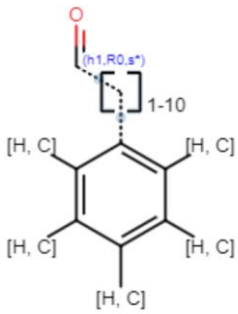
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 02 May 2022

Group Name: Aralkylaldehydes

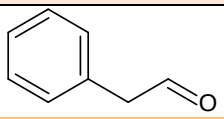
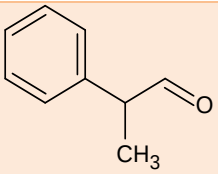
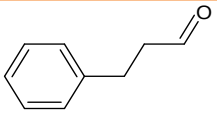
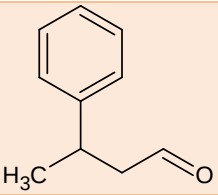
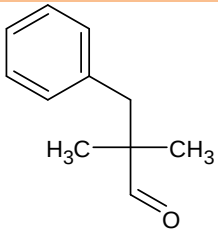
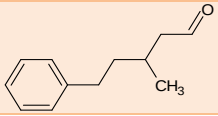
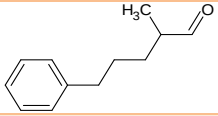
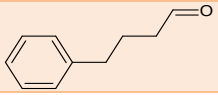
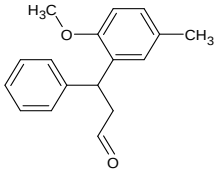
General structure:



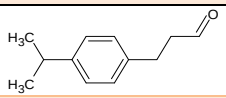
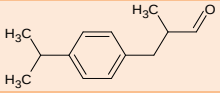
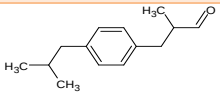
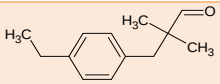
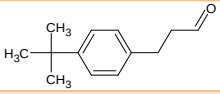
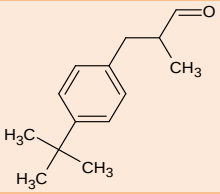
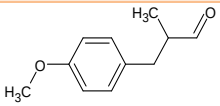
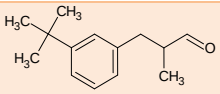
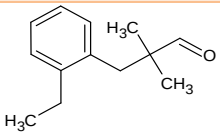
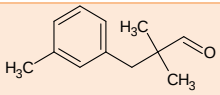
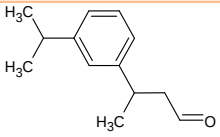
Revision history

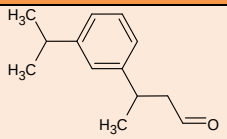
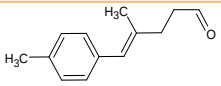
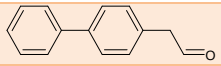
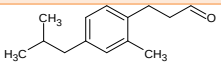
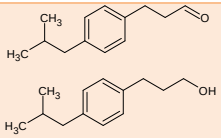
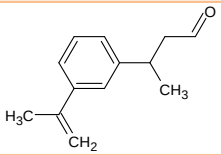
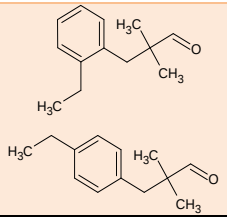
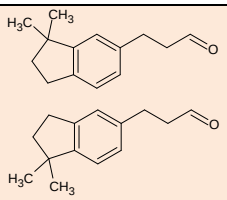
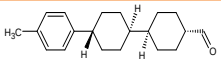
Version	*Date*	*Description*
1.0	19 Sept 2022	

Substances within this group:

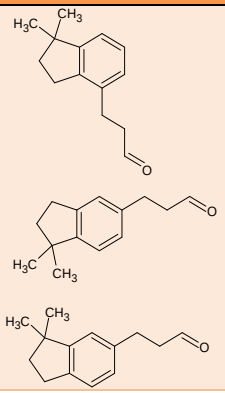
EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Subgroup 1: Phenylalkylaldehydes				
204-574-5	**122-78-1**	**phenylacetaldehyde**		Full, not (publicly) available;
202-255-5	**93-53-8**	**hydratropaldehyde**		Full, not (publicly) available;
203-211-8	**104-53-0**	**3-phenylpropionaldehyde**		Not registered
240-362-9	**16251-77-7**	**3-phenylbutyraldehyde**		Full, 1-10 tonnes
213-771-5	**1009-62-7**	**2,2-dimethyl-3-phenylpropionaldehyde**		TII or OSII
433-900-0	**55066-49-4**	**3-methyl-5-phenylpentan-1-al**		Unclaimed NONS
455-570-7	**N/A**	**2-methyl-5-phenylpentanal**		Claimed NONS
686-906-2	**18328-11-5**	**4-phenylbutanal**		Not registered
948-110-6	**857288-55-2**	**3-(2-methoxy-5-methylphenyl)-3-phenylpropanal**		TII or OSII

