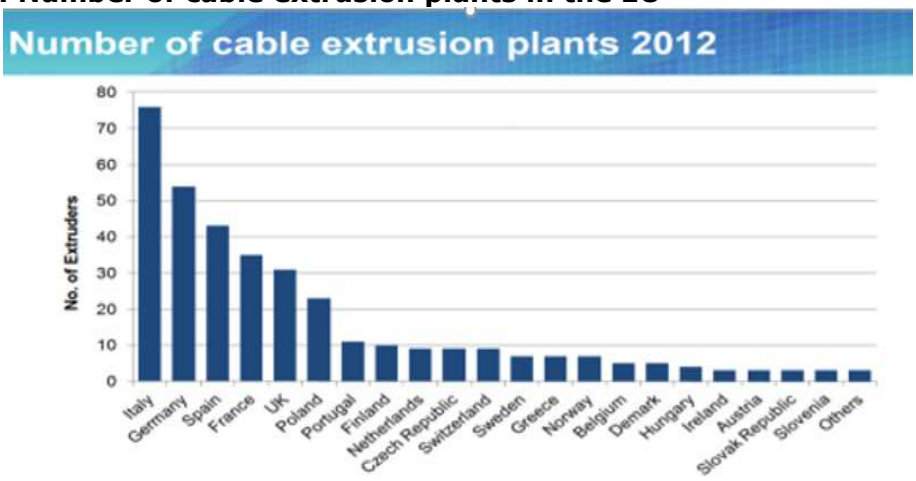
The exact number of PVC companies that would be affected by the restriction is unknown. Therefore, the Dossier Submitter adopted the following assumptions:

- As shown in Figure 11, there were 15 Member States with less than 10 extrusion plants in 2012.

[39] Please note that as reported in the main report, the difference between the option RO1 and RO3 is approximately €300 000 (annualised value), equivalent to approximately €4 million over the 20-year period. In other words the total cost of RO3 is €4 million higher compared to RO1 over the 20-year period. This difference captures the profit loss of substances' producers that would not be allowed to continue to export the substances under RO3. The profit loss is estimated on the basis that: approximately 5 % of the volume of manufactured substances containing CA:C14-17 is exported outside the EU, the price of substances containing CA:14-17 is approximately 1.06€/kg and that the profit margin for the sector is 12 %. 12 % is the average gross operating rate (2016-2020) of the economic activity: "Manufacture of other chemical products n.e.c. [C2059]". Data were extracted on 21/04/2022 from Eurostat Database.

[40] The testing costs refer specifically to the costs for testing PVC cables used in construction products. The compounds reformulated with an alternative need to be tested to verify their compliance with the relevant standards under the Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011, laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (https://eur-lex.europa.eu/eli/reg/2011/305/2021-07-16). Substances containing CA:C14-17 may however be used in articles other than construction products and – in that case – different types of tests would be required. The Dossier Submitter could not identify the testing costs for reformulating PVC compounds used in other types of articles, but the approximate costs of €300 000 can be considered a proxy for testing costs also in case of reformulating PVC compounds for cables that are used in other types of articles.

Figure 11: Number of cable extrusion plants in the EU



Source: PVC forum

- Assuming that in each of the Member States, there are 10 extrusion plants, it was then estimated that approximately 400 companies may be affected overall by this restriction in the EU.

Table 99: Calculation of one-off costs (total and annualised over 20 years at 3 %)

Country	Number of cable producers
Other countries (from Portugal onwards)(Figure 11)	160
Italy	70
Germany	50
Spain	40
France	35
Poland	20
Total (number of affected companies)	400
R&D cost per company (testing and revalidation included)	€300 000
Total one-off costs	€120 million
Annualised costs over a horizon of 20y	€8 million

These assumptions were triangulated with information from the ECHA market survey, which indicated that, in Italy, there are approximately 50 companies that could be affected by the restriction, including both PVC compound producers and PVC compounds & cable producers. For other Member States – Germany, Spain, France and Poland – the assumptions are based on Figure 11.

Dossier Submitter notes that some companies may have already phased out substances containing CA:C14-17 or will complete the substitution before the entrance into force of this restriction. Information on the exact number of companies that have already completed the substitution was however lacking. Therefore, the Dossier Submitter

conservatively assumed that each of the 400 companies would incur the one-off cost of €300 000 because of the restriction.

To estimate the increase in variable costs, the Dossier Submitter calculated first the variable costs for producing PVC compounds with substances containing CA:C14-17 in the baseline scenario, and then estimated the increase in variable costs expected because of the restriction.

Based on the available information, the concentration of CA:C14-17 in PVC ranges from 4 to 18 %.[41] For the impact assessment, the Dossier Submitter assumed an average concentration of 12 % in PVC compounds for cables, whilst noting that the average concentration of EC 287-477-0 in PVC cables manufactured Italy is 6 % (ECHA market survey) and that other concentration levels have been reported as summarised in Table 100.

Table 100: Reported concentration levels of substances containing CA:C14-17 in PVC compounds

Concentration	Source
18 %	EC 287-477-0 content within the PVC can be up to 18 % (CfE2#1474)
15 %	Up to 15 % (ECHA market survey)
15 %	Guida et al. (2020)
4 %	ECHA market survey (lower bound)
8 %	ECHA market survey (upper bound)
1 - >30 %	EC 287-477-0 content in Polymer preparations and compounds – this might include other polymers than PVC (BfR, 2022) Cf. Section A.2.2.2
1 -10 %	EC 264-150-0 content in Polymer preparations and compounds – this might include other polymers than PVC (BfR, 2022) Cf. Section A.2.2.2

Considering that the average cost per kg of PVC compound with substances containing CA:C14-17 is in the range of €2.5 (ECHA market survey), the baseline production costs of PVC compounds containing CA:C14-17 were estimated to be in the ballpark of €420 million, as explained in Table 101.

Table 101: PVC compounds production with substances containing CA:C14-17

Tonnage of substances containing CA:C14-17 used in PVC compounds (t/y)	PVC compounds production volumes (t/y)	PVC compounds production volumes (kg/y)	Approximate production costs (€)
20 268	170 000[1]	170 million	€420 million [2]

Note: [1] assuming a concentration of 12 % of substances containing CA:C14-17 in PVC compounds
[2] applying an average cost of €2.5/kg

[41] As reported in Table 100, some lower concentrations below 4 % were also identified. However this refer to Polymers, that might include other polymers than PVC.

One company interviewed by the Dossier Submitter that had successfully phased out substances containing CA:C14-17 from several PVC compounds that they manufacture indicated that the production costs of PVC compounds increased by approximately 2-4 % because of the phasing out of substances containing CA:C14-17. More specifically, the company in question removed EC 287-477-0 from PVC compounds used to manufacture certain types of PVC cables. Another company indicated that because of the substitution, the production costs (per kg of PVC compounds) increased by a few cents (ECHA market survey).

However, some stakeholders interviewed by the Dossier Submitter indicated that because of the recent general increase in the price of raw materials, it is extremely difficult to calculate the increase in variable costs attributable to the replacement of substances containing CA:C14-17 in PVC compounds.

Whilst noting these uncertainties and considering the overall information provided by relevant stakeholders on the available alternatives, the Dossier Submitter assumed the following for the purpose of estimating the restriction-induced increase in variable costs for this sector:

- 25 % of the tonnage of substances containing CA:C14-17 will be removed from PVC compounds formulations without replacement (expected to occur in PVC compounds for less demanding applications in terms of fire performance)
- 25 % of the tonnage of substances containing CA:C14-17 will be replaced by other alternatives (e.g. combination of flame retardant and plasticisers)
- 50 % of the tonnage of substances containing CA:C14-17 will be replaced by EC 264-150-0 (containing <0.1 % CA:C14-17).

When considering the removal of substances containing CA:C14-17 from PVC compounds, a 4 % increase in variable costs was assumed, which is in line with the information provided by the above-mentioned company that had successfully phased out (ECHA market survey). The Dossier Submitter notes that when substances containing CA:C14-17 are removed from PVC compound formulations, an increase in production cost could be expected because of the need to adapt other components in the formulation (ECHA market survey). In general, the Dossier Submitter expects that simply removing substances containing CA:C14-17 from PVC compounds would be only possible for less demanding applications.

When the substances containing CA:C14-17 are replaced by alternatives (assumed for 75 % of the overall tonnage), an increase in variable costs in the range of 10 % was assumed by the Dossier Submitter. While precise data are not available for quantifying the replacement costs in PVC compounds for more demanding applications, a higher percentage was applied in this case by the Dossier Submitter on the basis that the replacement costs can be expected to be higher for PVC compounds that need to comply with more stringent fire performance requirements and where the simple removal of substances containing CA:C14-17 would not qualify as a technically feasible alternative.

The Dossier Submitter calculated that under RO1, RO3, RO4a and RO4b, the PVC sector will incur an additional variable cost of approximately €36 million per year, expected to start at the end of the TP (Table 102). The annualised costs and the total costs for the PVC sector are reported in Table 103 and Table 104, respectively.

Table 102: Calculation of the increase in variable costs

Annual production of PVC compounds in the baseline scenario (using substances containing CA:C14-17)(kg)	Assumed costs per kg of PVC compounds	Total costs in the baseline scenario	Increase in production cost
42 million	€2.50	€105 million	€4.2 million (+4 %)
42 million	€2.50	€105 million	€10.5 million (+10 %)
84 million	€2.50	€211 million	€21 million (+10 %)
Total annual variable cost starting at the end of the 2-year TP		€420 million [1]	€36 million

Note: [1] as also reported in Table 101

Table 103: Present value (PV) of the variable costs and annualised figure over 20 years (assuming 2y TP)

Annual increase in variable costs (as from the end of the two-year TP)	PV in 2026[1]	PV in 2024[1]	Annualised costs over 20 years[2]
€36 million p.a.	€495 million	€467 million	€31 million p.a.

Note:

[1] The 2-year transition period is assumed to start in 2024. Therefore, the Dossier Submitter calculated first the present value (PV) in 2026 (on the basis that a constant annual increase in cost – expected to start in 2026 - is considered over 18 years). The present value in 2026 was then multiplied by the discounting factor $(1.03)^{-2}$, to derive the present value in 2024. The same approach was also applied in the following tables.

[2] This is the total costs over 18 years, annualised over 20 years at 3%.

Table 104: Total annual costs for the PVC sector (one-off costs and variable costs)

Annualised one-off costs	€8 million [1]
Annual increase in variable costs	€31 million [2]
Total compliance costs per year (annualised R&D + increase in production costs)	€39 million
Total compliance costs (PV)	€580 million

Note: [1] as reported in Table 99
[2] as reported in Table 103

The total compliance costs for the PVC sector were estimated at €580 million (NPV-20 years), equivalent to an annuity cost of €39 million per year assuming a social discount rate of 3 %.

E.3.2. Use in adhesives and sealants (Use#01)

The economic impacts on this sector were assessed in terms of consumer surplus loss because of the expected price increase of the affected products (OCFs and IG sealants). A consumer surplus loss occurs in the restriction scenario considering that sealants reformulated with alternatives are expected to be more expensive due to the higher price of alternative plasticisers and because of the need to adapt other raw materials in the sealant formulations. A separate analysis was conducted for each of the two subsectors.

Specifically, for assessing the impacts on this use, it is assumed that 80 % of the volumes of substances containing CA:C14-17 are used in OCFs and 20 % of the volumes are used in insulating glass (IG) polysulfide sealants.

The Dossier Submitter evaluated the available sources where the concentration levels of substances containing CA:C14-17 were reported in the affected product categories, see Table 105.

