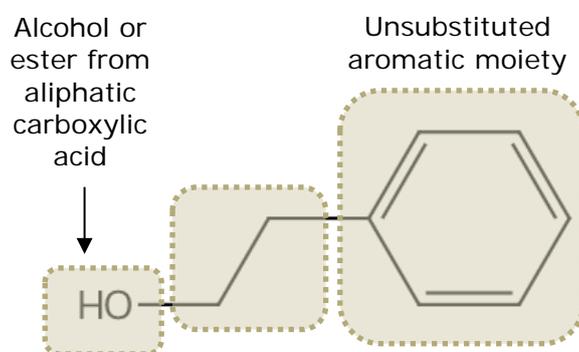


Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Phenyl-terminated linear alcohols and their aliphatic esters

General structure:

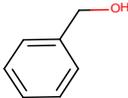
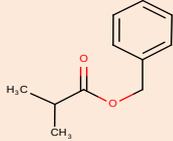
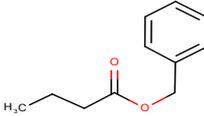
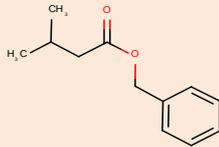
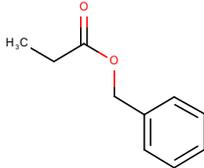
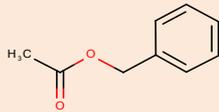
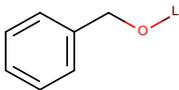


Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	11 January 2024	

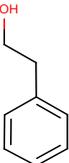
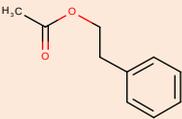
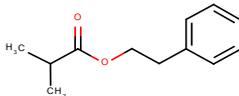
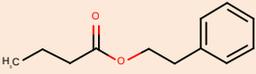
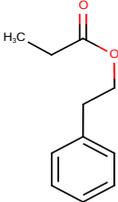
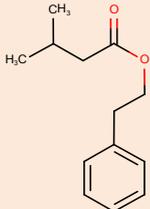
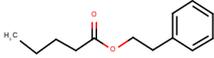
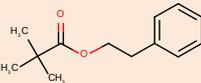
ASSESSMENT OF REGULATORY NEEDS

Substances within this group:

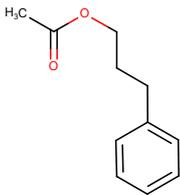
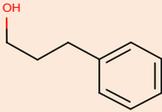
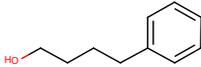
EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
Subgroup 1: substances with 1 aliphatic carbon in the linear aliphatic bridge				
202-859-9	100-51-6	Benzyl alcohol		Full, >1000
203-095-9	103-28-6	Benzyl isobutyrate		Full, not (publicly) available
203-105-1	103-37-7	Benzyl butyrate		Full, not (publicly) available
203-106-7	103-38-8	Benzyl isovalerate		Full, not (publicly) available
204-559-3	122-63-4	Benzyl propionate		Full, 10-100
205-399-7	140-11-4	Benzyl acetate		Full, >1000
943-617-9	15082-42-5	Benzenemethanol, lithium salt (1:1)		OSII or TII

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>

ASSESSMENT OF REGULATORY NEEDS

Subgroup 2: substances with 2 aliphatic carbons in the linear aliphatic bridge				
200-456-2	60-12-8	2-phenylethanol		Full, > 1000
203-113-5	103-45-7	Phenethyl acetate		Full, 100-1000
203-116-1	103-48-0	Phenethyl isobutyrate		Full, 10-100
203-119-8	103-52-6	Phenethyl butyrate		Full, not (publicly) available
204-567-7	122-70-3	Phenethyl propionate		Full, not (publicly) available
205-406-3	140-26-1	Phenethyl isovalerate		Full, not (publicly) available
231-246-9	7460-74-4	Phenethyl valerate		Cease manufacture
266-841-2	67662-96-8	Phenethyl pivalate		Full, not (publicly) available

