Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Aliphatic esters from branched carboxylic acids

General structure: -

Revision history

Version	*Date*	*Description*
1.0	2 May 2023	

Substances within this group:

EC / List no	CAS no	Substance name	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
202-595-4	97-62-1	Ethyl isobutyrate	Full, 1-10
203-602-3	108-64-5	Ethyl isovalerate	Full, not (publicly) available
208-929-5	547-63-7	Methyl isobutyrate	OSII or TII
212-429-2	816-19-3	Methyl 2-ethylhexanoate	Full, not (publicly) available
221-043-3	2983-37-1	Ethyl 2-ethylhexanoate	Full, not (publicly) available
231-225-4	7452-79-1	Ethyl 2-methylbutyrate	Full, 100-1000
254-384-1	39255-32-8	Ethyl 2-methylvalerate	Full, 100-1000
266-959-4	67707-75-9	Ethyl 3,5,5-trimethylhexanoate	Full, not (publicly) available
807-032-1	71500-39-5	Hexanoic acid, 3,5,5-trimethyl-, methyl ester	OSII or TII
286-065-8	85186-80-7	Fatty acids, C14-18 and C18-unsatd., branched and linear, Me esters	OSII or TII
441-620-5	-	Fatty acids, C16-18 and C18-unsatd., branched and linear, butyl esters	Full, not (publicly) available
614-560-4	68517-10-2	Isooctadecanoic acid, methyl ester	OSII or TII
219-075-8	2349-07-7	Hexyl isobutyrate	Full, 1-10
261-619-1	59130-69-7	Hexadecyl 2-ethylhexanoate	Full, 100-1000
298-078-6	93777-46-9	Decyl 2-ethylhexanoate	Full, not (publicly) available
291-445-1	90411-68-0	Hexanoic acid, 2-ethyl-, C16-18-alkyl esters	Full, 100-1000
601-141-6	111937-03-2	Isononanoic acid, C16-18-alkyl esters	Full, > 1000

This table does not contain group members that are only notified under the CLP Regulation.

[1] The total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

Contents

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Foreword

The assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)[2]. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level[3]. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

[2] Working with Groups - ECHA (europa.eu)

[3] Regarding hazard properties the focus is for instance on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website[4].

[4] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic / very persistent and very bioaccumulative
PMT/vPvM	Persistent, mobile, and toxic / very persistent and very mobile
RDT	Repeated dose toxicity
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
TPE	Testing proposal evaluation
UVCB	Substance of unknown or variable composition, complex reaction products or of biological materials

1 Overview of the group

Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances based on carboxylic acid esters derived from branched carboxylic acids and linear alcohols.

The group consist of 17 registered substances, of which 13 have full registrations and 4 are registered as intermediates. The corresponding acids have total carbon numbers from C4 to C18; the longest continuous chain of each acid is shorter due to the branching. The alcohols are all saturated and linear and have carbon numbers from C1 to C18. Four substances in these subgroups are UVCBs.

Based on information reported in the REACH registration dossiers, the majority of the substances in the group have a very similar use profile. They are used mainly as fragrance in a wide range of applications and have widespread uses in professional setting or consumer products. The main sectors of use are:

- washing and cleaning products
- polishes and waxes
- cosmetics
- biocides
- air care products

EC 291-445-1 has the broadest range of uses in the group. In addition to the uses mentioned above, the registered uses include construction products, textile and leather as well as rubber and plastic articles. For these uses the presence of the substances in the final article cannot be excluded.

ECs 219-075-8, 261-619-1 and List No. 601-141-6 have a different use profile compared to other substances of the group. All three substances are used as emollient in cosmetic products. In addition, EC 261-619-1 is also registered for uses in lubricants and welding products.

ECs 208-929-5, 286-065-8 and List Nos. 614-560-4 and 807-032-1 are only used as intermediates.

As a conclusion, the majority of the substances in the group have widespread uses in professional settings or consumer products, with high exposure potential and release to the environment.

