Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Alicyclic aldehydes (fused cycles)

General structure: R-CHO, R = aliphatic sequence containing two or three fused cycles.

Revision history

Version	*Date*	*Description*
1.0	10 October 2023	

Substances within this group:

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
250-078-7	30168-23-1	4-(tricyclo[5.2.1.02,6]dec-8-ylidene)butyraldehyde	O	Full; Not (publicly) available
250-333-2	30772-79-3	octahydro-4,7-methano-1H-indenecarbaldehyde	O	Full; Not (publicly) available
251-717-2	33885-51-7	6,6-dimethylbicyclo[3.1.1] hept-2-ene-2-propionaldehyde	O	Full; Not (publicly) available
251-718-8	33885-52-8	α,α,6,6-tetramethylbicyclo [3.1.1]hept-2-ene-2-propionaldehyde	C	Full; Not (publicly) available
262-062-7	60113-43-1	2,6,6-trimethylbicyclo [3.1.1]heptane-3-carbaldehyde	C	Full; Not (publicly) available
267-308-7	67845-30-1	8-isopropyl-6-methyl bicyclo[2.2.2]oct-5-ene-2-carbaldehyde	O	C&L notification
269-522-6	68259-31-4	5(or 6)-methyl-7(or 8)-(1-methylethyl)bicyclo[2.2.2] oct-5-ene-2-carbaldehyde	O	Full; Not (publicly) available
272-323-7	68804-33-1	3,7,7-trimethylbicyclo [4.1.0]heptane-2-carbaldehyde	O	OSII or TII, Not (publicly) available
299-795-7	93904-56-4	7-isopropyl-5-methyl bicyclo[2.2.2]oct-5-ene-2-carbaldehyde	O	Pre-registered

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

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
916-807-4	N/A	Reaction mass of 1,2,3,4,5,6,7,8-octahydro-5,5-dimethylnaphthalene-2-carbaldehyde and 1,2,3,4,5,6,7,8-octahydro-8,8-dimethyl-2-naphthaldehyde		Full; 1-10 tpa
940-300-7	1339119-15-1	4,7-Methano-1H-indene-5-acetaldehyde, octahydro-		Full; Not (publicly) available

This table contains also group members that are only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

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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

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 the presence of the aldehyde moiety and fused cycles. The general structure of alicyclic aldehydes (fused cycles) is R-CHO, where R is an aliphatic sequence that contains two or three fused cycles. The group is related to other aldehydes including cinnamaldehydes, short-chain alkylaldehydes, long-chain alkylaldehydes (branched and non-branched) and phenylalkylaldehydes.

There are 11 substances in the group of which eight with full registration, one with intermediate registration, one with C&L notification and one with pre-registration.

Based on information reported in the REACH registration dossiers, the substances in this group are used as fragrances (main use) in products such as air care products, biocides (e.g., disinfectants, pest control products), fragrances, polishes and waxes, washing and cleaning products and cosmetics and personal care products. Potential for exposure and/or release is expected from industrial, professional and consumer uses.

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 Substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
251-717-2 6,6-dimethylbicyclo[3.1.1] hept-2-ene-2-propionaldehyde	Known or potential hazard for reproductive toxicity and for skin sensitisation	Known or potential hazard for aquatic toxicity	Widespread professional and consumer use as fragrance in products (e.g., air care, cosmetics, washing and cleaning, polishes and waxes) with potential for exposure to humans and environment	**First step:** CLH **Potential last action (if hazard confirmed):** **Restriction** Justification: Harmonised classification as Repr. 1B would lead to generic restriction of the substance(s) in consumer mixtures by means of restriction entry 30. The harmonised classification as Repr. 1B may trigger regulatory action under the Cosmetic products regulation and render the substance unacceptable co-

EC/List no Substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				formulants in biocidal products The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk 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.
250-078-7 4-(tricyclo[5.2.1.02,6]dec-8-ylidene)butyraldehyde 250-333-2 octahydro-4,7-methano-1H-indenecarbaldehyde 251-718-8 α,α,6,6-tetramethylbicyclo[3.1.1]hept-2-ene-2-propionaldehyde	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity	Widespread professional and consumer use and industrial uses as fragrance in products (e.g., air care, cosmetics, washing and cleaning, polishes and waxes) with potential for exposure to humans and environment.	CCH for 250-078-7 <u>Justification</u>: Self-classification followed by implementation of necessary RMMs 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.

