ANNEX XV REPORT

AN ASSESSMENT OF WHETHER THE USE OF TRICHLOROETHYLENE IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH ARTICLE 69(2) OF REACH

SUBSTANCE NAME: Trichloroethylene

IUPAC Name: 1,1,2-trichloroethene

EC NUMBER: 201-167-4

CAS NUMBER: 79-01-6

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About the report

This draft report is prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006, which after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), requires ECHA to consider if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepare an Annex XV restriction dossier.

In general, ECHA gathers information on potential risks to human health and/or the environment for identified uses of the substance in articles from various sources. Information is gathered from authorisations, recommendation for inclusion in Annex XIV and substance of very high concern (SVHC) identification. Uses identified in the REACH registrations and in substances in articles notifications (in accordance with article 7(2) of REACH[1] and the Waste Framework Directive (SCIP database[2])) are also investigated. Information on possible uses of the substance in articles that were not identified during the screening phase, can be gathered through a subsequent call for evidence launched via ECHA's website.

In most cases, risks stemming from the incorporation of the substance into an article are not in the scope of this investigation as incorporation of a substance in articles has to be authorised, unless exempted in accordance with Article 56(1) of REACH[3]. The incorporation process carried out in third countries is outside the scope of EU legislation. However, it should be noted that imported articles are within the scope of this investigation. The incorporation is regarded to cover two type of uses[4]:

a) The substance is incorporated into an article during its production, or

b) The substance, alone or in a mixture is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g. coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

It is to be noted that there are several specific exemptions from the authorisation requirements[5], while only few exemptions are envisaged in case of restrictions. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to

[1] Producers and importers have to notify ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met: i) the substance is present in their relevant articles above a concentration of 0.1% w/w; ii) the substance is present in these relevant articles in quantities totalling over 1 tonne per year. Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. For further details see: https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles.

[2] In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products): https://echa.europa.eu/scip.

[3] Q&A ID: 0564: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564 Note that ECHA will investigate for this report whether applications for authorisation/authorisation decisions cover the incorporation of the substance into an article.

[4] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c

[5] https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

human health of the use of the substance in cosmetic products and when a substance is used as an on-site isolated intermediate.

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A. Conclusions

A.1 Conclusions based on the assessment

Trichloroethylene has been included on the candidate list (2010/06/18; ED/30/2010) and included into Annex XIV of REACH (entry #15, Commission Regulation (EU) No 1907/2006) with a sunset date of 21 April 2016 due to its carcinogenic properties. Trichloroethylene is classified in Regulation 1272/2008 (CLP) as carcinogen (category 1B) therefore meeting the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) of that Regulation. According to REACH, ECHA needs to consider whether the use of the substance listed in the Annex XIV in articles poses a risk to human health or to the environment that is not adequately controlled. In such cases, ECHA prepares a restriction dossier which conforms to the Annex XV to REACH.

ECHA has gathered information on the uses of trichloroethylene in articles from various sources. This includes information from authorisations, information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV, uses identified in the REACH registrations and substances in articles in articles notifications (in accordance with article 7(2) of REACH and the Waste Framework Directive). Furthermore, ECHA has conducted a targeted literature search of trichloroethylene uses from various sources and databases.

According to the literature and other aforementioned sources, trichloroethylene has been used in or discovered to have been present in the following articles

- Dyed cloth
- Alcantara material used in different articles
- Rubber flooring elements for underground use e.g. mines
- Swim articles
- Desk chairs, dining tables and sofas
- Electrical machinery and equipment and parts thereof
- Primary cells and primary batteries
- Parts and accessories of the motor vehicles and engines
- Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus

Dyed cloth and Alcantara material are both within the scope of authorisations with indication that the risks are controlled. There is scarce information available for the rubber flooring elements for underground use, swim articles desk chairs, dining tables and sofas. The four last groups of articles in the above list are from the SCIP database, with limited information on e.g. exposure. The limited evidence indicate levels of trichloroethylene below the detection and quantification limits provided in EN standard for toys in swim articles.

The call for evidence which took place from 18 August 2021 to 29 September 2021 did not bring any new information as regards rubber flooring elements or the articles identified from the SCIP database. One comment from the Member State (Denmark) was received referring to a study showing some emissions (below the limits in EN standard for toys) of trichloroethylene from desk chairs, dining tables and sofas and to another study which reported concentrations of trichloroethylene in 3D materials below the detection limit value. This information is added to the relevant parts of this report.

Following an assessment of the available evidence, ECHA considers that there are uses of the substance in articles that have the potential to lead to human exposure from trichloroethylene concentrations in articles. Trichloroethylene is a non-threshold carcinogen for which no threshold can be determined below which exposure would be safe. However, the information on the use and presence of the substance in articles is minimal. Therefore, under Article 69(2), ECHA's view is that at present, taking into account the emerging priorities in the Restriction Roadmap, ECHA concludes that before any further action on the substance it will monitor the presence of the substance in articles via SCIP (Substances of Concern In articles as such or in complex objects) and Substances in Articles notifications. The report was sent in November 2021 to CARACAL/Member States as an information document. After this some modifications of the tonnages reported and of the information from the review reports related to the applications were done.

The information in the SCIP database allows the users of the articles to assess the risk from their uses and take appropriate risk reduction measures, as information is available throughout the whole lifecycle of products and materials, including at the waste stage.

A.2 Targeting

This report is targeted on the potential release of or exposure to trichloroethylene from articles throughout its lifecycle (including the waste stage) and whether or not such use should be restricted. The report is focused on human health hazard due to which the substance is placed on the Annex XIV. Other hazards are not taken into account in this report.