2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g., on hazards through evaluation processes, or on uses) will become available, the document may be updated, and conclusions and actions revisited.

Table 1: Conclusions and proposed actions

EC/List no,	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
212-429-2 **221-043-3**	Known or potential hazard for reproductive toxicity	No hazard or unlikely hazard	Industrial and professional use, constituent in consumer products. Potential for exposure for workers and consumers and release to the environment.	**First step:** Substance evaluation after CCH for 212-429-2 **Potential next steps (if hazard confirmed after data generation):** CLH, restriction <u>Justification</u>: Harmonised classification as R1 will require company level risk management measures for workers to be in place and would lead to generic restriction of the substance in consumer mixtures by means of restriction entry 30. The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk

EC/List no,	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.
202-595-4 **203-602-3** **231-225-4** **254-384-1** **219-075-8** **261-619-1** **298-078-6** **291-445-1** **601-141-6**	No hazard or unlikely hazard	No hazard or unlikely hazard	Widespread uses in professionals and consumer products such as washing and cleaning products, polishes and waxes, cosmetics or air care products etc.	**First step:** CCH for 261-619-1, 231-225-4, 254-384-1 **Potential last action:** **Currently no need for EU RRM** Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses.
266-959-4 **441-620-5**	No hazard or unlikely hazard	Inconclusive hazard for PBT & aquatic toxicity.	Widespread uses in professionals and consumer products such as washing and cleaning products, polishes and waxes, cosmetics or air care products etc.	**First step:** CCH for 266-959-4 and 441-620-5 **Potential last action:** **Currently not possible to assess the regulatory needs**

EC/List no,	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
208-929-5 **807-032-1** **286-065-8** **614-560-4**	No hazard or unlikely hazard	No hazard or unlikely hazard	Uses as intermediate in industrial setting, with limited exposure potential and release in the environment.	No action **Currently no need for EU RRM** Justification: No or unlikely hazard and with low exposure potential.

3 Justification for the need for regulatory risk management action at EU level (if hazards confirmed)

Suggested regulatory risk management action for EC 212-429-2 and EC 221-043-3 if reproductive toxicity hazard is confirmed

Based on currently available information, there is a potential hazard for reproductive toxicity for EC 212-429-2 based on extrapolation from esters with short chain branched carboxylic acid. There is potential for hydrolysis to 2-ethylhexanoic acid (2-EHA) which has a harmonised classification as Repr. 1B[5]. The substance is reported to be used by industrial and professional workers and is contained in consumer products. Due to low tonnage, a substance evaluation (SEv) is suggested to clarify the hazard following a compliance check (CCH). The CCH/SEv process should define the appropriate studies needed to address the concern, as well as evaluate the proportionality of any requests for the substance. EC 221-043-3, similarly to EC 212-429-2 is potentially reproductive toxicant due to potential release of 2-EHA. The substance is used by industrial and professional workers and by consumers. At this stage due to its registration status, no CCH is proposed.

An endocrine disruptor (ED) mode of action might be assumed for the potential reproductive toxicity; however, at this stage the strategy is based only on the hazard hypothesis of reproductive toxicity.

No other hazards have been identified regarding carcinogenicity, mutagenicity, and skin sensitisation properties (as per the remaining group members, see next section). Similarly, the group members are not considered to be PBT/vPvB based on the available information.

The first step of the regulatory risk management action proposed, should the hazard exist, is to confirm via harmonised classification (CLH) the potential reproductive toxicity. If the CLH process confirms the substances as being R1A/B then the CLH i) will require company level risk management measures (RMM) for workers to be in place; ii) is needed or highly recommended in support of further regulatory processes under REACH; and iii) would lead to generic restriction of the substance(s) in consumer mixtures by means of restriction entry 30.

CLH is also a prerequisite to restrict the presence of the substances in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)).