Table 105: Concentration of substances containing CA:C14-17 in sealants

Concentration	Mixture category	Source
10-15 % [1]	OCF	ECHA market survey
8-58 %[1]	Insulating glass polysulfide sealants	ECHA market survey
10-14 % (up to 20 %)	Different mixture categories, such as polysulphide, polyurethane, acrylic and butyl sealants	(ECHA, 2021b)
30 % in OCF [1]	OCF	(CfE1 #1357)
10 % -20 % [1]	IG sealants	(CfE1 #1357)
14-18 %	Different mixture categories, such as OCF, polysulphide (potting), acrylic sealants	(CFE2 #1493)
10-30 % [1]	OCF	SDS OCF Krimelte
10-30 % [4]	OCF	SDS HandiFoam
5-10 % [2]	OCF	SDS Dow Prof OCF
10-30 % [1]	OCF	SDS Penosil OCF
10-20 % [1]	OCF	PENOSIL OCF
1.0 - 10.0 % [1] [2] 10 - >30.0 % [1]	Adhesives and sealants - household, office or school use	(BfR, 2022) cf. Section A.2.2.2
<0.1 - >30.0 % [1] 1.0 - 30.0 % [2]	Adhesives and sealants - building and construction works (except cement-based adhesives)	(BfR, 2022) cf. Section A.2.2.2
1.0 - 20.0 % [1]	Adhesives and sealants - transportation industry	(BfR, 2022) cf. Section A.2.2.2
1.0 - 20.0 % [2]	Adhesives and sealants - paper and board related processes	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [1] [2]	Adhesives and sealants - woodworking and joinery (includes putty)	(BfR, 2022) cf. Section A.2.2.2

Concentration	Mixture category	Source
1.0 - 10.0 % [1] [2] 10.0 - >30.0 % [1]	Multi-component adhesives and sealants	(BfR, 2022) cf. Section A.2.2.2
0.1 - >30.0 % [1] 1.0 - 20.0 % [2]	Other adhesives and sealants	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [2] [3]	Building protection and sealants	(BfR, 2022) cf. Section A.2.2.2
0.1 - >30.0 % [1] [2]	Foams	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [2] 10.0 - 20.0 % [1]	Construction materials, auxiliary materials and sealants - not classified	(BfR, 2022) cf. Section A.2.2.2
1.0 - 20.0 % [1]	Adhesives for the construction sector	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [1]	Rubber glue	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [1]	Wood glue, wood glue	(BfR, 2022) cf. Section A.2.2.2
0.1 - 10.0 % [2]	Adhesives for the construction sector	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [1] [3] 0.1 - 10.0 % [2]	Adhesives – unclassified	(BfR, 2022) cf. Section A.2.2.2
0.1 - >30.0 % [1] 1.0 - 10.0 % [2] [3]	Building materials, sealants and adhesives – unclassified	(BfR, 2022) cf. Section A.2.2.2

Note: [1] concentrations range reported for EC 287-477-0
[2] concentrations range reported for EC 264-150-0
[3] concentrations range reported for EC 287-478-6
[4] concentration range reported for CAS 198840-65-2

For the impact assessment, the Dossier Submitter assumed that the average concentration of substances containing CA:C14-17 in one typical OCF can of 750 ml is 20 %.

Table 106: Estimated number of 750 ml-OCF cans produced (per year) with substances containing CA:C14-17

Used volumes of substances containing CA:C14-17 in OCF cans (t/y)	Approximate number of cans produced every year (750 ml)
37 250	250 million[1]

Note: it is assumed that each can of 750 ml contains 0.150kg of substances containing CA:C14-17

The prices of some OCF products formulated with substances containing CA:C14-17 were identified by the Dossier Submitter from internet-based sources. However, it is important to note that prices may differ depending on the brand and quantity purchased, see Table 107.

Table 107: Prices of OCF products where substances containing CA:C14-17 are used as plasticisers

Name of the product	Link	Price	SDS (link)	Plasticiser
Penosil - Krimelte (Easy gun foam all season)	link	€6.81 (750 ml can)	SDS	Alkanes, C14-17, chloro are used (CAS: 85535-85-9) in concentration of 10-30 %
PENOSIL Max Gap Filler Foam Sealant	link	€7.7 (750 ml can)	SDS	Alkanes, C14, chloro are used (CAS: 198840-65-2) in concentration of 10-30 %
Straw foam Penosil	link	€5.6 (435 ml can)	SDS	Alkanes, C14, chloro are used (CAS: 198840-65-2) in concentration of 10-20 %

To estimate the consumer loss resulting from the restriction, it was thus assumed that the average price per OCF can of 750 ml was €8 in the baseline scenario.

Whilst noting various uncertainties, this price is considered to be a reasonable assumption by the Dossier Submitter in view of the information available online.

In the cost estimation it was assumed that all products produced in the EU are sold on the EU market. However, this might not be the reality because companies may export a share of their products to non-EU markets. Potentially one third of the products produced in the EU could be exported to non-EU markets. However, at the same time significant quantities of OCF products may be imported to the EU (ECHA market survey). Without having more precise information, the Dossier Submitter assumed that all OCF products produced in the EU are bought by EU actors.

Prices of alternatives are significantly more expensive when compared to prices of substances containing CA:C14-17. As indicated in Table 97 and Table 96, EC 287-477-0 is particularly cheap compared to the alternative plasticisers available on the market.

Moreover, apart from the price difference, it is expected that the producers of sealants will incur additional costs due to the need to adapt their OCF formulations. Substances containing CA:C14-17 (notably EC 287-477-0) can provide different properties to the final products and no drop-in alternatives appear to be currently available (ECHA market survey). Therefore, in addition to using an alternative plasticiser, the producers of OCF products will have to change the overall formulation, leading to additional costs (ECHA market survey).

Production costs are expected to increase by approximately €3 for each kg of substance being replaced (ECHA market, survey). This cost estimate of approximately €3 for each kg of substance replaced is based on the know-how of one of the main producers of OCFs in Europe that was interviewed by the Dossier Submitter. This means that replacing 0.15 kg of substances containing CA:C14-17, corresponding to the typical concentration in one 750 ml OCF can, will increase the production cost by approximately €0.45 per can. For the purpose of this assessment and considering that the concentration of substances containing CA:C14-17 could be up by 30 %, it was conservatively assumed that the price

of one 750-ml can will increase by €0.9 because of the restriction (implying a 11 % price increase compared to the baseline price).

The consumer loss was then calculated by considering three possible price elasticities of demand (0, 0.5 and 1).

When price elasticity is assumed to be between 0.5 and 1, the consumer loss is due to both an increase in the price and a decrease in consumed quantities. When demand price elasticity is assumed to be exactly 0, the quantity of sales is not affected, and the consumer loss is uniquely attributable to the price increase, while sales are assumed to be the same as in the baseline.

Table 108: Total consumer surplus loss, assuming various demand price elasticities (E_d)

When E_d = 0.5	When E_d = 1	When E_d = 0
€219 million	€212 million	€225 million

Note: The Dossier Submitter could not identify a study on the demand price elasticities of OCF products, so the expected consumer surplus loss was calculated for three different scenarios.

When applying different assumptions on the demand price elasticity, the consumer surplus loss was estimated to be between €212 million (for E_d = 1) and €225 million (for E_d = 0).

Whist noting the minor differences depending on the assumptions made, the Dossier Submitter decided to bring forward the central estimate of €219 million (corresponding to E_d = 0.5) .

Table 109: Consumer loss – present value (PV) and annualised figures

€219 million	Annual consumer surplus loss brought forward by the Dossier Submitter, based on the demand price elasticity of 0.5 (central estimate) – expected to start at the end of the 2-year TP
€3 billion	PV in 2026
€2.8 billion	PV in 2024
€190 million	Annualised value over 20 years

The same approach was applied by the Dossier Submitter to calculate the consumer surplus loss resulting from the expected price increase in IG sealants.

The total variable production costs are assumed to increase by approximately €3 for each kg of substance being replaced (ECHA market, survey), meaning that replacing 0.2 kg of substances containing CA:C14-17 in 1 kg of IG sealants may lead to an increase in the price of IG sealants – assumed to be 4.5 €/kg[42] under the baseline scenario - by approximately €0.6.

[42] It was not possible to retrieve the price of IG sealants formulated with substances containing CA:C14-17 from internet-based sources. However, one company producing IG sealants and that was interviewed by the Dossier Submitter indicated that the average price is in the range of 4-5 €/kg.

Table 110: Production volumes and value of IG sealants produced with substances containing CA:C14-17

Used volumes of substances containing CA:C14-17 (t/y)	Produced sealants (t/y)	Produced sealants (kg/y)	Assumed price of IG sealant (€/kg)	Approximate production value (€)
9 000	47 000	47 million	€4.50	€211 million

Table 111: Total consumer surplus loss assuming a demand price elasticity of 0/0.5/1 (€)

When E_d = 0.5	When E_d =1	When E_d=0
€27 million	€26 million	€28 million

When applying a demand price elasticity of 0.5, the consumer surplus was estimated at approximately €27 million and when assuming a totally rigid demand, with a demand price elasticity of 0, the consumer surplus loss was estimated at approximately €28 million.

Again, the Dossier Submitter brought forward the central value of €27 million as a measure of social cost for this sector under RO1, RO3, RO4a and RO4b.

Table 112: Consumer loss – present value (PV) and annualised figure (€)

€27 million	Annual consumer surplus loss brought forward, based on demand price elasticity of 0.5 (central estimate) – to start at the end of the 2-year TP
€370 million	PV in 2026
€350 million	PV in 2024
€24 million	Annualised value over 20 years

Table 113: Total consumer surplus loss – OCF and IG sealants (annualised surplus loss and PV) (€)

€214 million	Total annualised consumer surplus loss (both sealant sectors)
€3.2 billion	PV – 20-year period

As reported in Table 113, the total consumer loss was estimated at €3.2 billion (NPV – 20-year time period), equivalent to €214 million per year.

E.3.3. Use in rubber (Use#02)

This section reports the calculations of the one-off costs (reformulation and testing) and variable costs for the rubber sector. Information on one off-cost was provided to the Dossier Submitter by one of the EU producers of rubber conveyor belts for underground activities(ECHA market survey). Moreover, the Dossier Submitter hold bilateral exchanges with two other producers of rubber conveyor belts to gather other company specific substitution costs. However, the two companies were not able to provide information on

the economic impacts of the restriction on them. Also, no information on the economic impacts of the restriction on the rubber sector was provided by the relevant EU industry association.

Table 114: Calculation of one-off costs - present value (PV) and annualised figure

Quantitative indicator	Considerations and assumptions for the calculation of one-off costs
€6 000	The costs for verifying product compliance with the relevant EN standards (lower bound, ECHA market survey, CfE2#1474)
€30 000	The costs for verifying product compliance with the relevant EN standards (upper bound, ECHA market survey, CfE2#1474))
€30 000	Assumed cost per product (upper bound)
10	Assumed number of companies producing rubber conveyor belts in the EU (ECHA market survey)
10	Assumed number of products to be tested by each affected company.
€3 million	Total one-off costs, based on the upper bound cost (total for all companies)
€0.2 million	Annualised costs

In addition to one-off costs expected to occur during the TP, an increase in production costs is expected due to the higher price of alternatives. These incremental annual costs assume that substances containing CA:C14-17 are replaced by LCCP (264-150-0) with a concentration of PBT/vPvB congeners below 0.1 %. While the price of 264-150-0 is reported to be approximately 1.25-1.5 times the price of EC 287-477-0 (currently used by the interviewed companies), a price difference of 100 % (i.e. twice higher price) was assumed to account for potential additional costs that may result because of the need to adapt other components in the rubber mixture.