This targeting is based on the Article 69(2) of REACH Regulation that requires ECHA to consider if the use of the substance in articles poses a risk to human health or the environment that is not adequately controlled and prepare an Annex XV dossier for an appropriate restriction if this is the case. The incorporation of an Annex XIV substance into an article is a use which is subject to the authorisation requirement[6].

A.3 Summary of the justification

A.3.1 Identified uses, hazard, exposure/emissions and risk

Information on uses

Current use of trichloroethylene in the EU is limited to the uses within the scope of authorisation, unless exempted. The authorised uses cover different type of uses. None of these uses leads to trichloroethylene presence in articles or the incorporation of trichloroethylene in articles leads to releases below the detection limits (dyed cloth) or low releases (Alcantara material). Trichloroethylene has been registered in the total tonnage band of 10 000 – 100 000 tonnes per year by 6 registrants. Import of all types of articles containing trichloroethylene is currently not restricted.

One Substance in Articles (SiA) notification was made under Article 7(2) corresponding to 1-10 tonnes of trichloroethylene in bonding of rubber articles. The use likely refers to

[6] Q&A ID No 564: https://echa.europa.eu/support/qas-support/qas?p_p_id=journalqasearch_WAR_journalqaportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=2&p_p_col_count=3

rubber flooring articles such as panels in underground conditions, such as mines. No information is available of the exposure of workers.

In the early 2000s trichloroethylene was once detected in children's toy product, so called *magic* sand, in the European Union (EU), however this use is regarded to be a mixture. In this case an authorisation for this use would have been needed. As such application for authorisation is not received, this use is no longer relevant in EU. In addition, Norway conducted a targeted research of 5 such products in their market. There was no further evidence of the presence of the substance in these products. The Danish Environmental Agency (EPA) (2016) conducted a research of volatile organic compounds (VOCs) in children's rooms and discovered trichloroethylene emissions from painted surface and rubber swim toys, even though the concentration in swim toys was below the detection and quantification limits provided in EN standard 71-11 on toys[7]. Ho, D.X. et all reported some emissions (similarly below the detection and quantification limits in EN standard 71-11) from desk chairs, dining tables and sofas. Concentrations below the detection limit from 3D materials were reported by Danish EPA (2017).

According to a scientific literature search done for this screening, trichloroethylene was used since the early 1900s, primarily as a solvent but other uses can also be found from the literature such as in dry cleaning, textile, electronics, leather, and rubber industries (Bakke et al., 2007). Also products like adhesives, medicines, paints, inks, and various industrial products have had historical uses of trichloroethylene. Recent risk evaluation by US EPA lists some further detailed uses, such as in pepper sprays and hoof polishes (US EPA, 2020), but no specific uses in articles. Detailed list of uses associated with trichloroethylene can be found in Table 3. Whether some of these uses lead to the incorporation in articles outside EU and consequently imports of articles containing trichloroethylene is unknown.

As a summary, trichloroethylene is and has been used in articles, however due to its highly volatile nature it is uncertain how much, if any, is left in the final article.

Information on hazards

Trichloroethylene is included in Annex XIV based on its carcinogenic (category 1B) properties. In relation to the application for authorisation, when establishing a reference dose response relationship for carcinogenicity of trichloroethylene, the Committee for Risk Assessment (RAC) concluded in 2014, that the substance should be evaluated as a non-threshold carcinogen. Other endpoints are not relevant for this report.

Trichloroethylene is classified in Annex VI of CLP as: Carc. 1B, H350; Muta. 2, H341; STOT SE 3, H336; Skin Irrit. 2, H315; Eye Irrit. 2, H319 and Aquatic Chronic 3, H412.

Information on emissions/release/exposure

Only emissions and releases from articles are relevant for this report. As trichloroethylene is highly volatile, it is unclear to what extent it is or would still be present in a product or an article. There are indications that trichloroethylene is in imported articles, however before any further action on the substance ECHA will monitor

[7] EN 71-11:2005. Safety of toys - part 11: Organic chemical compounds - methods of analysis.

the presence of the substance in articles via SCIP (Substances of Concern In articles as such or in complex objects (products)) and Substances in Articles notifications.

Characterisation of risk

Trichloroethylene is considered to be a genotoxic carcinogen. No threshold can be determined below which exposure would be safe. The reference dose response relationship established by RAC for carcinogenicity of trichloroethylene (RAC, 2014) for inhalation, dermal and oral route, has to be considered. There are indications that trichloroethylene is in imported articles, however before any further action on the substance is taken, ECHA will monitor the presence of the substance in articles via SCIP and SiA notifications for potential increased use (presence) and increased exposure to the substance in the EU.

A.3.2 Justification that action is required on a Union-wide basis

No restriction is proposed at present.

A.2.3 Justification that the proposed restriction is the most appropriate Union-wide measure

No restriction is proposed at present.

B. Information on hazard and risk

B.1 Identity of the substance and physical and chemical properties

B.1.1 Name and other identifiers of the substance

Chemical name: Trichloroethylene

EC Number: 201-167-4

CAS Number: 79-01-6

IUPAC Name: 1,1,2-trichloroethene

B.1.2 Composition of the substance[8]

Chemical name: Trichloroethylene

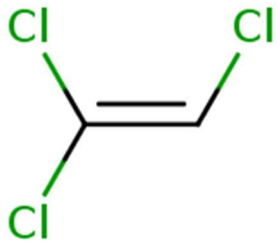
EC number: 201-167-4

CAS number: 79-01-6

IUPAC name: 1,1,2-trichloroethene

Molecular formula: C2HCl3

Structural formula:



Molecular weight: 131.39 -131.5

[8] Synonyms can be found from Brief profile available on ECHA's website: https://echa.europa.eu/brief-profile/-/briefprofile/100.001.062

B.1.3 Physicochemical properties

Table 1 provides certain physicochemical properties for trichloroethylene. ECHA's dissemination site provides further information as provided by the registrants.