CLH will also support regulatory action under other legislations. For instance,

- harmonised classification as CMR cat. 1 will trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009, since CMR cat. 1 are restricted by this regulation unless specifically derogated.
- harmonised classification as CMR cat. 1 would render the substances unacceptable co-formulants in biocidal products if present above the concentration limit leading to classification of the mixture as CMR cat 1 according to the Biocidal product regulation (EU) 528/2012.
- harmonised classification as CMR cat 1 would render the substances unacceptable co-formulants in Plant protection products if present above the

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1435&qid=1689155759608

concentration limit leading to classification of the mixture as CMR cat 1 according to the plant protection product regulation (EC) No 1107/2009.
- harmonised classification as CMR cat.1 will trigger the restriction of use of these substances in toys according to the Toy safety directive (2009/48/EC).

The professional uses in washing & cleaning products and polishes & wax blends are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

Consumers may be co-exposed to the substances used by professionals e.g. house cleaners.

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH.

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability**Error! Bookmark not defined.** which aims to extend to professional users under REACH the level of protection granted to consumers.

Currently no need to suggest (further) regulatory risk management actions for the remaining substances

No potential hazards are identified for human health for the remaining substances. These conclusions are based on the available data on the registered substances, the hypothesis of enzymatic hydrolysis and available information on the metabolites as well as extrapolation of hazard hypothesis due to structural similarity.

Most of the substances in this group are unlikely to fulfil the PBT/vPvB screening criteria, because they are considered to be readily biodegradable and are unlikely to fulfil the T criterion. The available data indicates that the group is not subject to hydrolysis and/or is not considered as a major pathway. Therefore, all screening was conducted on the registered substances. No specific PBT/aquatic toxicity hazard could be identified from the available data in the group.

Based on the evaluations[6] from other safety bodies, group members are expected to be rapidly hydrolysed into branched carboxylic acids and alcohols by carboxylesterase enzymes found in most tissues throughout the body, including the gastrointestinal tract. The resulting linear alcohols will be oxidised to their corresponding aldehydes and linear carboxylic acids, which will in turn be metabolised to carbon dioxide via the fatty acid pathways and the tricarboxylic acid cycle. The resulting branched carboxylic acids will undergo different metabolic pathways, depending on the carbon chain length and branching: beta-oxidation for

[6] JECFA, 1999 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3169/epdf; COM, 2003 https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out158_en.pdf; EFSA, 2013 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3169/epdf

short chains, omega-oxidation for long chains and alfa- and/or beta-oxidation for acids with a methyl substituent.

The majority of the carboxylic acid parts of these group members have been or are being assessed by ECHA (group on fatty acids expected to be of low toxicity and group on branched carboxylic acids, with short chain ones to be potential reproductive toxicants). Furthermore, the assessment of regulatory needs of the group of aliphatic alcohols has also concluded on potential low toxicity regarding the expected alcohol metabolites from the enzymatic hydrolysis of the esters in this group.

In vitro mutagenicity studies are available for the majority of the substances (mainly Ames studies but also two *in vitro* chromosomal aberration tests and two *in vitro* mammalian cell gene mutation tests) and are negative.

Experimental data on repeated dose toxicity are limited but the data from three group members tested do not show any relevant toxic effects.

Similarly, reproductive and developmental toxicity data are available for a limited number of substances in the group (OECD TG 422 and OECD TG 414 studies) and are negative. Regarding a potential ED hazard, the available systemic toxicity studies do not indicate any target organ toxicity in endocrine system such as the thyroid or the reproductive organs. Therefore, there is no apparent hazard finding that could be linked to endocrine-mediated effects for any substances in these subgroups. The absence of systemic toxicity potential is assumed to be applicable to the other substances in these subgroups based on structural similarity.

Overall, the reproductive and developmental toxicity hazard is considered unlikely for the substances of these subgroups with remaining uncertainty. This is due to the potential breakdown of the esters, more specifically regarding the rate of hydrolysis, the information available is mostly from literature sources and refers to the generic ability of carboxylesterases to breakdown the esters.