Table 115: Calculation of the annual increase in variable costs for companies producing rubber conveyor belts for underground activities

Alternatives (EC number)	Assumed price difference vs substances containing CA:C14-17 (EC 287-477-0) (€/kg)	Volumes to be replaced with the alternative (kg)	Direct substitution costs (annual) – to start at the end of the 2-year TP (€)
LCCP (EC 264-150-0) with a concentration of PBT/vPvB congeners below 0.1 %	1	3.9 million	€3.9 million

Table 116: Calculation of the variable costs – present value (PV) and annualised figure (€)

€3.9 million	Annual cost starting in 2026
€54 million	PV in 2026
€50 million	PV in 2024
€3.4 million	Annualised value over 20 years

Table 117: Total costs for the rubber sector – present value (PV) and annualised costs (€)

€3.6 million	Total annualised costs
€54 million	PV in 2024

As reported in Table 117, the cost for the rubber sector was estimated at €54 million (NPV – 20-year time period), equivalent to approximately €3.6 million per year.

E.3.4. Use in metalworking fluids (Use#03)

The impacts on the metalworking fluids sector are expected to differ under the considered restriction options. In the following, the Dossier Submitter reports the calculations of the costs for this sector under RO1(and RO3), RO4a and RO4b, as well as the main assumptions underpinning the analysis.

Under RO1 (and RO3), the additives suppliers, producers of metalworking fluids, and the metalworking sector (relying on these metalworking fluids) are expected to incur profit losses. This response is expected on the basis that the 2-year TP is deemed too short for the sector to identify, test and shift to suitable alternatives (ECHA market survey).

Under RO4a the metalworking fluids sector is not expected to be impacted (so the RO4a is equivalent to the baseline scenario for this sector).

Finally, under RO4b, the metalworking fluids' producers are expected to shift (at a certain cost) to a non-chlorinated paraffin-based alternative during the 7-year TP.

Table 118: Estimation of volumes of MWFs produced in the EU with substances containing CA:C14-17

Type of MWF [1]	Substance volumes (1/3 of the tonnage attributed to each type of MWFs) (t)	Conc. low (%)	Conc. high (%)	Central conc. (%)	Volumes of MWFs produced in the EU with substances containing CA:C14-17 (t)[3]
Low concentration	1 284	5 %	25 %	15 %	8 600
Medium concentration	1 284	25 %	50 %	38 %	3 400
High concentration	1 284	50 %	90 %	70 %	1 800

Type of MWF [1]	Substance volumes (1/3 of the tonnage attributed to each type of MWFs) (t)	Conc. low (%)	Conc. high (%)	Central conc. (%)	Volumes of MWFs produced in the EU with substances containing CA:C14-17 (t)[3]
Total	3 853[2]				13 800

Note: [1] Types of MWFs were identified based on the information collected by the Dossier Submitter (ECHA market survey). For each class a central value – between the low and the high concentration - was taken forward by the Dossier Submitter to calculate the volumes of MFWs attributable to each class. [2] Approximately 5 % of the total tonnage of substances containing CA:C14-17 is used in the MWFs. [3] The volumes were derived by dividing substance volumes with the concentration (central value).

The Dossier Submitter found very little information on the prices of MWFs containing CA:C14-17 and no information on prices was provided by companies that participated in the sector specific survey organised by the Dossier Submitter.

Therefore, based on the information retrieved from internet-based sources, the Dossier Submitter assumed that the price of a MWF containing CA:C14-17 is €6/L[43] in the baseline scenario. While noting that prices might change across brands and types of MWFs, the Dossier Submitter considers this value a plausible approximation for the price of MWFs manufactured with substances containing CA:C14-17. The value of 13 800 tonnes of MWF containing CA:C14-17, produced every year in the EU, was therefore estimated by the Dossier Submitter to be approximately €80 million.

The Dossier Submitter also calculated the value of the affected MWFs, with a different method, by assuming that 5 % of all the EU MWF products – currently produced in the EU - use substances containing CA:C14-17, as extreme pressure additives. The Dossier Submitter applied this percentage on the basis that the applications where these substances are used appear not to account for more than 5 % of the overall metalworking processes (CfE#1332). Considering that the EU MWF market was €2.44 billion[44] in 2020, the Dossier Submitter estimated – with this second method – that the value of the affected products could be approximately €122 million[45].

A central estimate of €100 million was then taken forward by the Dossier Submitter as the basis for the calculation of profit losses, as reported in Table 119.

In the quantification of economic impacts for this sector the Dossier Submitter assumed that the metalworking formulators will not be able to shift to an alternative during a 2-year transition period.

The additives suppliers are expected to incur profit losses due to the impossibility to

[43] BUY HOUGHTON Houghto-Draw TD51 x 20 litres (lubricantsupplies.co.uk) (£105.05/20*1.19). 1.19 corresponds to the average exchange rate over the 6th May-14th April period retrieved from the ECB database: (https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/eurofxref-graph-gbp.en.html)

[44] Europe Metalworking Fluids Market Share and Statistics - 2027 (gminsights.com)

[45] 5 % of €2.44 billion.

continue supplying substances containing CA:C14-17 to the metalworking fluids producers and metalworking fluids producers will incur profit losses for having to halt the production (and thus the sales) of metalworking fluids with substances containing CA:C14-17. Finally, the part of the metalworking sector – which requires the use of metalworking fluids with substances containing CA:C14-17 – will incur profit losses from not being able to supply metal parts, the forming and/or the cutting of which requires the use of metalworking fluids with substances containing CA:C14-17.

Considering that the imports of metal parts worked with the use of metalworking fluids produced with substances containing CA:C14-17 will still be allowed after the expiration of the 2-year transitional period, it is possible that some companies will decide to relocate their activities instead of ceasing the activity, relying on the use of metalworking fluids with substances containing CA:C14-17. In any of the two scenarios (production closure or relocation), there will be a producer surplus loss for EU companies.

Table 119: Calculation of profit losses for the different actors in the metalworking sector

EU metalworking market	Value of the production sold (annual) (€)	Assumed profit margin (%)	Producer surplus loss (annual) – starting at the end of the 2-year TP (€)
1. Extreme pressure additives' suppliers [1]	€2.8 million	12 %[4]	€0.34 million
2. Metalworking fluids' producers [2]	€100 million	5 %[5]	€5 million
3.Metalworking sector - using MWFs [3]	€3 billion	8 %[6]	€250 million
Total (profit loss for one year)			€260 million (rounded value)

Note: [1] For calculating the production value of extreme pressure additives (volumes of substances containing CA:C14-17 used in the production of metalworking fluids) a price of 1.06 €/kg was assumed for the substances containing CA:C14-17. Based on information retrieved from internet and the relevant stakeholders (that contributed to the calls for evidence or that were interviewed by the Dossier Submitter), the price of substances containing CA:14-17 appears to range between 1 and 1.8 €/kg. In particular, the price of EC 287-477-0 – the substance accounting for most of the volumes compared to other substances - is approximately 1 €/kg.

[2] The value of the metalworking fluids produced with substances containing CA:C14-17 was calculated in two different ways, as explained in the sections below (following pages).

[3]Production value of metal parts formed with the use of metalworking fluids produced with substances containing CA:C14-17, was determined by assuming that 5 % of the EU turnover of the activity C255: "Forging, pressing, stamping and roll-forming of metal; powder metallurgy" derives from metalworking processes that rely on the use of metalworking fluids containing CA:C14-17. In the estimation of the affected market, a 5 % share was applied based on the information gathered from stakeholders, according to which approximately 95 % of the metalworking market does not use meta working fluids containing CA:C14-17.

[4] Average gross operating rate (2016-2020) of the economic activity: "Manufacture of other chemical products n.e.c. [C2059]". The class includes also the manufacture of lubricating oil additives. Data were extracted on 21/04/2022 from Eurostat Database.

[5] Average gross operating rate (2016-2020) of the economic activity: "Manufacture of refined petroleum products [C192]". The class includes the manufacture of lubricating oils. Data were extracted on 21/04/2022 from Eurostat Database.
[6] Average gross operating rate (2016-2020) of the economic activity: "Forging, pressing, stamping and roll-forming of metal; powder metallurgy [C255]". Data were extracted on 21/04/2022 from Eurostat Database.

In line with the SEAC paper on producer surplus loss, profit losses were considered over 4 years and the total profit loss – annualised over 20 years – was estimated at €70 million per year. The Dossier Submitter applied a default period of 4 years of profit loss because the availability of alternatives in this sector resembles a no-SAGA (suitable alternative available in general) case. The total profit loss was estimated to be €1 billion (NPV over the 20-year analytical period), as reported in Table 120.

Table 120: Total costs for the metalworking fluid sector – present value (PV) and annualised costs (€)

€70 million	Total annualised costs (rounded up value)
€1 billion	PV in 2024

Under RO4a, no impacts are expected for this sector considering that this restriction option includes a specific derogation for the specific use.

Under RO4b, the metalworking fluid sector is expected to shift to a non-chlorinated paraffin-based alternative during the 7-year TP. The tables below report the calculation of the one-off costs (reformulation and testing) and the increase in annual variable costs (expected to start after the 7-year transition period).

The one-off costs (reformulation and testing) were estimated to be €90 million for the producers of metalworking fluids, as reported in Table 122.

In the calculation of the incremental variable costs, the Dossier Submitter applied three different methods to verify the consistency across the different pieces of information and the data collected from stakeholders that participated in the calls for evidence and ECHA market survey. In all three cases, the quantified annual costs – expected to start at the end of the transition period - were in the range of €12 million per year (€100 million, NPV - 20 years).

The one-off reformulation costs are expected to occur over the 7 year-time period. It is however not possible to predict when this will exactly occur for each of the companies affected.

Information on the exact number of companies producing MWFs with substances containing CA:C14-17 is missing, so several assumptions had to be made by the Dossier Submitter to estimate the number of companies expected to be impacted by the restriction and these are reported in Table 121 and Table 122, respectively.

Table 121: Estimation of the number of companies producing MWFs with substances containing CA:C14-17

96 companies	Upper bound	Assuming annual consumption (per company) of 40 tonnes [1]

23 companies	Lower bound	Assuming annual consumption (per company) of 170 tonnes [2]

Note: [1] Approximately 3 800 tonnes of substances containing CA:C14-17 are used in the production of metalworking fluid products. 40 tonnes were used for calculating the upper bound on the basis that one medium-size company that participated in the ECHA market survey indicated that they use this tonnage per year (3853t/40t).
[2] Another company indicated that they use 170 tonnes per year. This higher tonnage was used for deriving the lower bound estimate of the number of companies that could be affected by the restriction (3853t/170t).

Table 122: Calculation of one-off costs

Quantitative parameter	Upper bound estimate	Lower bound estimate	Value brought forward in the calculation of costs
Number of companies producing MWFs with substances containing CA:C14-17	23	96	59
Assumed one-off cost per product	€15 000	€15 000	€15 000
Assumed number of products per company	100	100	100
Total one-off cost per company	€1.5 million	€1.5 million	€1.5 million
Total one-off costs (for all affected companies)	€34 million	€144 million	€90 million

Note: assumption based on the ECHA market survey

The increase in variable cost was calculated by applying the following three different methods, as reported in Table 123, Table 124 and Table 125.

- The first method calculates the variable costs, by considering uniquely the price difference between substances containing CA:C14-17 and the alternatives.
- The second method calculates the possible increase in the overall raw material costs expected because of the substitution.
- Finally, the third method calculates the increase in variable costs by using the cost increase per company – collected from stakeholders that participated in the ECHA market survey – and extrapolating this information to all companies that are expected to be impacted by the restriction.

With the exception of RSS Molybdenum, bis(dibutylcarbamodithioato)di-μ-oxodioxodi-, sulfurized (the price of which is approximately 18 €/kg), the price of alternative extreme pressure additives is 1.32 to 7 times the price of substances containing CA:C14-17[46].