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

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Subgroup 2: (Alkylphenylen)alkylaldehydes				
231-885-3	**7775-00-0**	**3-(p-cumenyl)propionaldehyde**		Full, not (publicly) available;
203-161-7	**103-95-7**	**3-p-cumenyl-2-methylpropionaldehyde**		Full, 100-1000
229-695-0	**6658-48-6**	**3-(4-isobutylphenyl)-2-methylpropanal**		Full, not (publicly) available;
266-819-2	**67634-15-5**	**3-(p-ethylphenyl)-2,2-dimethylpropionaldehyde**		Not registered
242-016-2	**18127-01-0**	**3-(4-tert-butylphenyl)propionaldehyde**		Full, 10-100
201-289-8	**80-54-6**	**2-(4-tert-butylbenzyl)propionaldehyde**		Full, not (publicly) available;
226-749-5	**5462-06-6**	**3-(p-methoxyphenyl)-2-methylpropionaldehyde**		Full, 10-100
263-580-6	**62518-65-4**	**3-(m-tert-butylphenyl)-2-methylpropionaldehyde**		TII or OSII
266-818-7	**67634-14-4**	**3-(o-ethylphenyl)-2,2-dimethylpropionaldehyde**		Not registered
440-720-6	**not (publicly) available**	**2,2-dimethyl-3-(3-methylphenyl)propanal (not published in ELINCS)**		TII or OSII, NONS
412-050-4	**not (publicly) available**	**β-methyl-3-(1-methylethyl)benzenepropanal IUPAC: 3-(3-isopropylphenyl)butanal**		Full, 100-1000, NONS

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
641-004-8[2]	**125109-85-5**	**β-methyl-3-(1-methylethyl)benzenepropanal** **IUPAC: 3-(3-isopropylphenyl)butanal**		Not registered
700-748-4	**1226911-69-8**	**(4*E*)-4-methyl-5-(4-methylphenyl)pent-4-enal**		Full, not (publicly) available;
819-645-1	**61502-90-7**	**IUPAC: [biphenyl]-4-ylacetaldehyde**		Not registered
811-285-3	**1637294-12-2**	**3-(4-isobutyl-2-methylphenyl)propanal**		Full, not (publicly) available;
954-094-1	**not (publicly) available**	**Reaction mass of 3-(4-isobutylphenyl)propanal and 3-(4-isobutylphenyl)propan-1-ol**		TII or OSII
924-149-4	**not (publicly) available**	**IUPAC: 3-[3-(prop-1-en-2-yl)phenyl]butanal**		TII or OSII
916-329-6	**not (publicly) available**	**Reaction mass of 3-(o-ethylphenyl)-2,2-dimethylpropionaldehyde and 3-(p-ethylphenyl)-2,2-dimethylpropionaldehyde**		Full, 10-100
Subgroup 3: Other aralkylaldehydes				
437-470-5	**not (publicly) available**	**Reaction mass of 3-(1,1-dimethyl-2,3-dihydro-1H-inden-5-yl)propanal and 3-(3,3-dimethyl-2,3-dihydro-1H-inden-5-yl)propanal (not published in ELINCS)**		Claimed NONS
605-043-4	**156140-04-4**	**IUPAC: (1r,1'r,4r,4'r)-4'-(4-methylphenyl)[1,1'-bi(cyclohexyl)]-4-carbaldehyde**		TII or OSII

[2] 641-004-8 is only in C&L inventory and it is a duplicate of 412-050-4

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
700-617-1	**not (publicly) available**	**Reaction mass of 3-(3,3-dimethyl-2,3-dihydro-1H-inden-5-yl)propanal and 3-(1,1-dimethyl-2,3-dihydro-1H-inden-5-yl)propanal and 3-(1,1-dimethyl-2,3-dihydro-1H-inden-4-yl)propanal**		Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

Contents

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e., the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g., harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g., assessment done under REACH/CLP or other EU legislation or can be generated in some cases (e.g., further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process, but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[3].

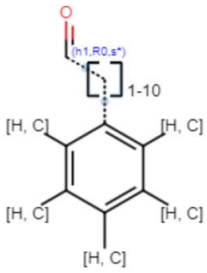
[3] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
GPMT	Guinea Pig Maximisation Test
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
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

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the aldehyde moiety and a phenyl substituent, as shown in the figure below:



The group is related to other aldehydes including cinnamaldehydes, short-chain alkylaldehydes, long-chain alkylaldehydes (branched and non-branched) and alicyclic aldehydes (fused cycles). It consists of 30 substances among which 14 are fully registered, 7 are registered as intermediates, 3 are notified and 6 are not registered.

The registrants identified some substances using generic names, many multi-constituent substances are regarded as mono-constituent substances. However, as racemates they are multi-constituent substances. The group does not include UVCB substances.