The substances (EC/List 202-595-4, 203-602-3, 208-929-5, 231-225-4, 254-384-1, 807-032-1, 219-075-8) are esters with short chain branched carboxylic acids that could potentially release branched carboxylic acid one of which is 3,5,5-trimethylhexanoic acid (EC 221-975-0) intended for classification as Repr. 1B; the short chain branched carboxylic acid have also structural similarity with known reproductive toxicity branched carboxylic acid (2-ethylhexanoic acid).

The substances (EC/ List 261-619-1, 291-445-1, 601-141-6) are esters of long chain fatty acid with 2-EHA; in this case the potential for release of 2-EHA might be slower due to the presence of the long fatty acid moiety; for EC 291-445-1 and 601-141-6 the available reproductive toxicity studies do not currently indicate a concern.

The substances (EC 286-065-8 and 614-560-4) are also esters of long chain fatty acids and due to potential slow hydrolysis and absence of short chain carboxylic acid moiety and are unlikely reproductive toxicants.

Applying the potential reproductive and developmental toxicity hazard for these group members would be a worst-case assumption, as it is not known whether the metabolites of concern resulting from their hydrolysis will be systemically available at concentrations sufficient to cause toxic effects. In general, it is assumed that the toxicity of the esters is expected to be lower than that of the corresponding carboxylic acids and alcohols since higher doses of the esters would be needed to reach equivalent toxic doses. At this stage only in case of known reproductive toxicity for the metabolite (harmonised classified) and potential release due to the

structure the hazard is extrapolated to the ester.

Further assessment and/or data generation is required for EC 261-619-1, 231-225-4, 254-384-1 to address the remaining uncertainties.

For the remaining group members where due to their uses (intermediates) or low tonnage no CCH is proposed, information from the branched fatty acids and alcohols ARNs and the structurally similar esters when available will further inform on their hazardous properties and the strategy can be revisited.

Based on the information available on composition provided in (some) registration dossiers, the substance EC 298-078-6, decyl 2-ethylhexanoate, contains as constituent or impurity the substance EC 149-57-5, 2-ethylhexanoic acid with harmonised classification as Repr. 1B[7] at concentrations above specific/generic concentration limits under the CLP Regulation, justifying the classification of the substance EC 298-078-6 as Repr. 1B. Such classification is however not applied by those registrants where the substance is present in the composition. Therefore, registrants are invited to update their registration dossiers and revise the classification of the substance(s) based on constituents/impurities, as appropriate, or if technically feasible to ensure that the concentration of the impurity is below the relevant concentration limit for Repro 1B. The Safety Data Sheet needs to be updated accordingly.

Currently not possible to suggest regulatory risk management actions for substances EC 266-959-4 and EC 441-620-5

For EC 266-959-4 and EC 441-620-5 the available data does not allow to conclude at this stage if they fulfil the P and the B criterion, therefore they are inconclusive P and B.
The substances are unlikely CMR/ED and skin sensitisers based on the available information and arguments presented for the majority of the substances above.

Further assessment under CCH is needed for both substances.

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1435&qid=1689155759608

Annex 1: Overview of classifications

Data extracted in February 2020.