[46] Prices of alternative extreme pressure additives are reported in Table 98

Table 123: Calculation of the increase in variable costs (1st method)

Volumes of substances containing CA:C14-C17 used as extreme pressure additives in MWFs (kg)	Annual increase in variable costs (lower bound, assuming price of alternatives is 1.3 €/kg)(€)	Annual increase in variable costs (upper bound, assuming price of alternatives is 7€/kg) (€)	Annual increase in variable costs (central estimate) - starting in 2031 (€)
3.8 million	€910 000	€23 million	€12 million

Note: As in Table 119, a price of 1.06 €/kg was assumed for the substances containing CA:C14-17.

Table 124: Calculation of the increase in variable costs (2nd method)

Production value of MWFs based on substances containing CA:C14-17 (€)	Assumed share of raw material costs (%)[1]	Raw material costs in the baseline (€)	Increase in raw material costs (lower bound, +20 %) (ECHA market survey) (€)	Increase in raw material costs (upper bound, + 30 %) (ECHA market survey) (€)	Increase in raw material costs (central estimate) – starting in 2031 (€)
€100 million	50 %	€50 million	€10 million	€15 million	€12.5 million

Note: [1] The basic raw material costs as a share in the costs of basic industry vary between around 10 % and over 50 % (Wilting and Hanemaaijer, 2014). The Dossier Submitter applied conservatively the share of 50 %, noting that this might lead to an overestimation of the variable costs in the baseline and so to an overestimation of the additional costs resulting from the restriction.

Table 125: Calculation of the increase in variable costs (3rd method)

Annual increase in costs (per company) lower value (ECHA market survey) (€)	Annual increase in production costs (per company) upper estimate (ECHA market survey) (€)	Average cost per company (€)	Assumed number of companies	Total annual cost per year (for all companies) – starting in 2031 (€)
€100 000	€300 000	€200 000	59[1]	€12 million

Note: [1] as per Table 122

Table 126: Total variable costs over 13 years (starting in 2031) and annualised values over 20 years

€12 million	Annual increase in variable costs starting in 2031. Considering the 20-year analytical period the costs are considered over 13 years, from 2031 to 2044. Production with alternatives is assumed to start in 2031, once substitution is completed (after 7-year TP).
€127 million	PV in 2031
€103 million	PV in 2024
€7 million	Annualised cost over 20 years

Table 127: Total compliance costs for the metalworking fluid sector (under RO4b) – present value (PV) and annualised costs

€13.3 million	Total annualised costs (rounded up value)
€200 million	**PV in 2024**

The total compliance costs under RO4b (one-off costs and incremental variable costs) were estimated to be approximately €200 million (NPV – 20-year time period), equivalent to €13.3 million per year (Table 127).

E.3.5. Use in paints and coatings (Use#04)

Substances containing CA:C14-17 (predominately EC 287-477-0) are used in the manufacturing of marine and protective coatings in various concentrations (Table 128).

Table 128: Reported concentration of substances containing CA:C14-17 in paints and coatings

Concentration	Mixture category	Source
5-10 % [1]	Chlorinated rubber marine coating	ECHA market survey
5 %[2]	Flame retardant paints	ECHA market survey
4-15 %[2]	Intumescent coatings	ECHA market survey
5-10 %[1]	Flame retardant paint and marine coatings	ECHA market survey
1-20 %	Different mixture categories, such as organic solvent borne chlorinated rubber system, intumescent coatings, etc.	(ECHA, 2021b)
0.1 - 10.0 % [1] [2]	Aerosol paints and coatings	(BfR, 2022) cf. Section A.2.2.2
0.1 – 1.0 % [1] [3] 1.0 – 20.0 % [1] [2]	Paints/coatings - Decorative	(BfR, 2022) cf. Section A.2.2.2
0.1 - 20.0 % [1] 0.1 - 30.0 % [2]	Paints/coatings - Protective and functional	(BfR, 2022) cf. Section A.2.2.2
0.1 - 10.0 % [1] 1.0 - 20.0 % [2]	Marine vessel coatings (excludes anti-fouling products)	(BfR, 2022) cf. Section A.2.2.2
0.1 - 10.0 % [1] 1.0 - 10.0 % [2]	Automotive and aerospace coatings	(BfR, 2022) cf. Section A.2.2.2
0.1 - 20.0 % [1] 1.0 - 20.0 % [2]	Other paints and coating materials	(BfR, 2022) cf. Section A.2.2.2
0.1 - 10.0 % [1] 1.0 - 10.0 % [2]	Antifouling products (Biocides)	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [1] 0.1 - 20.0 % [2]	Primers	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [1]	Universal paints including primers	(BfR, 2022) cf. Section A.2.2.2
0.1 - 10.0 % [2]	Enamel paints including primers, thinners and additives	(BfR, 2022) cf. Section A.2.2.2

Concentration	Mixture category	Source
1.0 - 10.0 % [1] 0.1 - 1.0 % [2]	Alkyd paint	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [1]	Hardener and other paint additives	(BfR, 2022) cf. Section A.2.2.2
0.1 - 1.0 % [1]	Interior wall paint	(BfR, 2022) cf. Section A.2.2.2
0.1 - 10.0 % [2] 1.0 - 10.0 % [4]	Acrylic paint	(BfR, 2022) cf. Section A.2.2.2
0.1 - 1.0 % [2]	Car paint	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [2]	Tinting paste/colour and colour pigments	(BfR, 2022) cf. Section A.2.2.2
0.1 - 10.0 % [1] 1.0 - 10.0 % [2]	Paints and primers - unclassified	(BfR, 2022) cf. Section A.2.2.2
0.1 - 10.0 % [1]	Paints, varnishes and dyes - not classified	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [1]	Underbody preserver for vehicles	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [2]	Metal surface treatment products	
1.0 - 10.0 % [1] 10.0 - 20.0 % [2]	Metal surface treatment agent - non-galvanic	(BfR, 2022) cf. Section A.2.2.2
1.0 - 10.0 % [2]	Anti-corrosion agent	
>30.0 % [1]	Anti-corrosive preparations for vehicles	(BfR, 2022) cf. Section A.2.2.2
0.1 - 10.0 % [1] 1.0 - 10.0 % [2]	Antifouling products for underwater devices (Biocides)	(BfR, 2022) cf. Section A.2.2.2
8 %		Assumed average concentration

Note: [1] concentrations range reported for EC 287-477-0
[2] concentrations range reported for EC 264-150-0
[3] concentrations range reported for EC 287-196-3
[4] concentrations range reported for EC 263-004-3

One of the major EU companies in this sector uses approximately 50 tonnes per year of Substances containing CA:C14-17 to produce marine coatings. Assuming that there might be smaller companies using less than half of this tonnage, the Dossier Submitter estimated that approximately 50 companies might be impacted by this restriction in the EU[47].

According to the information provided by stakeholders, the main impacts relate to testing costs (internal and external testing that will be carried out in the restriction scenario to verify the compliance of products with the relevant product requirements and EN standards). A possible increase in variable costs because of substitution was not indicated as a relevant factor by the companies operating in this sector.

[47] This sector uses approximately 1000 tonnes of substances containing CA:C14-17 per year, therefore the Dossier Submitter assumed that each company affected by this restriction is using 20 tonnes of substances containing CA:C14-17.

Information on the testing costs displayed in Table 129 were provided by one company producing marine coatings (CfE#1330).

Table 129: Calculation of one-off costs

Quantitative input	Information on the quantitative inputs and underlying assumptions
€200 000[48]	The cost for a test package (which can cover several coating systems). All internal and external tests are included. (ECHA market survey)
50	Number of companies that are assumed to be affected by the restriction (ECHA market survey)
€10 million	Considering that a test package covering several coating systems costs approximately €200 000, it was estimated the one-off cost for the above 50 companies would be in the range of €10 000 0000
€0.7 million	Annualised costs over 20-year time period.

The total cost for this sector - under RO1 (RO3), RO4a and RO4b - was estimated at €10 million (NPV – 20-year time period), equivalent €0.7 million per year.

E.4. Risk reduction capacity

E.4.1. Avoided emissions

For each restriction option, the Dossier Submitter calculated the emissions of CA:C14-17 to the environment avoided over 20 years in comparison with the baseline.

The following likely responses of industry for each of the uses are perceivable:

1. *Remove substance containing CA:C14-17 and do not replace it or use a different polymer for the same use*. In practice, it means that the use of the substances is completely stopped and hence the tonnage used (input for the estimation of releases) is set to 0.
2. *Replace the substance with other substances (distinct from chloroalkanes).* The use of the substances is completely stopped and replaced with a substance from another family which does not contain any CA:C14-17 congener. In practice, the tonnage is also set to 0.
3. *Replace the substance with chloroalkanes containing < 0.1 % CA:C14-17*. The tonnage is set to 0 for all substances for which it is not possible to reduce the concentration of CA:C14-17 below 0.1 % (EC 287-477-0 and Di-, tri- and tetrachlorotetradecane); and set to 0.1 % of the baseline tonnage for the substances for which it is possible to reduce the concentration of CA:C14-17 below

[48] The company indicated that the total cost to it could be above €1 million, considering the number of products manufactured by this actor (CfE2#1483). The Dossier Submitter could not however identify the number of products that each of the affected companies would have to test. The Dossier Submitter therefore notes that the overall costs might differ among the affected companies. Therefore, as part of the sensitivity analysis, all the cost-effectiveness ratios of the four restriction options were re-calculated - after multiplying by a factor of 3 all the estimated one-off costs - to test their sensitivity to changes in this parameter.

0.1 % (Paraffin waxes and hydrocarbon' waxes, chloro, sulfochlorinated, saponified'; 'Paraffin waxes and hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified'; EC 269-145-7 and unregistered substances). It is also assumed that the tonnage of EC 264-150-0 (LCCP) increases to compensate the reduced tonnage of the other substance, and 0.1 % of this tonnage is taken into account in the calculation of the releases.

4. *No alternative, closure of the facility and complete cease of production/use*. The use of the substances is completely stopped and hence the tonnage used (input in the release estimation) is set to 0.

For each use, the likely response from industry is a combination of one or more of the scenarios presented above. This is detailed in section 2.3.1 of the main report and Appendix E.3.

- Use#00: it is assumed that 25 % of companies follow scenario 1, 25 % follow scenario 2 and 50 % follow scenario 3.
- Use#01: it is assumed that 100 % of companies follow scenario 2.
- Use#02: it is assumed that 100 % of companies follow scenario 3.
- Use#03: it is assumed that 100 % of companies follow scenario 4.
- Use#04: it is assumed that 100 % of companies follow scenario 2.
- Use#05: it is assumed that some companies already use substances with chloroalkanes containing < 0.1 % CA:C14-17, and in case they are using substances with chloroalkanes containing > 0.1 % CA:C14-17, it is assumed that 100 % of companies follow scenario 3.
- Use#07: it is assumed that 100 % of companies follow scenario 2.

These assumptions on the likely response from industry have been combined with the description of the restriction options to calculate the new input tonnages for the release estimation.

- RO1 (ban on placing on the market): manufacture is still possible for export (tonnage exported is assumed unchanged compared to baseline), and to provide for the use of substances with CA:C14-17 < 0.1 %.
- RO2 (ban on placing on the market and use): in terms of release estimation, it is the same as RO1 because the avoided releases from banning the use cannot be quantified.
- RO3 (ban on the manufacturing and placing on the market): in terms of release estimation, it is the same as RO1 regarding releases from use; however, export would be banned and the remaining tonnage manufactured would be only to provide for use of substances with CA:C14-17 < 0.1 %.
- RO4a (ban on placing on the market, with a derogation for Use#03): in terms of release estimation, it is the same as RO1 except for Use#03 which remains unchanged compared to the baseline.
- RO4b (ban on placing on the market, with an extended transitional period for Use#03): in terms of release estimation, it is the same as RO1 but releases from Use#03 will continue for a longer duration than for other uses (7 years instead of 2).