EC/List no Substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
262-062-7 2,6,6-trimethylbicyclo [3.1.1]heptane-3-carbaldehyde 267-308-7 8-isopropyl-6-methyl bicyclo[2.2.2]oct-5-ene-2-carbaldehyde 269-522-6 5(or 6)-methyl-7(or 8)-(1-methylethyl)bicyclo[2.2.2]oct-5-ene-2-carbaldehyde 272-323-7 3,7,7-trimethylbicyclo [4.1.0]heptane-2-carbaldehyde 299-795-7 7-isopropyl-5-methyl bicyclo[2.2.2]oct-5-ene-2-carbaldehyde 916-807-4 Reaction mass of 1,2,3,4,5,6,7,8-octahydro-5,5-dimethylnaphthalene-2-carbaldehyde and 1,2,3,4,5,6,7,8-octahydro-				

EC / List no Substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
8,8-dimethyl-2-naphthaldehyde 940-300-7 4,7-Methano-1H-indene-5-acetaldehyde, octahydro-				

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

Suggested regulatory risk management action for substance 6,6-dimethylbicyclo[3.1.1]hept-2-ene-2-propionaldehyde (EC 251-717-2) if reproductive toxicity hazard is confirmed

Based on currently available information, there is a potential hazard for reproductive toxicity and skin sensitiser hazards. The registrant has self-classified EC 251-717-2 as Repr. 2. and Skin Sens. 1B. The classification for reproductive toxicity is warranted, but the observed effect, i.e., reduced fertility in a screening study according to OECD TG 422, is rather severe and classification as Repr. 1B cannot be excluded. The substance is used by consumers and professional workers in washing and cleaning products, biocidal products, perfumes, fragrances and air care products, cosmetics as well as polishes and waxes.

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 properties.

If the CLH process confirms the substance as being Repr. 1B, 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
iii) would lead to generic restriction of the substance(s) in consumer mixtures by means of restriction entry 30.

CLH will also support regulatory action under other legislations. For instance, in this specific case:

- 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.

The professional uses in washing and cleaning products and in polishes and waxes 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 in washing and cleaning products and in polishes and waxes.

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[5] 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 other substances than EC 251-717-2

Based on currently available information, there is no need for (further) EU regulatory risk management for other substances than EC 251-717-2 in the group.

All substances in the group are potential skin sensitisers. Although no data on skin sensitisation is available for EC 267-308-7 (only C&L notification), 272-323-7 (only registration as an intermediate) and 299-795-7 (only pre-registered), the hazard for skin sensitisation is likely also for these substances based on structural similarity including the aldehyde moiety. For EC 250-078-7, CCH is needed to confirm the hazard for skin sensitisation.

For industrial and professional uses, sufficient and consistent self-classification by registrants should require company level risk management measures (RMM) to be in place for workers.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing the substances of this group.

However, there is in general an overall 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.

Note also that for the use of the substance(s) in cosmetics, sufficient and consistent self-classification by registrants would inform on the need or not for classification of the final product and safety assessment to be done according to Cosmetic product regulation (EC) No 1223/2009.

All the registered substances in the group are toxic to the aquatic environment and they are properly self-classified as such. PBT/vPvB hazard is unlikely for all the substances in the group but with some uncertainty. Biodegradability screening tests are available for all substances and they consistently indicate that the substances are not readily biodegradable. The substances are not ionisable, and they are not surfactants.

Five out of the eight group members have a $LogK_{ow}$, which ranges from 3.2 to 4.3. Therefore, no bioaccumulation is expected for these substances.