Table 1. Selected physicochemical properties

REACH ref Annex	Property	Value
VII, 7.1	Physical state at 20º C and 101.3 KPa	Colourless non-flammable liquid with a characteristic odour detectable at around 20 to 30 ppm resembling that of chloroform.
VII, 7.2	Melting / freezing point	-84 to -87 °C according to source
VII, 7.3	Boiling point	85.9 to 88 °C according to source
VII, 7.5	Vapour pressure	78.7 to 86 hPa at 20°C according to source
VII, 7.7	Water solubility	According to source 1 to 2.85 g.l -1
VII, 7.8	Partition coefficient n-octanol/water (log value)	2.29 to 2.98 according to source
	Dissociation constant	-

Source: SVHC support document for trichloroethylene (ECHA, 2010)

B.1.4 Justification for grouping

In the context of this article 69(2) screening, no group has been assessed; only the Annex XIV substance trichloroethylene.

B.2 Manufacture and uses

B.2.1 Manufacture, import and export of a substance

According to the Background document for trichloroethylene in the context of ECHA's recommendation for the inclusion of substances in Annex XIV (ECHA, 2011), European manufacture and import of trichloroethylene has been about 50 000 – 100 000 t/y of which majority is used as intermediate in the manufacturing of other substances such as fluorinated compounds. REACH registration data shows that the quantities of TCE available on the EU market were about 53 000 tonnes in 2010. No information on exports is available.

There were two companies manufacturing trichloroethylene in 2010 (Annex XV, 2010). Several distributors for smaller amounts of imported trichloroethylene were listed in the background document (Annex XV, 2010). Currently trichloroethylene has been registered in the total tonnage band[9] of 10 000 – 100 000 tonnes per year by 5 registrants[10]. Manufacturing may continue today for authorised uses, uses exempted

[9] Total tonnage band – calculated per factsheet from all contributing registrations, based on the estimated quantity of the substance placed on the market. Data is excluded from dossiers where the tonnage is claimed confidential, from Intermediate registration dossiers, and from NONs (substances notified in accordance with Directive 67/548/EEC (known as NONS: Notification of New Substances) which have not been updated. (http://echa.europa.eu/information-on-chemicals/registered-substances).

[10] Registered substances, ECHA dissemination website (visited 26/10/2021).

from authorisation (such as on-site isolated intermediate and transported isolated intermediate) and for export.

B.2.2 Uses in articles

As referred in ECHA (2011) according to Annex XV (2010), the major non-intermediate use of trichloroethylene is for hot vapour degreasing of metal parts (surface cleaning), used for the removal of substances such as oils, greases, waxes and buffering compounds, or soils. The substance has high solvent power while having low flammability (ECHA 2011).

Authorisations

Current use of trichloroethylene in the EU is limited to the uses within the scope of authorisations, unless exempted[11]. The potential risk to humans, through workers' exposure or man via the environment, in the production of articles and when a substance (as such or in mixture) is incorporated into/onto an existing article has been evaluated in the applications for authorisations (AfAs) for the corresponding uses, therefore they are outside the scope of this report[12]. The authorised uses are listed in the Table 2. ECHA is publishing at the same time with this screening report a report "Case study: impacts of REACH authorisation on trichloroethylene. State of play in January 2022."[13] According to the report, the uses applied for were about 40 000 tonnes, after the inclusion of trichloroethylene on the Authrosation list. When using information from the current authorised uses and review reports, the total amount of trichloroethylene used currently in the EU is about 1 200 tonnes per year.

[11] Exemptions from authorisation requirements: https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

[12] Q&A ID No 564: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564

[13] https://echa.europa.eu/technical-scientific-reports

Table 2. Information on authorised uses of trichloroethylene[14]

Applicant(s)	Authorised use(s)	Tonnage per year	Incorporation in articles*	Date of expiry of review period	Date of submission of review report	Review decided
Vlisco Netherlands BV	Use of trichloroethylene as a solvent for the removal and recovery of resin from dyed cloth Use of trichloroethylene as a solvent in a process to recover and purify resin from process water	4.0 (for both uses combined)	Dyed cloth: Article category: AC 5: Resulting exposure is considered to be negligible as the content of trichloroethylene in the fabric that is produced is below the detection limit (the detection limit is 0.081 mg trichloroethylene /kg dry cloth). Recovery and purification of resin from process water: No article category.	21 April 2028		
Roquette Frères	Use as a processing aid in the biotransformation of starch to obtain betacyclodextrin	3.0 Review report: 8.0	No article category. BCD is used further for the manufacturing of Hydroxypropyl-betacyclodextrin (HPBCD). HPBCD is used in pharmaceuticals.	21 April 2028	7 August 2020 (Opinions adopted)	
Parker Hannifin Manufacturing Netherlands (Filtration and Separation) bv	Industrial use of trichloroethylene as a process solvent for the manufacturing of modules containing hollow fibre gas separation membranes	20.3 > 47.7 by 2025	No article category. The gas separation fibres containing traces of trichloroethylene are contained in an enclosed module and similar trichloroethhylene concentrations were determined	21 April 2028		