EC/ List No	Substance name	Harmonised classification	Classification in registrations
202-595-4	*ethyl isobutyrate*	*Not included in Annex VI*	*Skin Irrit. 2 H315 Eye Irrit. 2 H319 Flam. Liq. 2 H225*
203-602-3	*ethyl isovalerate*	*Not included in Annex VI*	*Flam. Liq. 3 H226 Skin Irrit. 2 H315*
208-929-5	*methyl isobutyrate*	*Not included in Annex VI*	*Flam. Liq. 2 H225*
212-429-2	*methyl 2-ethylhexanoate*	*Not included in Annex VI*	*Skin Irrit. 2 H315 Flam. Liq. 3 H226*
219-075-8	*hexyl isobutyrate*	*Not included in Annex VI*	*-*
221-043-3	*ethyl 2-ethylhexanoate*	*Not included in Annex VI*	*Eye Irrit. 2 H319*
231-225-4	*ethyl 2-methylbutyrate*	*Not included in Annex VI*	*Flam. Liq. 3 H226*
254-384-1	*ethyl 2-methylvalerate*	*Not included in Annex VI*	*Flam. Liq. 3 H226*
261-619-1	*hexadecyl 2-ethylhexanoate*	*Not included in Annex VI*	*-*
266-959-4	*ethyl 3,5,5-trimethylhexanoate*	*Not included in Annex VI*	*-*
286-065-8	*Fatty acids, C14-18 and C18-unsatd., branched and linear, Me esters*	*Not included in Annex VI*	*-*
291-445-1	*Hexanoic acid, 2-ethyl-, C16-18-alkyl esters*	*Not included in Annex VI*	*-*
298-078-6	*decyl 2-ethylhexanoate*	*Not included in Annex VI*	*-*
441-620-5	*Fatty acids, C16-18 and C18-unsatd., branched*	*Not included in Annex VI*	*-*

EC/ List No	Substance name	Harmonised classification	Classification in registrations
	and linear, butyl esters		
601-141-6	*Isononanoic acid, C16-18-alkyl esters*	*Not included in Annex VI*	*-*
614-560-4	*Isooctadecanoic acid, methyl ester*	*Not included in Annex VI*	*-*
807-032-1	Hexanoic acid, 3,5,5-trimethyl-, methyl ester	*Not included in Annex VI*	*Aquatic Chronic 2 H411*

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted in February 2020.

Main types of applications structured by product or article types	202-595-4	203-602-3	208-929-5	212-429-2*	219-075-8	221-043-3	231-225-4	254-384-1	261-619-1	266-959-4	286-065-8	291-445-1	298-078-6	601-141-6	614-560-4	807-032-1
Washing and cleaning products	F, **P, C**	F, I, **P, C**				F, I, **P, C**	F, I, **P, C**	F, I, **P, C**		F, I, **P, C**		F, I, **P, C**	F, I, **P, C**			
Polishes and wax	**C**	F, **P, C**				F, **P, C**	F, **P, C**	F, **P, C**		F, **P, C**		F **C**				
Cosmetics	**C**	F, **P, C**			F, **C**	F, **P, C**	F, **C**	F, **P, C**	F, **C**	F, **C**		F, **C**		F, **C**		
Tobacco products	F, **C**															
Biocides / Insecticide		F, **C**				F, **C**	F, **C**	F, **C**		F, **C**			F, **C**			
Air care products		F, **C**				F, **C**	F, **C**	F, **C**		F, **C**		F **C**	F, **C**			
Oral care products								F, **P**								
Manufacture of alcohol											I					
Functional fluid												F **C**		I		
Lubricants									F, I, **P, C**			F, I, **P, C**				
Welding and soldering prod									I, **P**							

Main types of applications structured by product or article types	202-595-4	203-602-3	208-929-5	212-429-2*	219-075-8	221-043-3	231-225-4	254-384-1	261-619-1	266-959-4	286-065-8	291-445-1	298-078-6	601-141-6	614-560-4	807-032-1
Adhesive and sealants												F, **C**				
Fuels												F, I, **P, C**				
Fertilisers, agrochemicals												**P, C**				
Construction products												F, I, **P, C, A**				
Textiles, leather												I, **P, A**				
Rubber												I, **A**				
Plastics												I, **A**				
Polymers												I				
Coatings												I, **P, C**				
Intermediate			I												I	I

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release. *The substance is used in industrial and/or professional settings and occurs in consumer products.

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted in February 2020.

There are no relevant completed or ongoing regulatory risk management activities for any of the substances.