Finally, the yearly releases (after the end of transitional periods) were calculated using the

same parameters as described in section B.5 and taking into account the new input tonnages as described above. The releases over 20 years reported in Table 130 were then calculated by summing releases during the transitional period (equal to baseline releases) and releases after the transitional period has elapsed (estimates with new input tonnages).

Table 130: Tonnage manufactured and used, and total releases to the environment after the transitional period, under each RO (tonnes of CA:C14-17 per year)

	Tonnage manufactured and used after the transitional period (tonnes of CA:C14-17 per year)		Total releases to the environment after the transitional period (tonnes of CA:C14-17 per year)	
	Tonnage manufactured	**Tonnage used**	**Lower bound**	**Upper bound**
Baseline - all Uses	33 000	55 000	5 214 (~ 5 200)	6 284 (~6 300)
Baseline - Use#03 only[49]	2 700	2 700	34	250
RO1	2 475	14	4.9	5.4
RO2	2 475	14	4.9	5.4
RO3	14	14	0.65	1.2
RO4a	5 192	2 731	41	259
RO4b	2 475	14	4.9	5.4

E.4.2. Additional calculation of avoided emissions and economic considerations

During the Annex XV Restriction proposal consultation, some respondents requested to increase the concentration limit of CA:C14-17 in LCCP to 1 % instead of 0.1 %. To assess how this increase limit would affect the releases under RO4b (option B), the Dossier Submitter has recalculated the releases and avoided releases by considering a concentration limit of 1% of CA:C14-17 in all chlorinated paraffins instead of 0.1 %. The difference is estimated to be an additional release of 115-254 tonnes in total over the next 20 years. For the calculation, it is assumed that:

- the transition period is 7 years (unchanged)
- the tonnage of chlorinated paraffin alternatives containing < 1% CA:C14-17 placed on the market would remain unchanged (no increase).
- industry of the metal working fluid sector would replace the substances with chlorinated paraffin alternatives containing < 1% CA:C14-17 at the end of the transition period, instead of switching to alternatives that contain no CA:C14-17.

[49] Including releases from manufacturing and waste stage strictly related to Use#03.

- the reaction of the industry in the other sectors would not change (in other terms, it is assumed that those companies that were assumed to switch to chlorinated paraffins with up to 0.1 % CA:C14-17 would switch to chlorinated paraffins with up to 1 % CA:C14-17, and that those companies that were assumed to remove the substances completely, replace them with non-chlorinated paraffin alternative or close their business, would continue to do so). In terms of economic impacts, this scenario would imply lower substitution costs for the metal working fluid sector, because the sector would have the possibility to shift to EC 264-150-0 with a concentration limit of ≤ 1 % (which is much cheaper compared to other alternatives, which appear to be up to 7 times more expensive). Specifically, the total substitution costs would be in the range of €97 million, so approximately €100 million less over 20 years compared to the costs estimated under RO4b.
- If all current users (for all uses) would switch to chlorinated paraffin with a concentration limit of 1 % instead however, the releases could be expected to represent about 1 300-1 600 additional tonnes of CA:C14-17 over the next 20 years in comparison with estimated releases under RO4b.

Some stakeholders also requested to increase the transition period for metal working fluid under RO4b (option B) and the transition period of 12 or 15 years have been considered.

A transition period of 12 years for metal working fluid before switching to alternatives containing less than 0.1 % of CA:C14-17, instead of 7 years, would lead to additional emissions of approximately 170-1250 tonnes of CA:C14-17 over 20 years. A transition period of 15 years instead of 7 years would lead to additional emissions of approximately 270-2000 tonnes of CA:C14-17 over 20 years. This calculation assumes that all other parameters, including the OCs and RMMs to minimise the releases during the transition period, are unchanged.

The Dossier Submitter notes that in case a derogation will be granted for 12 years or 15 years instead of 7 years, there will be no implications in terms of the overall one-off costs and annual substitution following the completion of the substitution process. However, considering that the companies will start incurring higher variable costs later compared to a scenario with a 7-year transition period, the overall costs over 20 years will be lower (€152 million and €126 million with a transition period of 12 and 15 years respectively compared to €198 million, in case of a transition period for 7 years).

Appendix F: Assumptions, uncertainties and sensitivities

The key input parameters and assumptions for the exposure assessment and the impact assessment of the different restriction options are summarised in sections B.5 Exposure assessment and Appendix E, respectively. Appendix F identifies the main uncertainties associated with either the input parameters or the methodological approaches used. It also explores the sensitivity of key input parameters to the calculation of the release estimates and the corresponding impact assessment. Whenever possible, the sensitivity has been explored by the Dossier Submitter in a simple quantitative manner.

F.1. Identification of uncertainties

The uncertainties identified by the Dossier Submitter are summarised in Table 131.

Table 131: Identified key uncertainties

#	Related section(s)	Short description of the uncertainty	Standard uncertainty [1]	Source of uncertainty	Assessment of the uncertainty
U1	1.2.2, 2.2.2 and Appendix B.1	Uncertainty on the list of substances potentially affected by the restriction proposal.	No	Input parameter	Qualitative (cf. section F.2.3)
U2	1.3.1 and Appendix B.5	Potential overestimate of the tonnages released to the environment	No	Input parameter	Qualitative (cf. section F.2.3)
U3	1.3.1 and Appendix B.5	Uncertainty related to imported mixtures and articles (tonnage, tonnage of CA:C14-17 in imported articles, impact of a lower concentration limit for mixtures and articles)	No	Input parameter	Qualitative (cf. section F.2.3)
U4	1.3.1 and Appendix B.5.2	Uncertainty re. the proportion of CA:C14-17 in the Chloroalkanes other than the one listed in the Candidate List. The fraction of CA:C14-17 in the substances EC 264-150-0, EC 269-145-7, 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified' may be lower or higher than the estimated 10 % by the Dossier Submitter for the release estimates.	No	Input parameter	Quantitative (cf. section F.2.1)
U5	1.4.3 and Appendix B.5.2	Uncertainty on the treatment of the industrial waste. Industrial waste may not all be incinerated/destroyed.	No	Input parameter	Quantitative (cf. section F.2.1)
U6	1.4.3 and Appendix B.5.2	Uncertainty on the WWTP effectiveness. According to the registrants, high biodegradation can take place in WWTP (OECD 314B study results submitted by the registrants during the calls for evidence (CfE2 #1527)).	No	Input parameter	Quantitative (cf. section F.2.1)

#	Related section(s)	Short description of the uncertainty	Standard uncertainty [1]	Source of uncertainty	Assessment of the uncertainty
U7	1.4.3 and Appendix B.5.3	The tonnage split between industrial use and professional/consumer use may be different for Use#01 and Use#04.	No	Input parameter	Quantitative (cf. section F.2.1)
U8	Appendix E	For the estimation of the one-off costs, precise data are lacking to identify the exact number of companies that would be affected in each sector and the exact one-off cost that would be borne by each company.	No	Input parameter	Quantitative (cf. section F.2.2)
U9	2.3.1.2	Some variances in the prices of sealant producers can be expected.	No	Input parameter	Qualitative (cf. section F.2.3)
U10	2.4	The costs effectiveness ratio is based on central estimates of avoided releases. The ratio would differ if upper or lower estimates of avoided releases are considered.	No	Methodology	Quantitative (cf. section F.2.2)
U11	2.4	The costs effectiveness ratio is based on discounted avoided releases (3 %), and not on non-discounted avoided releases (0 %).	No	Methodology	Quantitative (cf. section F.2.2)
U12	2.3.1.6	There is no certainty on whether the leather sector would be affected by the entry into force of the restriction.	No	Input parameter	Quantitative (cf. section F.2.2)
U13	2.3.1.4 and 2.4	No information is available to quantify potential impacts of the restriction options (RO1, RO3 and RO4a) on some actors, down the supply chain (e.g. the automotive, aerospace, and other sectors relying on the use of metal parts resulting from processes where substances containing CA:C14-17 are used).	No	Input parameter	Qualitative (cf. section F.2.3)

Note: [1] standard uncertainties are explicitly or implicitly addressed by the provisions of a standardised procedure/assessment element, i.e. should have been assessed when the standardised procedure was established (EFSA, 2018)

F.2. Sensitivity analysis

The aim of the sensitivity analysis is to evaluate the relative importance of different sources of uncertainties.

For each identified uncertainty, a sensitivity analysis is undertaken to assess the impact of different possible inputs and/or methodological choices on the results of the assessment and compare them to the result of the initial assessment. In a second step, the sensitivity analysis further considers the effects that the analysed sensitivities could exert on the overall outcomes and conclusions of the Restriction proposal, both individually (section F.2.1, F.2.2 and F.2.3) and collectively (section F.2.4).

F.2.1. Uncertainties that may impact the releases estimates (baseline and RO)

To assess the sensitivity of some of the parameters used in the assessment of the releases, the Dossier submitter recalculated the total annual releases under five different scenarios which corresponds to the different uncertainties U4 to U7 identified in Table 131:

1. U4: By taking into account fractions of tonnage of 1 % and 20 % (instead of 10 %) for EC 264-150-0; EC 269-145-7; 'Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated, saponified'; and 'Paraffin waxes and hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified', to represent the faction of CA:C14-17 in the substances, as best and worst-case respectively.
2. U5: By considering that waste from industrial use (manufacture, formulation and industrial end-use) undergo standard municipal waste treatment (instead of only incineration) as a worst case, i.e. assuming 47 % landfill and 53 % incineration.
3. U6: By taking into account biodegradation in the WWTP (CfE2 #1527). Based on the OECD 314B study (2022) provided by registrants, a biphasic degradation curve was shown with two first order rates (likely representing two different fractions of the test substance): k1: 14.2 day^{-1} (0.59167 h^{-1}) and k2: 1.022 day^{-1} (0.04258 h^{-1}). Calculation was reiterated using Simple Treat 4.0 and k1 as a worst-case.

   With regards to the OECD 314B study provided in the CfE2 #1527, it is important to note that high mineralisation based on formation of 3H2O (tritiated water) was observed in 24 hours under the conditions of the test. This contrasts with the significantly more limited degradation observed in other biodegradation screening studies. There was no specific analysis to confirm if the measured mineralised radioactivity related to parent substance (instead only to the kinetics of the radio tracer). This is an important drawback of the study since tritium is known to exchange with hydrogen atoms of protein related substances – of which there would be present in the test system (Nivesse et al., 2021). In addition, the dosing solution was prepared diluting the test material in ethanol and the test guideline does not offer the option of a solubiliser to administer the substance to the test vessels (unless testing is possible otherwise). Due to these factors, the results of the study are not currently considered to be reliable. However, despite the uncertainties related to this study, the Dossier Submitter used it in the sensitivity

analysis to estimate an alternative input value for biodegradation that may occur in sewage treatment plants and what could be the consequences of such high degradation for release estimation.

4. U7: By considering different tonnage split between industrial and professional/consumer uses for Use#01: 50 % for industrial end uses and 50 % for professional/consumer uses (instead of 20 % / 80 %).
5. U7: By considering different tonnage split between industrial and professional/consumer uses for Use#04, instead of 67 % for industrial end uses and 33 % for professional/consumer uses (which assumed 50 % tonnage for industrial protective coatings and marine coatings each):
    - 50 % / 50 % (this is based on an assumption that the tonnage is split between 25 % in industrial protective coatings and 75 % in in marine coatings).
    - 83 % / 17 % (this is based on an assumption that the tonnage is split between 75 % in industrial protective coatings and 25 % in in marine coatings).

The calculated releases (total release to the environment, after WWTP and including waste, expressed as tonnes of CA:C14-17 per year) are presented in Table 132.