[14] Search done on 25 February 2021 (updated on 16 February 2022): https://ec.europa.eu/docsroom/documents/44775 and https://echa.europa.eu/applications-for-authorisation-previous-consultations

			in "new" and "aged" modules which indicates that no trichloroethylene is released during service life.			
Grupa Azoty S.A.	Industrial use of trichloroethylene as a process chemical in caprolactam purification	100 - 1000	No article category. Trichloroethylene is not present in end-products, an exposure/risk assessment for professional users or consumers is not necessary.	21 April 2028		
RAG Aktiengesellschaft; RAG Anthrazit Ibbenbüren GmbH	Use of trichloroethylene containing vulcanising and bonding agents for endless connections and repair of chloroprene rubber coated conveyor belts in underground hard coal mining	1.4	No article category.	21 April 2020 (Authorisation expired)		
A.L.P.A. Azienda Lavorazione Prodotti Ausiliari S.P.A.; Caffaro Industrie S.P.A.	Use as solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers	40	No article category. Trichloroethylene is completely removed by distillation and not even traces have been detected in the final product.	21 April 2023	No review report received by the deadline (21 October 2021)	
Chimcomplex SA Borzesti	Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems	808	Article Service Life: n/a. Trichloroethylene is used in a closed, batch or continuous process and is not detectable in the final degreased components.	21 February 2019 (Authorisation expired)		
Richard Geiss GmbH	Use of trichloroethylene in formulation Use of trichloroethyle	100 - 1000 100 – 1000	Formulation: No article category. Packaging: No article category.	21 April 2028		

	ne in packaging					
Spolana s.r.o. [Original applicant: Spolana a.s.]	Use of trichloroethylene as an extraction solvent in caprolactam production	150 Review report: 100	No article category. As trichloroethylene is not present in end-products, an exposure/risk assessment for professional users or consumers is not necessary. Review report: There are no consumer, downstream user or article service-life exposure scenarios relevant to the use applied for.	21 April 2020	16 August 2018 Review report: Article category related to subsequent service life (AC): n/a	21 April 2032
Microporous GmbH	Use of trichloroethylene as degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries Review report: Use as extraction solvent in the manufacture of polyethylene separators for lead-acid batteries	10 - 100 Review report: 10 - 30	No article category. A very low residue of trichloroethylene is present in the finished product. Review report: Article category related to subsequent service life (AC): N/A	21 April 2023	23 July 2021 (Opinion development)	
DOMO Caproleuna GmbH	Industrial use of trichloroethylene as an extraction solvent for the purification of caprolactam from caprolactam oil	245 Review report: 30 - 100	No article category. As trichloroethylene is not present in end-products, an exposure/risk assessment for consumers is not necessary. Review report: Article category related to subsequent service life (AC): N/A	21 April 2023	9 August 2021 (Opinion development)	

Blue Cube Germany Assets GmbH & Co. KG [Original applicant: DOW Deutschland Anlagengesellschaft GmbH]	Use of trichloroethylene in industrial parts cleaning by vapour degreasing in closed systems where specific requirements (system of use-parameters) exist Industrial use as process chemical (enclosed systems) in Alcantara Material production Use of trichloroethylene in packaging Use of trichloroethylene in formulation Use of trichloroethylene as extraction solvent for bitumen in asphalt analysis	1000 – 2000 10 – 100 Review report: 10 - 200 10000 – 100000 1000 – 10000 100 - 1000	Industrial parts cleaning: No article category. Alcantara material production: No article category. Key properties of solvent: must ensure a residue-free end product (≤ 0.5% of the solvent). Review report: Substance ≤0.1% in Alcantara®. Substance (≤ 0.5% in Alcarene chips as an impurity). Packaging: No article category. Formulation: No article category. Extraction solvent for bitumen in asphalt analysis: No article category	21 October 2020 for use REACH/18/9/0, 21 April 2023 for uses with authorisation numbers, REACH/18/9/1 and REACH/18/9/4, 21 April 2028 for uses with authorisation numbers REACH/18/9/2 and REACH/18/9/3	Alcantara material production: 22 August 2019 (Opinions adopted) No review report received by the deadline (21 October 2021) for extraction solvent for bitumen in asphalt analysis.	

*Information from the application and the adopted opinions.

In addition, there is one authorisation for an UK company ENTEK International Limited (UK) with a use of trichloroethylene as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries. The tonnages per year is 10 – 100 tonnes, no article category is reported and the expiry date of the review period is 21 April 2023. Any authorisation granted to a UK applicant has expired in the EU/EEA from 1 January 2021. For these the UK Authorisation system has transitional measures, as explained in https://www.hse.gov.uk/reach/authorisation.htm. As article category was not included in the authorisation, ECHA does not expect any imports of articles containing trichloroethylene from UK related to this use.

According to the authorisations, most of them do not report any use of a substance in articles. The only article category is reported to be the use as solvent for the removal and recovery of resin from dyed cloth, however, the concentration limit is below the detection limit of 0.081 mg trichloroethylene/kg dry cloth. As the technical function is as a solvent, it provides indication that if this use occurs also outside the EU, it is not expected that the dyed cloth imported would contain trichloroethylene.

As regards the authorisation for industrial use as process chemical (enclosed systems) in Alcantara material production, the authorisation indicates that the concentration limit value for end products from Alcantara material is higher than the limit value triggering Substance in Articles (SiA) notifications (≤0.5% versus >0.1%). However, in the review report received by ECHA in 2019 for which an opinion by RAC and SEAC has been adopted, the concentration of trichloroethylene in Alcantara material is informed to be ≤0.1%. According to the application Alcantara is a composite material which has many applications, e.g. covering of car seats. However, similarly trichloroethylene is used as a solvent in the production of Alcantara material, thus no imports of these articles containing trichloroethylene is expected. The review report submitted to ECHA in 2019 indicated that Alcarene™, the polystyrene (PST) chips are gained in the extrusion process as a byproduct. These PST chips contain trichloroethylene ≤0.5%. The applicant supplies the chips to one company in European Economic Area and this downstream user supplies the shoe industry and uses polystyrene for manufacturing of, for instance, heels of women shoes. Even though the use of Alcarene™ is not subject to the authorisation (TCE being an impurity in another substance), the applicant provided some information. As regards the endproducts of Alcarene™, the applicant states that the produced article does not contain trichloroethylene anymore.

according to local requirements which is sufficient.Furthermore, no SiA notifications of trichloroethylene in these articles are available, which would indicate that the concentrations are below 0.1%.