Based on information reported in the REACH registration dossiers, all substances with full registration dossiers have widespread uses in diverse professional and consumer applications potentially leading to human and environmental exposure. The substances are mainly used to manage the odour of mixtures/articles (e.g., odour control, fragrance, etc.). Almost all substances are primarily used in polishes and waxes, perfumes and fragrances, air care products, washing and cleaning products, cosmetics and personal care products, biocides (e.g., disinfectant, pest control). All registered substances report industrial uses, with several only used as intermediates (precursors), *e.g.*, in the manufacture of fine chemicals. All but one substance with full registration report the substances being used in formulation.

EC 201-289-8 has a harmonised classification as Repr.1B H360Fd. The substance has been identified as SVHC and included in the candidate list following a proposal made by Sweden. Following its inclusion in the Candidate List, ECHA has recommended the substance for inclusion in Annex XIV in its draft recommendation which is under consultation[4]. ECHA regularly assesses the priority for substances from the Candidate List to be included in the Authorisation List (Annex XIV)[5].

During the SEv, the evaluating MSCA (SE) identified additional concerns for potential endocrine disrupting properties for both, the environment and human health as the current data is inconclusive regarding ED properties. However, this hazard was not investigated further as the evaluating MSCA did not foresee that

[4] Consultation on draft recommendation for inclusion in the Authorisation List - ECHA (europa.eu)

[5] More information on the process at https://echa.europa.eu/authorisation-process

this would lead to a significant improvement of the regulatory risk management for the substance in addition to the identified Repr. 1B hazard[6].

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is 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 table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g., neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e., professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted, and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction of professional uses for potential reproductive toxicity hazards due to the potential for exposure of several substances (EC 201-289-8, EC 203-161-7, EC 231-885-3, EC 242-016-2, EC 263-580-6, List 954-094-1, EC 229-695-0).

Based on ECHA's assessment of currently available information, seven substances in the Aralkylaldehydes group have **known or potential hazard for toxicity for reproduction** warranting Repr 1B classification.

One of the substances (EC 201-289-8) has a harmonised classification Repr. cat.1B H630Fd. The potential factor driving the reproductive toxicity is the presence of the tert-butyl-moiety in para-position. The plausible mode of action is the metabolization of EC 201-289-8 to p-tert-Butyl-benzoic acid (p-tBBA) which is known to adversely affect the reproductive system in male rats. Three structurally closely related para-substituted substances (EC 203-161-7, EC 242-016-2, EC 231-885-3) are considered to be potentially toxic for reproduction based on the testicular toxicity observed in the studies available. Two additional substances (List

[6] SEv conclusion document

954-094-1, EC 263-580-6) are flagged as potentially toxic for reproduction because of their self-classification. List 954-094-1 and EC 263-580-6 are used as intermediates only. Experimental data are only available in the registration dossiers for EC 263-580-6 (self-classification as Repr. 1B) and indicate developmental toxicity and no testicular toxicity is reported. EC 263-580-6 is showing different toxicity than the four other substances (EC 201-289-8, EC 203-161-7, EC 242-016-2, EC 231-885-3) and this can be explained by the structural dissimilarity. Indeed, EC 263-580-6 has no substituent in para position. Therefore, a different mode of action driving the reproductive toxicity cannot be excluded. It is also noted that no testicular toxicity is observed in a screening study conducted with EC 226-749-5 which has substituents in para position. It seems that the para position, although plausible, is not necessarily the only factor sufficient to drive the toxicity for reproduction.

The screening study performed with EC 229-695-0 does not indicate any toxic effects on reproduction but the study has been conducted via dermal route. EC 229-695-0 is structurally similar to EC 201-289-8, EC 203-161-7, EC 242-016-2, and EC 231-885-3 and has the same mode of action (metabolization to TBBA[7]). It is therefore assumed that this substance is expected to have the same toxicity for reproduction. It is proposed to open a CCH to clarify the hazard.

The first step of the regulatory risk management action proposed, should the hazard exist for the substance where it is still unclear is the confirmation of hazard via data generation (CCH is proposed for EC 229-659-0) and harmonised classification (CLH) as Repr. 1B.

CLH proposals could be developed to confirm the hazard for the above-mentioned substances for which there is already sufficient hazard information (EC 203-161-7, EC 231-885-3, EC 242-016-2, List 954-094-1, and EC 263-580-6). When preparing the proposals, it may be considered what would be the best way to develop them, for instance whether to make a proposal for the group of substances, to submit them individually or jointly.

These seven substances have additional hazards. Similar to the rest of the substances in the group, they have **known or potential hazard for skin sensitisation**. This is on the basis of:

- harmonised classification or self-classification as Skin Sens. 1B (H317) for EC 201-289-8, 203-161-7, 229-695-0, 231-885-3, and 242-016-2, or Skin Sens. 1 (H317) for List 954-094-1,

- the structural similarity of all the substances in this group and the conclusions of the assessment of various other aldehyde groups.