Table 132: Sensitivity analysis for the releases of CA:C14-17 to the environment

	Input value to calculate the releases to the environment	**Total releases to environment (tonnes CA:C14-17 per year)**		**Delta (tonnes CA:C14-17 per year)**		**Change compared to values used in the restriction proposal (%)**	
		lower bound	**upper bound**	**lower bound**	**upper bound**	**lower bound**	**upper bound**
Values used in the restriction proposal (cf. section B.5.2)		**5 214 (~5200)**	**6 284 (~6300)**	-	-	-	-
Alternative input values for the sensitivity analysis:							
U4	1 % CA:C14-17	5 009	6 036	-205	-248	-3.9 %	-3.9 %
	20 % CA:C14-17	5 470	6 631	+256	+347	+4.9 %	+5.5 %
U5	Industrial waste - 47 % to landfill and 53 % to incineration	5 257	6 340	+43	+56	+0.8 %	+0.9 %
U6	Biodegradation constant of 0.59 h^{-1}	5 035	5 969	-179	-315	-3.4 %	-5.0 %
U7	Use#01: 50 % tonnage to industrial end-use, 50 % to professional/consumer end-use	5 293	6 346	+79	+62	+1.5 %	+1.0 %
U7	Use#04: 50 % tonnage to industrial end-use, 50 % to professional/consumer end-use	5 216	6 286	+2	+2	+0.04 %	+0.03 %
	Use#04: 83 % tonnage to industrial end-use, 17 % to professional/consumer end-use	5 212	6 282	-2	-2	-0.03 %	-0.04 %

To assess the collective influence of uncertainties on the release estimation, a 'best-case'

(i.e. the combination of parameters values leading to lower releases than releases under the baseline) and 'worst-case' (i.e. the combination of parameters values leading to higher releases than releases under the baseline) have been calculated. The results are shown in Table 133.

Table 133: Collective influence of uncertainties on the releases of CA:C14-17 to the environment

Input value to calculate the releases to the environment	**Total releases to environment (tonnes CA:C14-17 per year)**		**Delta (tonnes CA:C14-17 per year)**		**Change compared to values used in the restriction proposal (%)**	
	lower bound	upper bound	lower bound	upper bound	lower bound	upper bound
Values used in the restriction proposal (cf. section B.5.2)	5 214 (~5200)	6 284 (~6300)	-	-	-	-
'Best-case'	4836	5732	-378	-552	-7.2 %	-8.8 %
'Worst-case'	5604	6762	+390	+478	+7.5 %	+7.6 %

The conclusion is that the uncertainties U4, U5, U6 and U7 – both individually and jointly – have only a minor impact on the total releases (<10 % compared to the values used in the restriction proposal). It can therefore be concluded qualitatively that the release reduction under each RO, and hence the C/E ratios, would be affected in a negligible way only.

F.2.2. Other uncertainties that may impact the cost effectiveness ratio of the ROs

To assess the sensitivity of the cost-effectiveness ratios to different sources of uncertainties, the Dossier Submitter recalculated the cost-effectiveness ratio under four different scenarios which corresponds to the different assumptions U8, U10, U11 and U12 identified in Table 131:

- By multiplying all total estimates of one-off costs by a factor of three (U8)
- By applying lower bound release estimates in terms of avoided releases (U10)
- By applying upper bound release estimates in terms of avoided releases (U10)
- By calculating costs effectiveness ratio using (not discounted) avoided releases instead of discounted avoided releases (U11)
- By including the leather sector in the scope of the restriction (with a 2-year transition period) (U12)

Table 134: Cost effectiveness of RO1, RO3, RO4a and RO4b (after multiplying all the estimated one-off costs by a factor of 3)

Restriction option	Total costs (NPV over 20 years)	Total emission Reduction (NPV over 20 years, central estimates)	C/E-ratio (€/kg)	Incremental change in costs (NPV over 20 years)	Incremental reduction of kg (NPV over 20 years)	Incremental C/E-ratio (€/kg)
RO4a	€4.2 billion	73 million kg	58	€4.2 billion	73 million kg	58
RO4b	€4.5 billion	73.9 million kg	61	€300 million	0.9 million kg	333
RO1(and RO3)	€5.2 billion	74.5 million kg	70	€700 million	0.6 million kg	1 167

Note: Cost-effectiveness ratios are based on central estimates in terms of avoided releases (cf. Table 77). Only one parameter -one off costs - was changed in this simulation.

Table 135: Cost effectiveness of RO1, RO3, RO4a and RO4b (applying lower bound estimates in terms of avoided releases)

Restriction option	Total costs (NPV over 20 years)	Total emission reduction (NPV over 20-year, central estimates)	C/E-ratio (€/kg)	Incremental change in costs (NPV over 20 years)	Incremental reduction of kg (NPV over 20 years)	Incremental C/E-ratio (€/kg)
RO4a	€3.9 billion	67.1 million kg	58	€3.9 billion	67.1 million kg	58
RO4b	€4.1 billion	67.4 million kg	61	€200 million	0.3 million kg	667
RO1(and RO3)	€4.9 billion	68 million kg	72	€800 million	0.6 million kg	1330

Note: Lower bound estimates in term of avoided releases based on data from Table 77

Table 136: Cost effectiveness of RO1, RO3, RO4a and RO4b (applying upper bound estimates in terms of avoided releases)

Restriction option	Total costs (NPV over 20 years)	Total emission Reduction (NPV over 20-year, central estimates)	C/E-ratio (€/kg)	Incremental change in costs (NPV over 20 years)	Incremental reduction of kg (NPV over 20 years)	Incremental C/E-ratio (€/kg)
RO4a	€3.9 billion	78 million kg	50	€3.9 billion	78 million kg	50

Restriction option	Total costs (NPV over 20 years)	Total emission Reduction (NPV over 20-year, central estimates)	C/E-ratio (€/kg)	Incremental change in costs (NPV over 20 years)	Incremental reduction of kg (NPV over 20 years)	Incremental C/E-ratio (€/kg)
RO4b	€4.1 billion	80 million kg	51	€200 million	2 million kg	100
RO1(and RO3)	€4.9 billion	81 million kg	61	€800 million	1 million kg	800

Note: upper bound estimates in term of avoided releases based on data from Table 77

Table 137: Cost effectiveness of RO1, RO3, RO4a and RO4b (using non-discounted avoided releases instead of discounted avoided releases)

Restriction option	Total costs (NPV over 20 years)	Total emission reduction (central estimates)	C/E-ratio (€/kg)	Incremental change in costs (NPV over 20 years)	Incremental reduction of kg	Incremental C/E-ratio (€/kg)
RO4a	€3.9 billion	100.8 million kg	39	€3.9 billion	101 million kg	39
RO4b	€4.1 billion	102.7 million kg	40	€200 million	1.9 million kg	105
RO1(and RO3)	€4.9 billion	103.4 million kg	47	€800 million	0.7 million kg	1 143

Note: cost-effectiveness ratios are based on central estimates in terms of avoided releases (cf. Table 77)

As indicated in Table 134, Table 135, Table 136, the uncertainties U8 and U10 have only a minor impact on the C/E ratio (<10 % compared to the values used in the restriction proposal[50]).

With regard to the influence of U11, as expected and indicated in Table 137, RO1, RO3, RO4a, RO4b are more cost-effective (~25 % more cost effective) when using avoided releases without discounting instead of 3 % discounted avoided releases. However, it is important to note that this higher effectiveness (so lower cost effectiveness ratios) is only attributable to the methodological choice of choosing a 0 % discount rate, which automatically decreases the cost effectiveness ratio by increasing the denominator in the ratio.

Regarding the leather sector, the Dossier Submitter assessed the impacts for this sector assuming that the concentration of CA:C14-17 with PBT and/or vPVB properties cannot be

[50] i.e. 53 €/kg for RO4a, 55 €/kg for RO4b and 66 €/kg for RO1 and RO3

reduced below 0.1 % in the two substances used in the post-tanning process of leather, namely:

- 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and
- 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified' (U12).

As part of the uncertainty analysis, the Dossier Submitter estimated the potential profit losses for the actors in the leather supply chain.

In estimating the profit losses, the Dossier Submitter assumed that the 2-year transition period would not be sufficient for the industry to identify, test and switch to an alternative, meaning that the production of the affected fatliquors as well as the related post-tanning activities would have to be halted at the end of the 2-year transition period. This industry's response was assumed by the Dossier Submitter based on the information provided by the relevant stakeholders, according to which no drop-in alternatives appear to be available, and the testing of alternatives and the full products' requalification might require up to five years (ECHA market survey)[51].

The Dossier Submitter also notes that some fatliquor producers may decide to relocate the production of the products outside the EU. This might happen in case of large companies that export an important share of the products outside the EU (for example to India, one of the leading worldwide exporting countries of leather products, after China [52] (ECHA market survey).

However, some stakeholders interviewed by the Dossier Submitter indicated that this would not be possible for small producers of fatliquors, considering that they do not have the financial resources to relocate their business or do not have - already established - branch companies outside the EU. The number of fatliquor producers that might be affected by the restriction could be more than 150 in the EU (ECHA market survey). However, most of the chemical companies that produce chemical products for tanneries as well as tanneries appear to be located in Italy (ECHA market survey).

The profit losses in Table 138 were estimated:

- for the suppliers of 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified'
- for the producers of fatliquors and
- for the actors using fatliquors in the post-tanning process.

[51] Some stakeholders indicated that it is possible that more than five years are needed (ECHA market survey).

[52] https://mahileather.com/blogs/news/the-global-leather-industry

Table 138: Calculation of profit losses for the suppliers of 'Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified'

Volumes produced in the EU (two substances) (kg)	Production value(€)	Gross margin (%)	Profit loss (1 year) (€) expected to start at the end of the 2-year TP
2.3 million	2.5 million [1]	12 % [2]	305 000

Note: [1] The Dossier Submitter could not identify the exact price of the two specific chemicals. So, for calculating the production value of the two substances, a price of 1.06 €/kg was assumed for each of the two substances (see also Table 119).
[2] 12 % is the average gross operating surplus/turnover (gross operating rate) from 2016 to 2020 of the sector: 'Manufacture of other chemical products (C2059)', which also includes production of various chemical products, including materials used in the finishing of leather. The data were extracted on 21/04/2022 from Eurostat database (Dataset: Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E)).

For quantifying the total profit losses over the 20-year time period, the Dossier Submitter applied a default period of 4 years of profit loss because the availability of alternatives in this sector resembles to a no-SAGA (suitable alternative available in general) case. The total profit loss and the annualised figure is reported in Table 139.

Table 139: Profit losses for substances' producers (annualised value and PV)

€305 000	Annual profit loss (starting at the end of the two-year TP)
€1.2 million	Profit losses (4 years)
€80 000	Annualised/rounded value

Table 140: Calculation of profit losses for the producers of fatliquors

Annual quantity of fatliquors produced in the EU (assuming 10 % of substance concentration [1])(kg)	Production value of fatliquors, containing the two substances (€)	Gross profit margin (%)	Profit loss (1 year) (€)
22 million [2]	44 million	12 % [4]	5.4 million

Note: [1] Concentration based on the findings from the ECHA market survey.
[2] The volumes used in the EU (2 215 tonnes) are slightly lower than the volumes produced (2 315 tonnes, as reported in Table 138*), because of the exports.*
[3] A price of 2€/kg was applied to derive the production value of fatliquors. This is based on the information provided by one of the major producers of fatliquors in the EU that indicated that the price of these products is in the range of 1-2€/kg (ECHA market survey).
[4] 12 % is the average gross operating surplus/turnover (gross operating rate from 2016 to 2020) of the sector: 'Manufacture of other chemical products (C2059)', which also includes production of various chemical products, including materials used in the finishing of leather. The data were extracted on 21/04/2022 from Eurostat database (Dataset: Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E).