Substance in Articles (SiA) and SCIP notifications

Import of all types of articles containing trichloroethylene is currently not restricted. One Substance in Articles (SiA) notification was made under Article 7(2) corresponding to 1-10 tonnes of trichloroethylene in bonding of rubber articles. The details provided with the notification indicate use of trichloroethylene in rubber flooring products (i.e. rubber sheets, floor coverings and rubber panels) in underground environments such as mines.

There are several submission to the database for information on Substances of Concern In articles as such or in complex objects (Products) (SCIP) established under the Waste Framework Directive (WFD). The data submitted by suppliers of articles to the SCIP database identify the presence of trichloroethylene in a concentration above 0.1% w/w in articles as such or in complex objects, in particular in the following categories of articles or complex objects:

a) Electrical machinery and equipment and parts thereof (Combined Nomenclature (CN) chapter and heading: 8543)

b) Primary cells and primary batteries (CN chapter and heading: 8506)

c) Parts and accessories of the motor vehicles and engines (CN chapters and headings: 8408, 8708)

d) Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus (CN chapters and headings: 9032, 9033)

From the data submitted to the SCIP database, it seems that the presence of that substance results from the use or incorporation of the following type of mixtures containing trichloroethylene in their composition, during the production or assembling of the articles or complex objects listed above:

- adhesives and sealants (EuPCS code: PC-ADH-7).

In addition, suppliers of articles also submitted data referring to the presence of trichloroethylene in articles made of plastic such as epoxide resins or other halogenated (co)polymers, and fibres obtained from miscellaneous or new materials, e.g. metal, paper, etc.

Information from other sources

Several other databases were screened for identifying uses in articles[15]. Also literature search was carried out.

Two studies related to children for toys, investigated trichloroethylene in toy sand and in swimming articles. A survey of carcinogenic, mutagenic or toxic for reproduction (CMR) substances in toys in Denmark and in Europe reported release of trichloroethylene from children's toy product magic sand (Umweltbundesamt, 2011). However, magic sand is not regarded as an article but rather a mixture, being thus outside the scope of this investigation. It is to be noted that the supply to the general public of trichloroethylene in mixtures is restricted with entry 28 of Annex XVII to REACH. The magic sand may also fall under the restriction on microplastics[16]. The Danish Environmental Protection Agency (Danish EPA, 2016) recorded trichloroethylene and other VOC releases in children's rooms and found swim articles (swim rings, beach balls and water wings) as one source of trichloroethylene release. As referred by Danish EPA, one study found emissions mostly below 1 µg/m^3, only emissions from sofa were in some cases higher (max 2.36 µg/m^3), but still below the detection and quantification limits in EN standard 71-11) of trichloroethylene from desk chairs, dining tables and sofas. (Ho et al. (2011)).

Another study by Danish_EPA (2017) assessed the risks of 3D printers and 3D printer products. As discussed in the study there are an increasing number of private consumers that buy 3D printers and install them at home. In addition, consumers can make 3D printed products at several institutions (e.g., libraries) and shops, or order 3D printed products through homepages. The Danish EPA investigated two Resin printing materials and seven Acrylonitrile Butadiene Styrene (ABS) materials using migration tests. The results showed trichloroethylene values below the detection limit (0.02 µg/l), indicating no presence of trichloroethylene in 3D printing materials.

Several registrants have reported the industrial use of trichloroethylene as an intermediate. Intermediate use of trichloroethylene covers the production of HFC 134a (1,1,1,2-tetrafluoroethane) and HCFC 133a (1-chloro-2,2,2-trifluoroethane). HFC 134a is used as a refrigerant and HCFC 133a is used to manufacture the anaesthetic, halothane (EU RAR, 2004). HFC 134a is used as an alternative refrigerant to CFCs. A recent US estimate of trichloroethylene use reports that 83.6% of trichloroethylene's

[15] Example of databases used in the search: OECD global portal on product recalls, Consumer Product Information Database (USA & Canada).

[16] Background document to the opinions by the Committees for Risk Assessment and Socio-economic Analysis on the microplastics proposals: Microplastics are reported to be used in toys or for arts and crafts. For example, glitters, certain sequins (that are not articles) and modelling clays. https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

annual US production volume is used as an intermediate to produce HFC 134a (US EPA, 2020).

According to a scientific literature search done for this screening, trichloroethylene has had uses since the early 1900s, primarily as a solvent but uses in other industries can also be found from the literature such as in dry cleaning, textile, electronics, leather, and rubber industries (Bakke, Stewart, & Waters, 2007). Also products like adhesives, drugs, paints, inks, and various industrial products have had historical uses of trichloroethylene. Many of the uses were identified in EU RAR (2004) as well as in the Background document for trichloroethylene recommendation to be listed in Annex XIV (ECHA, 2011). In 2020, US EPA published the final risk evaluation for trichloroethylene (US EPA, 2020)[17]. The report provided an exposure scenario for processing category 'Processing – incorporated into articles' where trichloroethylene as a solvent was used, with a remark 'becomes an integral component of articles'. Consumer use patters were e.g. spot removers, cleaning fluids, glues and adhesives, lubricants, paints, paint strippers, fabric water repellents, wood stains, tire cleaners, engine degreasers, carburetor cleaners, and specialized electronic cleaners, shoe polish, adhesive removers, rust removers, primers, outdoor water repellents, gasket removers and brake cleaners. The consumer condition of use scenarios were exclusively for trichloroethylene containing mixtures[18]. The information indicates that no articles with release of trichloroethylene were identified in USA.