Furthermore, four of the substances have **known or potential hazard for STOT RE**. EC 242-016-2 is self-classified as STOT RE 2. EC 201-289-8 and EC 203-161-7 have indications of liver toxicity in the available data. The plausible mode of action (MoA) explaining the liver toxicity is the accumulation of the TBBA-CoA conjugate, i.e. tert-butylbenzoic acid (TBBA) forms conjugates with Coenzyme A (CoA) in the hepatocytes. The same MoA has been reported for EC 231-885-3. Therefore, even though no data are available because of the low tonnage band, EC 231-885-3 is

[7] Laue et al. (2017); p-Alkyl-Benzoyl-CoA Conjugates as Relevant Metabolites of Aromatic Aldehydes with Rat Testicular Toxicity—Studies Leading to the Design of a Safer New Fragrance Chemical. TOXICOLOGICAL SCIENCES, 160(2), 244–255

expected to have the similar liver toxicity. Further data generation (CCH) is proposed for EC 229-695-0 to clarify the hazard.

For EC 203-161-7, 231-885-3 and 242-016-2, STOT RE could be included in the same CLH proposal addressing reproductive toxicity (Repr. 1B) as described above. EC 229-695-5 could be also included if the hazard for STOT RE exists. Similarly, skin sensitisation could be included in the same CLH proposal for all substances (EC 203-161-7, EC 231-885-3, EC 242-016-2, EC 263-580-6, List 954-094-1, EC 229-695-0).

The seven substances have wide dispersive use in diverse professional and consumer applications (see Annex 2), in addition to industrial uses, potentially leading to human and environmental exposure.

The confirmation of the Repr 1B hazard via CLH is seen as sufficient risk management measure to address:

- Consumer exposure: The substances with known or potential reproductive toxicity hazard with full registration find application in a broad range of consumer uses (see Annex 2), potentially leading to human exposure. A harmonised classification as Repr 1B would trigger the application of Annex XVII, entry 30, restricting the presence of these substances in consumer mixtures above the applicable CLP concentration limit. In addition, the harmonised classification as Repr 1B will trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009 for uses as fragrance or other cosmetic ingredients as well as under the biocidal product regulation (EU) 528/2012, which does not allow the use by the general public of a product containing substances above the concentration limit leading to classification of the mixture as CMR cat 1.

- Worker exposure for industrial uses and formulation: A harmonised classification as Repr. 1B would render the substances unacceptable co-formulants in plant protection products and will impact the authorisation of biocidal products containing the substances, if present at concentrations above the relevant specific concentration limits for mixtures. It can be expected that these actions together with the impact of Annex XVII, entry 30 on consumer uses may lead to an overall reduced use of the substances also in industrial settings, thereby potentially reducing the number of industrial uses and as a consequence the overall worker exposure to the substances. Furthermore, classification for CMR cat 1 will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place.

CLH action on the basis of the reproductive toxicity hazard is seen as insufficient to address exposure to professional users. These substances, have professional uses in either air care, biocidal, perfumes and fragrances, polishes and waxes, washing and cleaning. These professional uses 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 present in the above-mentioned product categories.

Therefore, a **restriction of the substances 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[8].

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[9] which aims to extend to professional users under REACH the level of protection granted to consumers.

When developing the restriction on professional uses it could be considered to investigate whether there would be some industrial uses for which company level risk management measures (RMM) under the OSH legislation for workers would not adequately control the risks to human health due to the reproductive toxicity of the substances. Such uses could be considered to be included in the scope of the restriction on professional uses.

As all substances with known or potential hazard for reproductive toxicity also have known or potential skin sensitisation and the majority also have known or potential STOT RE, these hazards could also be considered during the development of the restriction proposal.

EC 201-289-8 and 203-161-7 are inconclusive for ED hazard for the environment. Currently, it is not possible to conclude if there are ED effects and if they would be with or without thresholds. Hence, no further action including no data generation is proposed for now. Any possible concerns with ED properties of EC 201-289-8 and 203-161-7 are expected to be addressed with the action on Repr. 1B.

The seven substances with known or potential toxicity for reproduction have also **known or potential aquatic toxicity**, similar to the majority of the remaining substances in the Aralkylaldehydes group. This is on the basis of self-classification as aquatic chronic 3 (EC 201-289-8, EC 203-161-7, EC 242-016-2) and/or aquatic acute 1 (e.g., EC 231-885-3) or on the basis of structural similarity of all the substances in this group and the conclusions of the assessment of various other aldehyde groups. Compliance check (CCH) and potential data generation is needed to clarify the toxicity of some substances (CCH is proposed for EC 229-695-0 and EC 242-016-2).

Note that despite the poor data set for several substances, PBT, vPvB properties are considered as unlikely for the whole Aralkylaldehydes group as most of the substances are biodegradable and not bioaccumulative.

It is expected that based on the harmonised or self-classification for aquatic toxicity registrants have implemented necessary RMMs to ensure safe use. It is also expected that following data generation, registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use. In addition, and as said above the restriction proposed above will likely lead to decline in the use of the substances as well.