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

EC 250-078-7 has a $LogK_{ow}$ of 4 but was identified as surface-active substance. List 916-807-4 has a $LogK_{ow}$ of 5.13. For EC 250-078-7 and List 916-807-4 further data generation under CCH is not possible. Therefore, conclusion is not possible at this point. Data generation under substance evaluation seems also not possible as both substances are low tonnage substances and would not likely meet the criteria for the inclusion on the CoRAP. EC 251-718-8 has a $LogK_{ow}$ of 5.3 and a valid bioaccumulation study (OECD 305 I) is available indicating no bioaccumulation potential for fish (BCF < 27 L/Kg).

Aldehydes are expected to be metabolised to more water-soluble products and thus easily excreted from the organism. Therefore, further data generation is not proposed at this point. None of the substances fulfil the Annex XIII criteria for aquatic toxicity. EC 251-717-2 is the only substance that fulfil the T criterion as it is potentially toxic to reproduction.

Annex 1: Overview of classifications

Data extracted on 13 January 2023

EC/ List No	CAS No	Substance name	Classification in registrations
250-078-7	30168-23-1	4-(tricyclo[5.2.1.02,6]dec-8-ylidene)butyraldehyde	Acute Tox. 4 H332 Skin Irrit. 2 H315 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
250-333-2	30772-79-3	Octahydro-4,7-methano-1H-indenecarbaldehyde	Skin Sens. 1B H317 Aquatic Chronic 2 H411
251-717-2	33885-51-7	6,6-dimethylbicyclo[3.1.1] hept-2-ene-2-propionaldehyde	Repr. 2 H361 Acute Tox. 4 H302 Acute Tox. 3 H311 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
251-718-8	33885-52-8	α,α,6,6-tetramethylbicyclo [3.1.1]hept-2-ene-2-propionaldehyde	Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
262-062-7	60113-43-1	2,6,6-trimethylbicyclo[3.1.1] heptane-3-carbaldehyde	Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Acute 2 H401 Aquatic Chronic 2 H411
267-308-7	67845-30-1	8-isopropyl-6-methylbicyclo[2.2.2]oct-5-ene-2-carbaldehyde	-
269-522-6	68259-31-4	5(or 6)-methyl-7(or 8)-(1-methylethyl)bicyclo[2.2.2]oct-5-ene-2-carbaldehyde	Skin Sens. 1B H317 Aquatic Chronic 2 H411
272-323-7	68804-33-1	3,7,7-trimethylbicyclo[4.1.0] heptane-2-carbaldehyde	Skin Irrit. 2 H315
299-795-7	93904-56-4	7-isopropyl-5-methylbicyclo[2.2.2]oct-5-ene-2-carbaldehyde	Skin Sens. 1B H317 Aquatic Chronic 2 H411
916-807-4	-	Reaction mass of 1,2,3,4,5,6,7,8-octahydro-5,5-dimethylnaphthalene-2-carbaldehyde and 1,2,3,4,5,6,7,8-octahydro-8,8-dimethyl-2-naphthaldehyde	Acute Tox. 4 H302 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
940-300-7	1339119-15-1	4,7-Methano-1H-indene-5-acetaldehyde, octahydro-	Acute Tox. 4 H332 Skin Irrit. 2 H315 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

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

Data extracted on 30 August 2021

Main types of applications structured by product or article types	EC/List	940-300-7	250-078-7	269-522-6	262-062-7	272-323-7	251-717-2	916-807-4	251-718-8	250-333-2
PC 35: washing and cleaning products		I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**			**P**, **C**	I, **P**, **C**	I, **P**, **C**	I, **P**, **C**
PC8: Biocidal products (e.g., disinfectants, pest control)		**C**	F, I, **P**, **C**	F, I, **P**, **C**			**C**	**C**	**C**	**C**
PC28: Perfumes, fragrances		F, I	F, **C**	F, **C**			F, **C**	F, **C**	F, **C**	F, **C**
PC 3: Air care products		I	F, **C**	F, **C**			**C**	**C**	**C**	**C**
PC 39: Cosmetics, personal care products			**P**, **C**	F, **C**			**C**	**P**, **C**	**P**, **C**	**P**, **C**
PC 31: Polishes and wax blends			F, **P**, **C**	F, **P**, **C**			**P**, **C**	**P**, **C**	**P**, **C**	**P**, **C**
PC 14: metal surface treatment			I	I						
PC 19: 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

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

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