Detailed list of uses associated with trichloroethylene can be found in Table 3. Some of these uses may cover the uses in articles, which could be imported to the EU/EEA, even though the SiA notification is only for rubber flooring products (i.e. rubber sheets, floor coverings and rubber panels) in underground environments such as mines.

As the sunset date for an application for authorisation has passed, only the uses falling within the scope of the uses applied for before the latest application date for trichloroethylene, and those exempted from authorisation, are allowed in the EU/EEA. In the event they lead to the presence of the substance in imported articles, these uses may be relevant for this report.

B.2.3 Uses advised against by the registrants

There are uses advised against in the registrations. Typically, all consumer uses are advised against by the registrants, with one specific remark stating 'must not form part of the composition of any cosmetic products marketed for sale or use in the EU'.

B.2.4 Description of targeting

This restriction report is targeted on the potential release of trichloroethylene from articles and exposure to trichloroethylene when used in articles and whether or not such use should be restricted. Furthermore, targeting is based on the hazard for which the substances were included on Annex XIV, i.e. carcinogenity (1B).

[17] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-trichloroethylene-tce-0

[18] In EU/EEA, placing on the market of trichloroethylene as such and in mixtures for supply to the general public is restricted with entry 28 of Annex XVII to REACH.

This targeting is based on the Article 69(2) of REACH Regulation that requires ECHA to consider if the use of the substance in articles poses a risk to human health that is not adequately controlled and prepare an Annex XV dossier for an appropriate restriction if this is the case. The incorporation of an Annex XIV substance into an article is a use which is subject to the authorisation requirement[19].

B.3 Classification and labelling

Classification according to CLP

Carc. 1B, H350; Muta. 2, H341; STOT SE 3, H336; Skin Irrit. 2, H315; Eye Irrit. 2, H319 and Aquatic Chronic 3, H412.

Classification according to the Classification and Labelling Inventory

There have been 515 notifications to the C&L inventory for trichloroethylene most of them reproducing the harmonised classification[20]. Some of them have a lower hazard class for certain endpoints or they are deviating e.g. on the pictograms.

B.4 Environmental fate properties

Not relevant.

B.5 Human health hazard assessment

Trichloroethylene is carcinogenic, category 1B substance. In developing its opinions on the application for authorisation, RAC concluded that due to the genotoxic potential trichloroethylene should be evaluated as a non-threshold carcinogen with respect to risk characterisation[21]. Therefore, RAC calculated dose-response relationships for inhalation exposure for workers, continuous inhalational exposure for the general population, dermal exposure for workers, dermal exposure for the general population and oral exposure for the general population.

Other human health endpoints are not relevant for this dossier.

B.6 Human health hazard assessment of physicochemical properties

Not relevant

B.7 Environmental hazard assessment

Not relevant.

[19] Q&A ID No 564: https://echa.europa.eu/support/qas-support/qas?p_p_id=journalqasearch_WAR_journalqaportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=2&p_p_col_count=3

[20] Search done from ECHA's dissemination site: 09/03/2021

[21] https://echa.europa.eu/documents/10162/13641/carcinogenicity_dose_response_tce_en.pdf/ad8db350-0e22-4c45-b721-028579c371cb

B.8 PBT and vPvB assessment

Not relevant.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

For this report only releases of a substance from articles and exposure when used in articles are relevant.

Danish EPA conducted an exposure and risk assessment for children´s room with respect to evaporation of VOCs from building materials, furniture and toys (Danish EPA 2016). Swim articles produced concentration of 2.8 µg/m^3 of trichloroethylene in climate chamber after 24 hours (Danish EPA 2016). The concentration is below the detection and quantification limits in EN standard 71-11[22], as mentioned in the Umweltbundesamt, 2011. Ho, D.X. et all (2011) studied VOC concentrations (µg/m^3) measured in air from different furniture type. Emissions of trichloroethylene were measured from desk chair, dining table and sofa. The mean emission values for all these articles were low (below 1 µg/m^3), only emissions from sofa were in some cases higher (max 2.36 µg/m^3), but still below the detection and quantification limits in EN standard 71-11.

Even though magic sand is regarded to be a mixture[23], information on releases a is given here as reference. A survey of CMRs in toys in Denmark and in Europe reported 4 µg/m^3 release of trichloroethylene from children's toy product magic sand (Umweltbundesamt, 2011). The release level was below the detection and quantification limits for trichloroethylene emission reported in EN standard 71-11, which are 11 µg/m^3 and 33 µg/m^3, respectively. In 2016, Norwegian Environment Agency tested 5 brands of indoor play sands for chlorinated organic solvents and did not find trichloroethylene in the products (Torgersen, 2016).

Releases from rubber flooring in underground environment are unknown, and further information is needed to assess the exposure of workers. Inhalation and dermal exposure of workers may be relevant. Similarly further information on articles identified from the SCIP database and exposure to trichloroethylene from these articles is needed. No further information on the rubber flooring or articles identified from the SCIP database was received during the call for evidence.

There are indications that trichloroethylene is in imported articles, however before any further action on the substance ECHA will monitor the presence of the substance in articles via SCIP and SiA notifications for increased use (presence) and potential exposure. The information in the SCIP database allows the users of the articles to assess the risk from their uses and take appropriate risk reduction measures, as information is

[22] EN 71-11:2005: Safety of toys - Part 11: Organic chemical compounds - Methods of analysis https://standards.cencenelec.eu/dyn/www/f?p=CEN:110:0::::FSP_PROJECT,FSP_ORG_ID:1219,6036&cs=1E09EF56687483766D7107EED461CC053

[23] Mixtures outside the scope of this investigation. Trichloroethylene in mixtures restricted with entry 28 of Annex XVII to REACH.

available throughout the whole lifecycle of products and materials, including at the waste stage.