[8] Although EC 201-289-8 is recommended for inclusion in Annex XIV based on the Annex XIV prioritisation approach, ECHA views that as a group the substances should go to restriction.

[9] European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on the reproductive toxicity of the substances EC 412-050-4, List 811-285-3, and List 916-329-6 (with constituents EC 266-819-2 and EC 266-818-7 which are not registered).

It is not possible to assess the needs for regulatory risk management for EC 412-050-4, List 811-285-3, and List 916-329-6 (with constituents EC 266-819-2 and EC 266-818-7 which are not registered) as information on hazard is not sufficient to conclude on their reproductive toxicity for all five substances.

In addition, similar to the remaining substances in the Aralkylaldehydes group, these five substances have known or likely skin sensitisation hazard. This is on the basis of self-classification as Skin Sens. 1B (H317) for List 811-285-3 and 916-329-6. While EC 412-050-4 is considered as potential skin sensitiser based on the structural similarity of all the substances in this group and the conclusions of the assessment of various other aldehyde groups (despite a on negative results from an GPMT (Guinea Pig Maximisation Test) study, as a false negative result is not excluded).

Furthermore, similar to the remaining substances in the Aralkylaldehydes group, these five substances also have known or potential aquatic toxicity, on the basis of harmonised classification for aquatic Chronic 2 (EC 412-050-4) or self-classification as aquatic Chronic 2 (EC 811-285-3) or aquatic acute 1 (EC 916-329-6).

The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH is proposed for EC 412-050-4, List 811-285-3, and List 916-329-6).

Based on currently available information, there is no need for (further) EU regulatory risk management for all remaining substances in the group.

As said above, all substances in the whole group have known or potential hazard for skin sensitisation. This is on the basis of harmonised classification or self-classification as Skin Sens. 1B (H317) or Skin Sens. 1 (H317) or on the basis of the structural similarity with substances with known skin sensitisation hazard and based on the conclusions of the assessment of various aldehyde groups.

Most of the substances with skin sensitisation hazard and full registration dossiers have appropriate harmonised or self- classification for Skin Sens 1B or Skin Sens 1, except EC 240-362-9 (CCH proposed to clarify the hazard), where data generation may prompt self-classification.

For industrial and professional uses, sufficient and consistent harmonised/self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing the substances in the Aralkylaldehydes group. Furthermore, it is likely that odour agents are present in small concentrations in the final mixture and the substances are likely medium potency sensitisers.

However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern.

Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic

issue by both Member States and ECHA which may affect the regulatory actions on substances in this group. Regulatory action on the substances for consumer use would likely also have an impact on their industrial uses.

As said above, the majority of the substances in the group have known or potential hazard for aquatic toxicity (except EC 240-362-9 and EC 226-749-5). Of the remaining substances in the Aralkylaldehydes some are either self-classified as aquatic chronic 2 or aquatic chronic 3 (e.g., EC 440-720-6, EC 700-748-4, EC 700-617-1). Compliance check is proposed in order to clarify hazards for aquatic toxicity, and also to clarify unreliable data provided for persistence or discrepancies observed: EC 204-574-5, EC 202-255-5, EC 240-362-9, EC 226-749-5.

It is expected that based on the harmonised or self- classification for aquatic toxicity registrants have implemented necessary RMMs to ensure safe use. It is also expected that following data generation, registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use. Therefore, no action due to aquatic toxicity hazard is proposed at this stage.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. 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 will be updated and conclusions and actions revisited

Subgroup, EC/list number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
201-289-8	Known or potential hazard for reproductive toxicity Known or potential hazard for skin sensitisation Known or potential hazard for STOT RE	Inconclusive hazard for ED Known or potential hazard for aquatic toxicity	Widespread professional and consumer use as fragrance in products (e.g., air care, biocidal, coatings, finger paint, fillers, cosmetics, washing and cleaning, polishes and waxes)	**Need for EU RRM: Restriction** <u>Justification:</u> The harmonised classification as Repro 1B would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management	**First step:** Restriction
203-161-7 **231-885-3,** **242-016-2** **263-580-6,** **954-094-1**	Known or potential hazard for reproductive toxicity	Inconclusive hazard for ED for 203-161-7 Known or potential hazard	Widespread professional and consumer use as fragrance in products for 203-161-7 and 231-885-3 (e.g., air care, biocidal, cosmetics,		**First step:** CLH CCH for EC 242-016-2 (for other endpoints than reproductive toxicity)

Subgroup, EC/list number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
	Known or potential hazard for skin sensitisation Known or potential hazard for STOT RE for EC 203-161-7, 231-885-3 and 242-016-2	for aquatic toxicity	perfumes, washing and cleaning, polishes and waxes)	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. Harmonised/self-classification for skin sensitisation and STOT RE followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation	**Next steps (if hazard confirmed):** Restriction
229-695-0	Known or potential hazard for reproductive toxicity Known or potential hazard for skin sensitisation Known or potential hazard for STOT RE	Known or potential hazard for aquatic toxicity	Widespread professional and consumer use as fragrance in products (e.g., air care, biocidal, cosmetics, perfumes, washing and cleaning, polishes and waxes)		**First step:** CCH **Next steps (if hazard confirmed):** CLH Restriction