Table 141: Profit losses for fatliquor producers (annualised value and PV)

€5.4 million	Profit loss (1 year)
€21.6 million	Profit loss (4 years) – total loss over the 20-year period
€1.5 million	Annualised/rounded value

Table 142: Profit loss for the leather sector

Annual quantity of fatliquors - based on the two substances - used in the EU in the treatment of leather (kg)	Dosage rate assumed (0.1kg of fatliquor per 1 kg of leather)[1]	Annual quantity of leather treated with fatliquor containing the two substances (kg)	Production value of leather treated with fatliquors containing the two substances – assuming a price of 5.5 €/kg (€)[2]	Gross margin (%)	Profit loss (1 year) (€)
22 million	0.1	221.5 kg	1.2 billion	11 % [3]	66.6 million

Note: [1] 0.1kg per kg of leather was used considering that "the amount of fatliquor used is around 70-120 g of fatliquor/kg of leather" (HSE, 2008)

[2] To derive the price per kg of leather, the price of 25 €/m^2 was used and a conversion factor of 4.63 kg/m^2 - as reported in De Rosa-Giglio et al. (2020) - was applied. 25 €/ m^2 is the average value of leather after tanning per m^2 calculated as the weighted average of the value of three types of leather (in 2019) that are identified with the following PRODCOM codes:15114150, 15114250, 15114350.

[3] 11 % is the average gross operating surplus/turnover (gross operating rate from 2016 to 2020) of the sector: "Manufacture of leather and related products". The data were extracted on 21/04/2022 from Eurostat database (Dataset: 'Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E)).

Table 143: Profit losses for the leather sector using fatliquors based on the two substances (annualised value and PV)

€66.6 million	Profit loss (1 year)
€266 million	Profit losses (4 years) - total loss over the 20-year period
€18 million	Annualised value rounded up

Table 144: Total profit losses for the three sectors

Sector	Total profit loss
Substance producers	€1.2 million (for 4 years)
Fatliquors producers	€21.6 million (for 4 years)
Leather sector	€266 million (for 4 years)
Total	€290 million (sum of total profit losses, rounded value)
Annualised profit loss	€19 million (annualised loss over 20 years at 3%)

Considering these potential additional costs for the industry – totalling at €290 million over the 20-year period of analysis -, the cost effectiveness ratios of each RO were recalculated and are reported in Table 145.

Table 145: Cost effectiveness of RO1, RO3 and RO4a (assuming that the leather sector is in the scope of the restriction)

Restriction option	Total costs (NPV over 20 years)	Total emission reduction (NPV over 20 years, central estimates)	C/E-ratio €/kg	Incremental change in costs €(NPV over 20 year)	Incremental reduction of kg (NPV over 20 year)	Incremental C/E-ratio €/kg
RO4a	€4.2 billion	73 million kg	58	€4.2 billion	73 million kg	58
RO4b	€4.4 billion	73.9 million kg	60	€200 million	0.9 million kg	222
RO1(and RO3)	€5.2 billion	74.5 million kg	70	€800 million	0.6 million kg	1 333

Note: Cost-effectiveness ratios are based on central estimates in terms of avoided releases (cf. Table 77)

As indicated in Table 145, the uncertainties U12 have only a minor impact on the C/E ratio (<10 % compared to the values used in the restriction proposal).

Finally, the Dossier Submitter also calculated the economic impacts under the assumption that a 5-year transition period would be granted for this specific sector.

This scenario assumes that the producers of fatliquors would engage in reformulating the affected products, even though some of them (having for example branch companies outside the EU) might decide to relocate the production – instead of bearing the substitution costs – and so keep supplying exclusively non-EU customers (ECHA market survey).

Based on inputs collected from the relevant stakeholders, the period of 5 years may be considered sufficient for the industry to test and shift to an alternative[53].

The above scenario also assumes that during the five-year transition period, the EU suppliers of the two substances will be able to continue to supply the producers of the fatliquors.

The estimation of the compliance costs for the producers of fatliquors under this scenario and the related assumptions are reported in the following tables.

Table 146: Increase in variable costs as a result of substitution

Value of the production (€)	Total annual raw material costs in the baseline(€)	Increase in annual raw material costs (+50 %)[3] (€) (ECHA market survey)	PV in 2024 (€)
44.3 million [1]	€22.1 million [2]	€11 million	€114 million

Note: [1] As reported in Table 140.
[2] The basic raw material costs as a share in the costs of basic industry vary between 10 % and over

[53] The Dossier Submitter however notes that some stakeholders indicated that more than five years might be needed, however others indicated that 4-5 years are expected to be sufficient.

50 % (Wilting and Hanemaaijer, 2014).The Dossier Submitter applied conservatively the share of 50 %, noting that the choice of the upper bound might lead to an overestimation of the variable costs and so of the additional costs resulting from the restriction.
[3] A company interviewed by the Dossier Submitter indicated that: "a phase out would increase the production costs with an estimated 30-50 %". Therefore, the Dossier Submitter brought forward the value of 50 %, noting that the final increase might be however lower and differ among the affected companies. The increase in variable costs is expected to start at the end of the five-year transition period.

Table 147: One-off costs (testing)

Number of potentially affected companies	Assumed one off costs per producer (ECHA market survey)	Total one-off costs (for all producers)
150	€0.6 million [1]	€90 million

Note: [1] The one-off costs include the costs for: a) finding a suitable raw material candidate for substitution, b) perform small laboratory production of final products, 3) perform tests (chemical, analytical and technical) on the products and 4) validation of the new process (ECHA market survey).

Table 148: Total compliance costs for the fatliquors producers and annualised costs

€204 million	Total compliance costs (PV in 2024)
€14 million	Annualised value - rounded up

The total compliance costs - under the scenario with a five-year transition period for the producers of fatliquors – were estimated at approximately €200 million (PV in 2024) for the EU fatliquor industry. This scenario would be therefore less costly for the industry and entail a saving of approximately €85 million compared to a scenario with a two-year transition period. However, the costs for this sector account only for a minor share (approximately 5 %) of the overall economic impacts of the different ROs. Therefore, also under this scenario – assuming a five-year transition period for the leather sector - , the cost effectiveness ratios are expected to be the approximately the same as in Table 145.

Overall, the Dossier Submitter notes that even when considering different assumptions as examined in this section, the cost-effectiveness ratios remain within the same range – 50-72 €/kg – indicating that none of the changes in the considered parameters have a substantial impact on the overall conclusions on proportionality of the consideration restriction options.

F.2.3. Uncertainties that cannot be quantified

For the remaining uncertainties (i.e. U1, U2, U3, U9, and U13), a quantitative uncertainty analysis was not possible, and the Dossier Submitter therefore performed a qualitative analysis based on expert judgement.

U1 – Uncertainty on the list of substances potentially affected by the restriction proposal

The list of substances potentially affected by the restriction proposal is non-exhaustive and depends on the quality and specifications of the feedstock or on the manufacturing circumstances as described in section B.1.1 and B.1.2. The presence and concentration of CA:C14-17 with PBT and/or vPvB properties is therefore specific to each supplier/manufacturer of the substances.

This uncertainty may affect the restriction proposal in two ways. First, it may affect the baseline and release calculations which are based on tonnage information for this list of substances (and therefore the cost effectiveness ratio). Secondly, this uncertainty may affect the availability of alternatives and the associated substitution costs for Use#02 (use in rubber) and Use#04 (use in paints and coatings) as chloroalkanes such as EC 264-150-0, or substances identified with the names ''Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' or 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified' may be either considered an alternative or be within the scope of the restriction proposal depending on the presence and concentration level of CA:C14-17 with PBT and/or vPvB properties.

In order to better understand the possible consequences entailed by this uncertainty, the Dossier Submitter conducted a thorough literature and database review as well as a comprehensive market survey by contacting registrants, suppliers and downstream users of the substances identified as potentially affected by the restriction proposal.

Based on this work, and the responses from supply chain, the Dossier Submitter concluded that the uncertainty has only a negligeable effect on the baseline and release estimates as the calculations are essentially driven by EC 287-477-0 tonnages. In addition, the Dossier Submitter concluded that it is plausible for chloroalkanes (except the one on the Candidate List) and other paraffin waxes to be manufactured and placed on the market with CA:C14-17 of concern in concentration below 0.1 %. This was confirmed by several registrants and downstream users. More specifically, according to the intumescent paint industry, this is already the case today (Use#02). Finally, as other substances than the one in B.1.2 are available as alternatives, this uncertainty does not affect the cost estimations for Use#04. The consideration of any other alternative is indeed expected to negligibly impact the overall compliance and substitution because the annual increase in variable costs assumed that the alternative for rubber is 100 % more expensive.

U2 - Potential overestimate of the tonnages released to the environment and U3 - Uncertainty related to imported mixtures and articles

U2 and U3 are uncertainties that may affect the estimated releases to the environment.

First, due to a lack of specific tonnage data on CA:C14-17 with PBT and/or vPvB properties, the estimates of CA:C14-17 are used as a proxy for risk. This approach affects the baseline and release estimates by overestimating them, which as a consequence could reduce the cost-effectiveness of each RO (i.e. calculated ratio increase). Nevertheless one may consider that (i) the release estimates are essentially driven by EC 287-477-0 tonnages (which contains essentially CA:C14-17 with PBT and/or vPvB properties), (ii) other congeners may raise similar concerns as the one formally identified with PBT and/or vPvB properties, and (iii) C/E ratios would remain in the same order of magnitude of recent REACH restrictions on PBT / vPvB substances[54] even if the release estimates would be 10 or 20 times lower than the one calculated in the restriction proposal. The pragmatic approach proposed by the Dossier Submitter would therefore not have any implications

[54] https://echa.europa.eu/documents/10162/ca0e70c1-db56-5d5f-55e1-76668c2d9623

on the overall conclusions on the examined restriction options in terms of proportionality.

In addition, the registered tonnages considered for the baseline calculation (and release reduction potential of the different ROs) are still high considering that substitution may be already ongoing following the SVHC identification of some chloroalkanes. Some registrants indicated also that they may intend to cease manufacture in the future, but this information is not taken into account as a decrease in registered tonnages is not yet visible in the registration dossiers. Similarly, if substitution would already be considered ongoing without a restriction this would affect the costs as well because then there is no substitution cost, ie both numerator and denominator of the C/E would be affected. So while this uncertainty on the registered tonnage may lead to an overestimation of the releases, this similarly would not have any implications on the overall conclusions on the assessed restriction options in terms of proportionality.

Finally, as described in section 1.3 of the main report, there is no precise information or data on the tonnages of CA:C14-17 in imported mixtures and articles despite multiple attempts of the Dossier Submitter to obtain such data. The Dossier Submitter therefore did not account any releases of CA:C14-17 from imported products. Considering that Asia is the main producer and consumer of substances containing CA:C14-17 (cf. section A.1.1.1), and that Europe is a key importer of articles and mixtures produced in Asia (Eurostat), the approach of the Dossier Submitter with regard to imported products would lead to an underestimate of the releases, which as a consequence could either reduce the C/E ratio if the main costs of the restrictions are incurred by non-EU producers, or keep the C/E in the same order of magnitude in case the restriction costs would be passed through to EU customers.

U9 - Some variances in the prices of sealant producers can be expected

The Dossier Submitter notes that market prices of OCF products might vary depending on the brand, quantity purchased and the country where the products are sold. However, the Dossier Submitter also notes that the EU market is competitive with many firms offering products at prices in the range of 6.8 to 9.7 €/kg.

U13 - No information is available to quantify the potential impacts of the restriction options on specific industry sectors and U14 -

Despite repeated and targeted contacts with specific sectors (cf. section G), no substantiated information was provided during the restriction preparation on the restriction costs and impacts for specific sectors (e.g. automotive), and uses (MetalWorking Fluids).

F.2.4. Collective influence of the uncertainties

To gain an impression of the joint influence of the uncertainties described in sections F.2.1 and F.2.2, this part of the analysis will implement best-case assumptions for all uncertainties and compare the resulting conclusions on the restriction option(s) with the other extreme scenario of implementing only worst-case assumptions for all uncertainties. This best-case vs worst-case analysis will thus demonstrate by how much all elements together may shift the conclusions on cost effectiveness in one or the other direction.