B.9.1.1 Summary of the existing legal requirements

REACH has several requirements for substances on the candidate list including notification of its presence in articles if ≥0.1% and 1 tonne per year (Article 7(2)) and that suppliers must inform their customers on request if an article contains more than 0.1% by weight of trichloroethylene (Article 33(b)).

The entry in Annex XIV for trichloroethylene sets a last application date of 21/10/2014 and a sunset date of 21/04/2016.

Under the Toy Safety Directive (2009/48/EC) carcinogenic, category 1B substances such as trichloroethylene are not allowed in the accessible parts of toys beyond the concentration limits set in the Regulation on Classification, Labelling and Packaging of substances and mixtures, or unless they are considered safe following a rigorous scientific evaluation. Some of the swim articles mentioned in the previous sections may fall under this directive.

Trichloroethylene, as a substance or in a mixture, is restricted by entry 28 of Annex XVII in REACH (placing on the market for supply to the general public), being placed on the Appendix 2.

Information on existing legislations in the European Union relevant for trichloroethylene is available on ECHA's website under the EU Chemicals Legislation Finder (EUCLEF): https://echa.europa.eu/fi/legislation-obligation/-/obligations/100.001.062

B.10 Risk characterisation

Articles containing or releasing trichloroethylene identified so far are rubber for flooring used in underground environments, swim articles, desk chairs, dining tables, sofas, electrical machinery and equipment and parts thereof, primary cells and primary batteries, parts and accessories of the motor vehicles and engines and optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus.

Trichloroethylene is considered to be a genotoxic carcinogen. No threshold can be determined below which exposure would be safe. The reference dose response relationship established by RAC for carcinogenicity of trichloroethylene (RAC, 2014) for inhalation, dermal and oral route, has to be considered.

Scarce information is available in in order to reach conclusions whether there are risks to human health from the identified uses. As regards swim articles, desk chairs, dining tables and sofas the limited information on concentrations emitted to the air seemed to be low (below the detection and quantification limits in EN standard 71-11). Considering the dose-response equations for general population derived by RAC (2014) (at 6.2 mg/m^3 and above: Excess kidney cancer risk = 6.9×10^{-4} $(mg/m^3)^{-1}$ × concentration (mg/m^3) – 0.0039 and below 6.2 mg/m^3: Excess kidney cancer risk = 6.4×10^{-5} $(mg/m^3)^{-1}$ × concentration (mg/m^3)/24-h average concentrations of trichloroethylene for 70 years) and taking into account e.g. the reported max concentration from sofa (2.36 $\mu g/m^3$) of trichloroethylene, the cancer risk level seems relatively low. Moreover,

the dose-response derived is for lifetime, and with the information available for the emissions from consumer articles, the lifetime exposure seems to be an overestimation.

Due to the non-threshold nature of the substance, the exposure of workers and consumers should be as low level as possible.

There are indications that trichloroethylene is in imported articles, however before any further action on the substance ECHA will monitor the presence of the substance in articles via SCIP (Substances of Concern In articles as such or in complex objects) and Substances in Articles notifications.

C. Available information on alternatives

The SVHC identification report for trichloroethylene provides information on alternatives especially for the uses of cleaning and degreasing of metal parts, fabric cleaning and asphalt cleaner in public works (Annex XV, 2010). Alkaline mixtures, halogenated (e.g. perchloroethylene, methylene chloride) and non halogenated solvents (oxygen solvents, aliphatic and cycloaliphatic hydrocarbons, as well as n-methyl 2-pyrrolidone are reported to be alternatives for the substance in concern.

Similarly, ECHA (2010) provides some information on alternatives for trichloroethylene in its main use as cleaning agent or degreaser. Moreover, the report is stated that in most of these cases substitution has already taken place and for the only remaining uses (repair of conveyer belts in mines and rubber coating) alternatives might be more difficult to find. It is to be noted that in the application for this specific use the applicant presented three types of alternatives to the use of trichloroethylene in the repair and maintenance of conveyor belts in underground mining: a) Change of the type of belts, b) Use of separable joints and c) Use of alternative solvent mixture. However, all were considered not suitable alternatives at the moment by the applicant. The Committee for Socio-economic Assessment (ECHA, 2015) agreed with the applicant that no suitable alternatives exist at this moment in time. This specific authorisation has expired[24].

D. Justification for action on a Community-wide basis

Not relevant, as no restriction is proposed at present.

E. Justification why the proposed restriction is the most appropriate Community-wide measure

Not relevant, as no restriction is proposed at present.

F. Socio-economic Assessment of Proposed Restriction

Not relevant, as no restriction is proposed at present.

[24] Applicant provided information that in 2020 all of the mines will be closed down as well as decommissioned and the use of TCE will cease completely.

G. Stakeholder consultation

The Annex XV screening report was subject to a Call for evidence from 18 August 2021 to 29 September 2021. A comment was received from one Member State (Denmark), who provided references to certain studies indicating low concentrations/concentrations below the detection limit of trichloroethylene emitted to the air from specific articles.

H. Other information

Scientific literature provides several uses of trichloroethylene. Detailed list of uses associated with trichloroethylene can be found in Table 3. Whether some of these lead to the incorporation in articles outside EU and consequently imports of articles containing trichloroethylene is unknown.