Subgroup, EC/list number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				Harmonised/self classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment	
412-050-4, **811-285-3,** **916-329-6 (and its constituents: 266-819-2 and 266-818-7)**	Inconclusive hazard for reproductive toxicity Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity	Widespread professional and consumer use as fragrance in products (e.g., air care, biocidal, cosmetics, perfumes, washing and cleaning, polishes and waxes)	**Currently not possible to assess the regulatory needs** <u>Justification:</u> It is not possible to assess the needs for regulatory risk management for as information on hazard is not sufficient to conclude on the potential reproductive toxicity of the substances. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).	CCH
204-574-5	Known or potential hazard	Known or potential hazard	Widespread professional and	**Currently no need for EU RRM**	CCH

Subgroup, EC/list number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
202-255-5 **226-749-5** **240-362-9**	for skin sensitisation Known or potential hazard for reproductive toxicity for EC 202-255-5 Known or potential hazard for STOT RE for EC 204-574-5	for aquatic toxicity for EC 204-574-5 and EC 202-255-5 Inconclusive hazard for aquatic toxicity for EC 240-362-9 and EC 226-749-5	consumer use as fragrance (e.g., air care, biocides, cosmetics, washing and cleaning, polishes and waxes)	<u>Justification</u>: Self-classification for Repro 2, skin sensitisation and STOT RE followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation Harmonised/self classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment.	
203-211-8, **213-771-5,**	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity	No widespread use (or have no information on uses)	**Currently no need for EU RRM** Justification:	No action

Subgroup, EC/list number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
433-900-0, **437-470-5,** **440-720-6,** **455-570-7,** **605-043-4,** **641-004-8,** **686-906-2,** **700-617-1,** **700-748-4,** **819-645-1,** **924-149-4,** **948-110-6**				Most of these substances are either not registered, intermediates, NONS or CLP notification. Therefore, data generation to confirm the potential hazards is not possible Harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace and for the environment. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation	

Annex 1: Overview of classifications

Table: Harmonised classification and reported self-classification

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
204-574-5	**122-78-1**	**phenylacetaldehyde**	NA	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1B H317 Aquatic Chronic 3 H412	Skin Sens. 1B H317 Aquatic Chronic 3 H412 Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335 Flam. Liq. 2 H225
202-255-5	**93-53-8**	**hydratropaldehyde**	NA	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 3 H412 Skin Sens. 1B H317 Repr. 2 H361	Eye Irrit. 2A H319 STOT Single Exp. 3 H335, affected organs: lungs Repr. 2 H361, specific effect:H361f Suspected of damaging fertility Repr. 2 H361, specific effect:Suspected of damaging fertility STOT Single Exp. 3 H335, affected organs: Respiratory tract STOT Single Exp. 3 H335, affected organs
203-211-8	**104-53-0**	**3-phenylpropionaldehyde**	N/A	N/A	Eye Irrit. 2 H319 Skin Sens. 1 H317 Skin Sens. 1A H317 STOT Single Exp. 3 H335, affected organs: lungs Flam. Liquid 2 H225 Skin Irrit. 2 H315
240-362-9	**16251-77-7**	**3-phenylbutyraldehyde**	N/A	Not classified (LR)	STOT Single Exp. 3 H335, affected organs: Respiratory tract Eye Irrit. 2A H319[Skin Sens. 1 H317 Skin Irrit. 2 H315 Skin Sens. 1B H317
213-771-5	**1009-62-7**	**2,2-dimethyl-3-phenylpropionaldehyde**	N/A	Not classified (LR)	N/A
433-900-0	**55066-49-4**	**3-methyl-5-phenylpentan-1-al**	Acute Tox. 4 H302 Skin Irrit. 2 H315 Aquatic Chronic 2 H411	N/A	-