The Dossier Submitter took a pragmatic approach and performed this collective influence analysis on one RO only (RO1) rather than making the comparisons for all ROs assessed (RO1, RO3, RO4a and RO4b).

Table 149 gives an overview of the assumptions used to perform the collective best-case and worst-case uncertainty analysis on the 20-year study period.

The lower estimates for the total emission reduction for RO1 were recalculated based on the 'best-case' and lower-bound data from Table 133 and applying a discount rate of 3 % over 20 years. The upper estimates for the total emission reduction for RO1 were recalculated based on the 'worst-case' and upper bound data from Table 133 – no discount rate applied.

The lower estimates for the total costs are the ones of the initial assessment presented in section 2.3 of the main report, and the upper estimates are the ones from Table 134 where the estimated one-off costs have been multiplied by a factor of 3.

Table 149: Lower and upper assumption used to perform the collective best-case and worst-case uncertainty analysis for RO1 (20-year study period)

	Value for RO1
Total emission reduction over 20 years	
Lower estimate (with NPV over 20-year)	62.6 million kg
Upper estimate (no discounting)	121.6 million kg
Point estimate used in the restriction report (central value)	74.5 million kg
Total costs (NPV over 20 years)	
Lower estimate	€4.9 billion
Upper estimate	€5.2 billion
Point estimate used in the restriction report (central value)	€4.9 billion

To assess the collective influence of uncertainties on the cost effectiveness and proportionality of the restriction, a 'collective best-case' (i.e. combination of parameters values leading to the highest costs/ combination of parameters values leading to the lowest releases) and 'collective worst-case' (i.e. combination of parameters values leading to the lowest costs / the combination of parameters values leading to higher releases than releases under the baseline) have been calculated. The results are shown in Table 150.

Table 150: Summary of the collective best-case and worst-case analysis (C/E) for RO1

Cost per kg of avoided emissions	**RO1**
Collective best case	78 €/kg of avoided emissions
Collective worst case	43 €/kg of avoided emissions
Point estimate used in the restriction report	66 €/kg of avoided emissions

Appendix G: Stakeholder information

G.1. Calls for evidence

In the frame of the SVHC identification process, a call for evidence to gather information on manufacture, import, use, environmental release, as well as on the possibility for substitution (potential alternative substances or techniques) and on the socio-economic impacts of substitution was open on the ECHA website from 11/11/2020 to 15/12/2020. This call for evidence (referred to as CfE1 in this report) was targeted to EC 287-477-0. In addition, two calls for evidence to support the preparation of the restriction were open on the ECHA website from 06/10/2021 to 28/11/2021 (CfE2), and then from 23/02/2022 to 25/03/2022 (CfE3).

The list of substances covered in the scope of CfE2 and CfE3 as well as the background notes, and list of questions asked during the calls for evidence are available on ECHA website here:

- CfE2:https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/67101/term
- CfE3:https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/68902/term

In these two calls for evidence, stakeholder organisations have been invited to submit comments on updated data and information on the uses of the substances under investigation, and information on availability of alternatives as well as substitution costs.

ECHA also contacted ~120 stakeholder organisations, and all registrants and C&L notifiers of the substances containing CA:C14-17 under the scope of investigations via email and REACH-IT to make them aware of the publication of the call for evidence, and to organise follow-up discussions with specific sectors and companies.

Figure 12 and Figure 13 give an overview of the types of respondents, and the topics raised in the comments received during CfE1, CfE2 and CfE3.

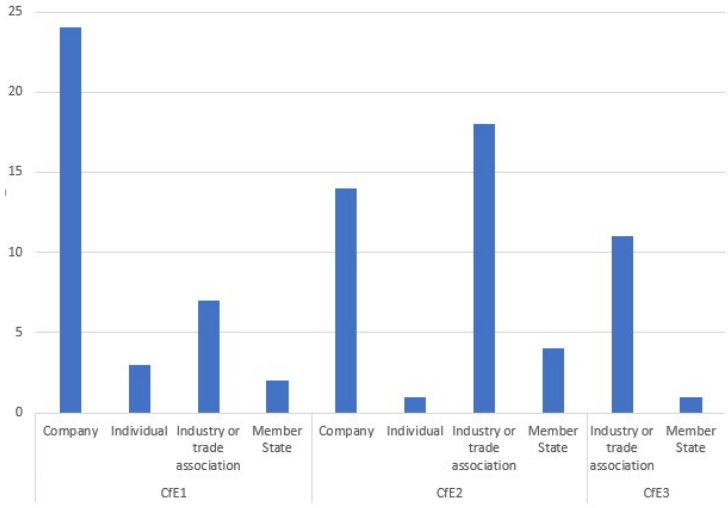


Figure 12: Number and type of respondents to CfE1, CfE2, and CfE3

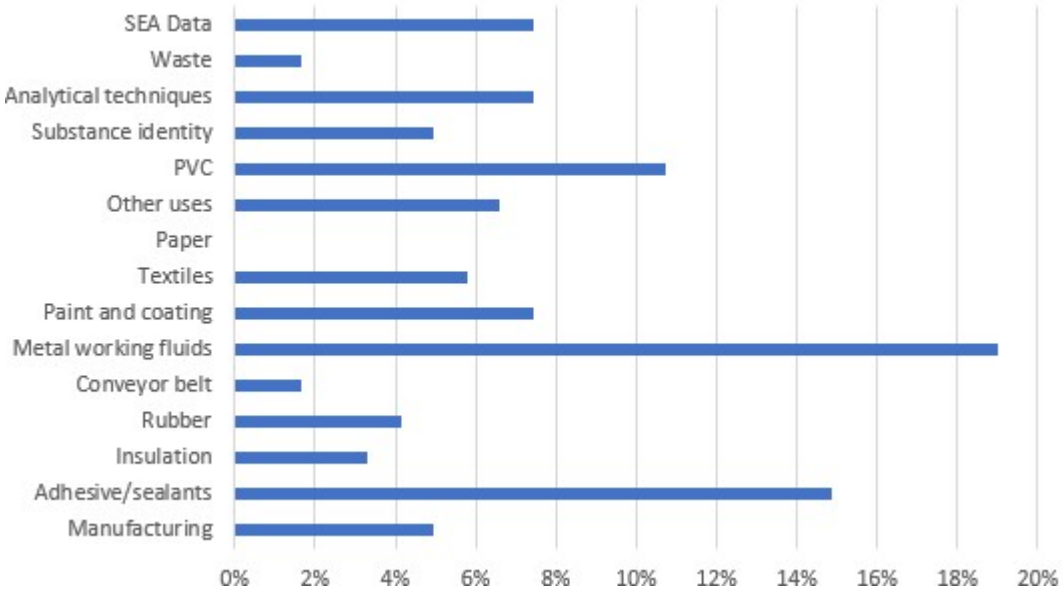


Figure 13: Topics raised by the respondents during CfE1, CfE2 and CfE3 (expressed in % of the topics raised)

G.2. ECHA Market Survey

Ad-hoc meetings and calls were also organised between November 2021 and April 2022 to collect additional information.

Dossier Submitter contacted more than 90 stakeholders (companies and industry associations) from the PVC, sealant, paint, rubber, textile, automotive, electronic devices (including medical devices) sectors to collect additional information on the relevant uses, availability of alternatives and the expected economic impacts of the different restriction

options.

With 40 of them, Dossier Submitter held calls and/or exchanged emails on aspects related to the alternatives and substitution costs.

Among the relevant associations, the Dossier Submitter engaged in bilateral calls/exchanges with:

- The European Council of the Paint, Printing Ink, and Artist's Colours Industry (CEPE)
- The German association of producers of textile, paper, leather (TEGEWA)[55]
- The European Tyre and Rubber Manufacturer's Association (ETRMA)
- The association of the European polyurethane (PUR / PIR) insulation industry (PU Europe)
- The European Apparel and Textile Confederation (Euratex)
- The Italian Paint association (Assovernici)
- Dutch paint association (VVF)
- European Man-Made Fibres Association (CIFRS)
- The European association representing the paper industry (CEPI)
- The Confederation of National Associations of Tanners and Dressers of the European Community (COTANCE)
- European Association representing European Aeronautics, Space, Defence and Security industries (ASD)
- The European adhesive tape industry network (AFERA)
- PVC Forum
- European Plastics Converters (EuPC)
- German leather association (VDL)
- Technical Association of the European Lubricants Industry (ATIEL).

Moreover, with the support of two external consultants the Dossier Submitter run two sector specific surveys:

- One survey aimed at getting further information on the uses in sealants and paints as well as on the availability of alternatives and economic impacts on these sectors. 31 stakeholders were contacted to participate to the survey (22 paints and coatings producer, 13 sealants and adhesives producers, and 4 companies producing both paints/coatings and sealants/adhesives).
- The second survey was specifically addressed to the metalworking fluid sector (suppliers of extreme pressure additives, producers of metalworking fluids and users of metalworking fluids). This investigation had the objective of providing an overview of metalworking applications (process and metals) still using CA:C14-17, and collecting more information on the availability of alternatives, on operating conditions and risk management measures (RMMs) that could be implemented for metalworking operations, and the economic impacts of various restriction options

[55] Association includes also producers of fur auxiliaries and colourants, surfactants, complexing agents, antimicrobial agents, polymeric flocculants, cosmetic raw materials, pharmaceutical excipients and allied products

on this sector. 76 stakeholders (EU, UK, US, Japan) from the metalworking supply chain were contacted to participate to the survey.

G.3. Registrants' Survey

The Dossier Submitter contacted the registrants of five registered substances[56] (EC 287-477-0, 'di-, tri- and tetrachlorotetradecane', 'paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated, saponified', EC 264-150-0 and EC 269-145-7) between January 2022 and February 2022, and asked a set of questions related to the manufacturing process and concentration ranges of CA:C14-17 in the registered substances (to manufacturers only), the uses of the substances, the tonnages, the measures in place to minimise emissions during manufacture (to manufacturers only) and other life cycle stages, the substitution efforts and their likely response to a restriction. In addition one of the questions was specifically related to the implications on the substances' production costs if feedstock with lower concentration of C14-17 alkanes is used (question sent to the registrants of EC 269-145-7, EC 264-150-0, di-, tri- and tetrachlorotetradecane' and paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated, saponified).

In total, 37 registrants have been contacted, among which 63 % responded. However registrants did not always respond to all questions exhaustively.

G.4. Laboratories working for enforcement authorities

Please refer to section B.1.5.5.

G.5. Clarification requests made by the Dossier Submitter during the Annex XV consultation

During the Annex XV consultation, the Dossier Submitter requested few follow-up clarifications from the respondents.

- 23 January 2023: Conference call between the Dossier Submitter and Japanese sector associations

JAPIA, JAMMA, CEMA, JIVA, JEITA, JFMDA, JAIMA, NECA, SEAJ, JIMA, JMIF, JEMIMA submitted early comments to the Annex XV Consultation.

The aim of the teleconference was to clarify some aspects of the information already provided and explain where further information would be needed to be submitted via the Annex XV consultation.

After the teleconference, the Japanese sector associations provided complementary information via the Annex XV Consultation.

[56] Registrants of 'paraffin waxes and hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified' have not been contacted directly as the substance was brought to the attention of the Dossier Submitter later in the dossier preparation.

- 22 March 2023: Request for clarification on the assumptions and justifications underpinning the impact assessment provided via the respondent #3826.

The respondent provided complementary information on 7 April. The complementary information has been added to the RCOM.

- 30 March and 3rd April 2023: Request for call with respondent European Plastics Converters (EuPC) to clarify information re. recycling of electric cables.

The respondent did not follow-up.

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