Table 3. Trichloroethylene uses, adjusted from Bakke et al. (2007) and Morrison & Murphy (2015)

Industry	Use in/as	Additional info	Source
Dry cleaning and dyeing and other fabric cleaning (rugs, wool and fur)	Batch process cleaning large quantities of textiles		
	Spot remover on individual pieces		
Textile mill products and apparel	Solvent scouring; process of removing waxes, pectins, dirt, and lubricants generated mostly from coning and knitting.		16,24
	Desizing of textiles		14,47
	Extraction of wax from cotton and for impregnation		45
	Extraction of oils and fats from wool		11,39,49,54
	Removal of basting threads		40
	Constituent of soap solutions		56
	Swelling agent in the disperse dyeing of polyesters		40
	Solvent in waterless dyeing and finishing operations		13
	Dye fixative and mordant		14,56
	Artificial fabrics (rayon, glass fibers, silk, and cotton-polyester materials) for impregnating and dressing.		49,56
	Degreasing of organic fibers, asbestos, glass, carbon,or silicon carbide fibers prior to bonding or lamination		20
	Leather dressing and preparation	Active in 2005 in France	M&M
	Water repellent agent		

Leather and leather products	Fat removal from hides in the processing of leather		14,49,56
	Disinfecting of hides and skin		56
	Rubber cement for crepe soles		56
	Recovering fat-free glue from residues of glue boilers in tanneries		56
	Impregnation of leather		56
Electronic components and accessories	Degreasing semiconductor wafers before, during, and after fabrication of the integrated circuits on them		59-61
	Manufacture of silicon (trichloroethylene may be added to help control unwanted impurities)		63
	Cleaning of ingot and wafer materials		63
	Stripping of developed photoresist coatings from printed circuit boards		59
	Solvent for binding and cementing materials (treads, tire, and bead building)		8,65
	Rubber solvent		66-68
	Solvent for neoprene (synthetic rubber)		39
	Tire repair		65,70
	Solvent in the manufacture of large, rigid, plastic products		73
	Plastic cements		56,74
Agricultural production and agricultural chemicals	Production of insecticides		46
	Synthesis of chlorophenols and phenoxy herbicides		78
	Component of fungicides, including difolatan		11,41,80
Food and kindred products	Extractant in decaffeination of coffee and spice oleoresins	Historical use	Morrison & Murphy13,84
	Extraction solvent for natural fats and oils, such as palm, coconut and soybean oils; olives; corn; grape seeds; and other food products	Historical use	Morrison & Murphy 13,18,39,49,56,86
	In a wax solution applied to eggs as a preservative		45,49,56
Health service	Anesthetic		
	Abreaction reagent (a drug that releases repressed emotions) in psychoanalysis		45
	Disinfectant (for example, for sterilization of hands prior to surgery)		56
	Detergent for skin		50,94
	Extracting resin from wood		

Chemical and allied products	Production of waxes, gums, resins, tars		82
	Dye manufacturing		50,96
	Dye fixative and mordant		14
	Raw material in the manufacture of chlorinated aliphatics, glycolic and dichloroacetic acids) and chlorofluoromethane refrigerants		46, 49, 13, 79
	Cleansing soap solutions used to make spirit soap (25% trichloroethylene; 75% potassium oleate)		56
	Solvent for sulfur chloride		8
	Cellulose esters and ethers		13, 50, 95
	Chain terminator in the production of polyvinyl chloride		11,13,40
	Secondary raw material in PVC suspension process		M&M
	Processing solvent in the production of an antioxidant for tire manufacturing		19
	Dewaxing lubrication oils by causing the wax in the oil to crystallize		49,79,82
	Specialty lubricants		11,47
	Cellulose acetate adhesives		
Paints varnishes, lacquers, enamels and allied products	Thinner for paints and varnishes		13,14,39,55,95,100
	Component of quick-drying paints in a foundry in the U.K.		102
	Applying protective phosphate layers to metallic articles by immersing the paint into a trichloroethylene solution of an organic phosphate		M&M,13, 49, 103
	Paint stripper		50,54,96
	Lacquers		Morrison & Murphy
	Scouring agent for paint	Active in 2005	Morrison & Murphy
Aircraft industry	Vapor degreaser		Morrison & Murphy
	To flush liquid oxygen		
Paper and allied products and printing and publishing	Impregnating cardboard paper board boxes		56,108,109
	Solvent for a paraffin-synthetic resin mixture used for processing paper		110
	Ingredient in printing inks		45, 109, 111
	Clean cylinders and type		56, 97,112
Research, development	In low temperature research		

and testing services			
Perfumes, cosmetics and other toiletry preparations	Component in dry shampoo		50
	Perfume, soap and bath toilet products manufacturer - use as a detergent	Active in 2005 in France	
Adhesives	Solvent in adhesives	US, 2003 MSDS for adhesive used for the foam furniture industry had 25% of trichloroethylene as a stabiliser	M&M
	Solvent in adhesives (2)	trichloroethylene containing adhesives used in a cold lamination process to bond paper to a foam core or fabric to a cardboard core (US, production of glass headliners)	M&M
	Rubber repair & rubber lining in automotive and mining industries	AU 2000	M&M
	hot/cold vulcanisation of patches to tyres, sealing tire inner linings after buffing, lining tanks with rubber, repair of rubber belting	AU 2000	M&M
	Solvent in adhesives (3)	Adhesion of rubber coatings to vessel walls (UK 2005)	
Miscellaneous uses	Typewriter correction fluids		121
	Vehicle in a silicone parting agent in shell molding for foundries		122
	Wound healers for trees, in aerosol spray chimney cleaners, air fresheners, surface disinfectants, in preservation and deodorizers		14,50
	Smoke bombs used to evaluate ventilation		123,124
	Caulking substance for shipbuilding		14
	Waterproof material for brickwork		56
	Degreasing skins in the taxidermy industry		125
	In fire extinguishers		126

	Refrigerant and in air-conditioning installations		13,50
	Aerosol in spray cans		115
	Degreasing small arms		M&M
	Metal polishes		M&M
	Drain cleaners		M&M
	Septic system cleaners		M&M
	Consumer automotive products		M&M
	Rust preventative coatings		M&M

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