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
			Skin Sens. 1 H317		
455-570-7	**N/A**	**2-methyl-5-phenylpentanal (not published in ELINCS)**	N/A	N/A	Skin Sens. 1 H317
686-906-2	**18328-11-5**	**4-phenylbutanal**	N/A	N/A	Skin Irrit. 2 H315 Eye Irrit. 2A H319 Acute Tox. 4 H302 Resp. Sens. 1 H334 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: Respiratory tract
948-110-6	**857288-55-2**	**3-(2-methoxy-5-methylphenyl)-3-phenylpropanal**	N/A	Acute Tox. 4 H332 Acute Tox. 4 H312 Acute Tox. 4 H302	-
231-885-3	**7775-00-0**	**3-(p-cumenyl)propionaldehyde**	N/A	Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Acute 1 H400	Repr. 2 H361
203-161-7	**103-95-7**	**3-p-cumenyl-2-methylpropionaldehyde**	N/A	Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Chronic 3 H412	Repr. 2 H361, specific effect:suspected of damaging fertility Aquatic Chronic 1 H410 Eye Irrit. 2 H319 Aquatic Acute 1 H400 Repr. 2 H361 Skin Sens. 1 H317 Repr. 2 H361, specific effect:Suspected of damaging fertility Repr. 2 H361, specific effect:Suspected of damaging fertility Aquatic Chronic 2 H411 Repr. 2 H361, specific effect:H361f suspected of damaging fertility
229-695-0	**6658-48-6**	**3-(4-isobutylphenyl)-2-methylpropanal**	N/A	Skin Irrit. 2 H315 Skin Sens. 1B H317	Skin Sens. 1 H317 Flam. Liquid 3 H226 Repr. 2 H361
266-819-2	**67634-15-5**	**3-(p-ethylphenyl)-2,2-dimethylpropionaldehyde**	N/A	N/A	Skin Sens. 1B H317 Skin Irrit. 2 H315 Aquatic Chronic 2 H411 Eye Irrit. 2 H319 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
242-016-2	**18127-01-0**	**3-(4-tert-butylphenyl)propionaldehyde**	N/A	Skin Irrit. 2 H315 Skin Sens. 1B H317 STOT Rep. Exp. 2 H373, affected	STOT Rep. Exp. 2 H373, affected organs: Stomach, liver Aquatic Chronic 2 H411 Repr. 2 H361

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
				organs: Stomach, Liver Aquatic Chronic 3 H412	STOT Rep. Exp. 2 H373, affected organs: stomach;liver Repr. 2 H361, specific effect:Suspected of damaging fertility STOT Rep. Exp. 2 H373 STOT Rep. Exp. 2 H373, affected organs Repr. 2 H361, specific effect:fertility STOT Rep. Exp. 2 H373, affected organs: skin, eyes Acute Tox. 4 H302 Skin Sens. 1 H317 Repr. 2 H361, specific effect:Suspected of damaging the unborn child Acute Tox. 3 H301
201-289-8	**80-54-6**	**2-(4-tert-butylbenzyl)propionaldehyde**	Repr. 1B H360Fd	Repr. 1B H360, specific effect:May damage the unborn child Repr. 2 H361, specific effect:Suspected of damaging fertility Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Chronic 3 H412	Acute Tox. 5 H313 Aquatic Chronic 2 H411 Skin Sens. 1 H317 Repr. 2 H361, specific effect:fertility Resp. Sens. 1B H334
226-749-5	**5462-06-6**	**3-(p-methoxyphenyl)-2-methylpropionaldehyde**	N/A	Skin Sens. 1 H317 Skin Sens. 1B H317	Eye Irrit. 2 H319[3 out of 58] Aquatic Chronic 3 H412[42 out of 58]
263-580-6	**62518-65-4**	**3-(m-tert-butylphenyl)-2-methylpropionaldehyde**	N/A	Repr. 1B H360, specific effect:May damage the unborn child [intermediate (active)]	Acute Tox. 4 H302 Aquatic Chronic 2 H411 Repr. 2 H361, specific effect:F Skin Irrit. 2 H315 Skin Sens. 1 H317
266-818-7	**67634-14-4**	**3-(o-ethylphenyl)-2,2-dimethylpropionaldehyde**	N/A	N/A	Eye Irrit. 2 H319[16 out of 29] Aquatic Chronic 2 H411[1 out of 29] Aquatic Chronic 1 H410[1 out of 29] Skin Irrit. 2 H315[20 out of 29] Skin Sens. 1B H317[1 out of 29] Aquatic Acute 1 H400[2 out of 29]

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
440-720-6	**N/A**	**2,2-dimethyl-3-(3-methylphenyl)propanal (not published in ELINCS)**	N/A	Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 2 H411 Skin Irrit. 2 H315 Acute Tox. 4 H302	-
412-050-4	**N/A**	**β-methyl-3-(1-methylethyl)benzenepropanal** **IUPAC: 3-(3-isopropylphenyl) butanal**	Aquatic Chronic 2 H411	Aquatic Chronic 2 H411	-
641-004-8	**125109-85-5**	**β-methyl-3-(1-methylethyl)benzenepropanal** **IUPAC: 3-(3-isopropylphenyl) butanal**	N/A	N/A	Aquatic Chronic 2 H411 Skin Irrit. 2 H315
700-748-4	**1226911-69-8**	**(4*E*)-4-methyl-5-(4-methylphenyl)pent-4-enal**	N/A	Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Chronic 2 H411	-
819-645-1	**61502-90-7**	**IUPAC: [biphenyl]-4-ylacetaldehyde**	N/A	N/A	STOT Single Exp. 3 H335, affected organs: Respiratory tract[2 out of 2] Acute Tox. 4 H302[2 out of 2] Skin Irrit. 2 H315[2 out of 2] Eye Irrit. 2A H319[2 out of 2]
811-285-3	**1637294-12-2**	**3-(4-isobutyl-2-methylphenyl)propanal**	N/A	Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1B H317 Aquatic Chronic 2 H411	-
954-094-1	**N/A**	**Reaction mass of 3-(4-isobutylphenyl)propanal and 3-(4-isobutylphenyl)propan-1-ol**	N/A	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 Repr. 2 H361	-
924-149-4	**N/A**	**IUPAC: 3-[3-(prop-1-en-2-yl)phenyl]butanal**	N/A	N/A	Not classified

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
916-329-6	**N/A**	**Reaction mass of 3-(o-ethylphenyl)-2,2-dimethylpropionaldehyde and 3-(p-ethylphenyl)-2,2-dimethylpropionaldehyde**	N/A	Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 2 H411	-
437-470-5	**N/A**	**Reaction mass of 3-(1,1-dimethyl-2,3-dihydro-1H-inden-5-yl)propanal and 3-(3,3-dimethyl-2,3-dihydro-1H-inden-5-yl)propanal (not published in ELINCS)**		N/A	Acute Tox. 4 H302 Skin Sens. 1B H317
605-043-4	**156140-04-4**	**IUPAC: (1r,1'r,4r,4'r)-4'-(4-methylphenyl)[1,1'-bi(cyclohexyl)]-4-carbaldehyde**			
700-617-1	**N/A**	**Reaction mass of 3-(3,3-dimethyl-2,3-dihydro-1H-inden-5-yl)propanal and 3-(1,1-dimethyl-2,3-dihydro-1H-inden-5-yl)propanal and 3-(1,1-dimethyl-2,3-dihydro-1H-inden-4-yl)propanal**		Acute Tox. 4 H302 Skin Sens. 1B H317 Aquatic Chronic 2 H411	

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

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

Data extracted on 16/11/2021

EC number	201-289-8	202-255-5	203-161-7	204-574-5	226-749-5	229-695-0	231-885-3	240-362-9	242-016-2	412-050-4	811-285-3	916-329-6
REACH Annex	X	VII	IX	VIII	VIII	VIII	VII	VII	VIII	IX	VIII	VIII
PC 1: Adhesives, sealants										C		
PC 2: Adsorbents										C		
PC 3: Air care products	F, C	C	F, I, P, C	F, C	F, I, C	F, C	C	F, C	F, I, P, C	F, C	F, C	c
PC 4: Anti-freeze and de-icing products										C		
PC 8: Biocidal products (e.g. disinfectants, pest control)	F, C	C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	C	F, C	F, I, P, C	F, I, P, C	F, I, P, C	c
PC 9a: Coatings and paints, thinners, paint removes	C									C		
PC 9b: Fillers, putties, plasters, modelling clay	C									C		
PC 9c: Finger paint	C											
PC 12: Fertilisers										C		
PC 13: Fuels										C		

EC number	201-289-8	202-255-5	203-161-7	204-574-5	226-749-5	229-695-0	231-885-3	240-362-9	242-016-2	412-050-4	811-285-3	916-329-6
PC 14: Metal surface treatment products			I	I	I	I			I	I	I	
PC 18: Ink and toners	C									C		
PC 19: Intermediate	I	I		I	I				I			
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents					I					C		
PC 21: Laboratory chemicals					I				I	C		
PC 23: Leather treatment products										C		
PC 24: Lubricants, greases, release products										C		
PC 26: Paper and board treatment products										A		
PC 27: Plant protection products										C		
PC 28: Perfumes, fragrances	F, C	C	F, I, P, C	F, C	F, I, C	F, C	F, C	F, C	F, I, P, C	F, I, P, C, A	F, C	f, c,0)
PC 29: Pharmaceuticals									I	C		
PC 30: Photo-chemicals										C		

EC number	201-289-8	202-255-5	203-161-7	204-574-5	226-749-5	229-695-0	231-885-3	240-362-9	242-016-2	412-050-4	811-285-3	916-329-6
PC 31: Polishes and wax blends	F, P, C	P, C	F, I, P, C	F, P, C	F, I, P, C	F, P, C	P, C	F, P, C	F, I, P, C	F, P, C	F, P, C	p, c
PC 32: Polymer preparations and compounds										C, A		
PC 34: Textile dyes, and impregnating products										C		
PC 35: Washing and cleaning products	F, I, P, C	I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	F, I, P, C	i, p, c
PC 36: Water softeners										C		
PC 37: Water treatment chemicals					I					C		
PC 38: Welding and soldering products, flux products			P						P			
PC 39: Cosmetics, personal care products	F, C	C	F, I, P, C	P, C	I, P, C	P, C	P, C	F, P, C	F, I, P, C	P, C	P, C	f, c

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

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

Data extracted on 23 November 2021

EC/List number	RMOA	Authorisation		Restriction*	CLH	Other REACH related work	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
201-289-8		YES	REC		YES		

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g., when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

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