ASSESSMENT OF REGULATORY NEEDS

Subgroup 3: substances with 3 aliphatic carbons in the linear aliphatic bridge				
204-569-8	122-72-5	3-phenylpropyl acetate		Full, not (publicly) available
204-587-6	122-97-4	3-phenylpropan-1-ol		Full, 10-100
Subgroup 4: substances with 4 aliphatic carbons in the linear aliphatic bridge				
222-128-8	3360-41-6	4-phenylbutan-1-ol		OSII or TII

This table does not contain group members that are only notified under the CLP Regulation. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may 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

Foreword.....	7
Glossary	9
1 Overview of the group.....	10
2 Conclusions and proposed actions.....	12
3 Justification for the need for regulatory risk management action at EU level (if hazards confirmed)	15
Annex 1: Overview of classifications	19
Annex 2: Overview of uses based on information available in registration dossiers.....	20
Annex 3: Overview of completed or ongoing regulatory risk management activities	23

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. Assessments 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 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 level³. 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 \(europa.eu\)](https://eucha.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).

ASSESSMENT OF REGULATORY NEEDS

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 website⁴.

⁴ <https://echa.europa.eu/understanding-assessment-regulatory-needs>

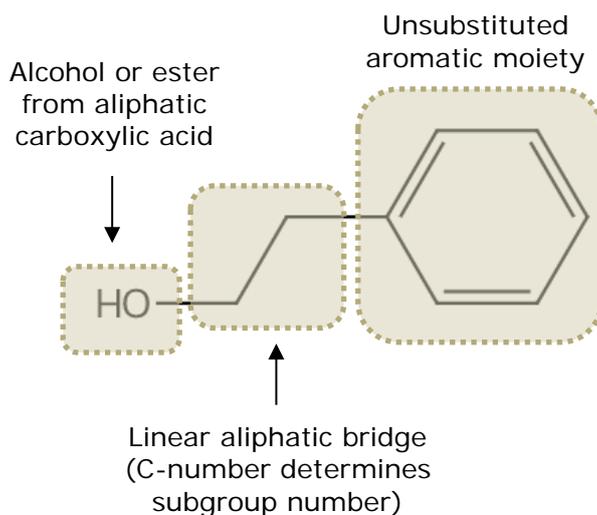
Glossary

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 are available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together similar substances based on the presence of the three common structural blocks reported in the figure below. All the substances in the group include an unsubstituted aromatic moiety, bonded to a C1-C4 linear alcohol or ester. The group consists of phenyl-terminated linear alcohols, esters from benzyl alcohols, and esters from phenethyl alcohol and phenylpropyl alcohol. All the group members are well-defined mono-constituent substances.



The substances were divided into subgroups 1-4, which correspond to the number of aliphatic carbons in the linear aliphatic bridge (C-number = subgroup number) and some differences in toxicity profiles:

Subgroup 1: EC/List 202-859-9, 203-095-9, 203-105-1, 203-106-7, 204-559-3, 205-399-7, 943-617-9

Subgroup 2: EC 200-456-2, 203-113-5, 203-116-1, 203-119-8, 204-567-7, 205-406-3, 231-246-9, 266-841-2

Subgroup 3: EC 204-569-8, 204-587-6

Subgroup 4: EC 222-128-8

For the environment no subgrouping is considered necessary as the environmental hazards are similar throughout the group.

The registration status of these substances is the following: 16 with full registrations and 2 intermediate registrations.

Based on information reported in the REACH registration dossiers, the substances in the group (excluding intermediates) are mainly used in the following ways:

- All substances are used as fragrances and/or precursors/processing aids in all or most of the following uses: washing and cleaning products, biocidal products,

ASSESSMENT OF REGULATORY NEEDS

perfumes and fragrances, air care products, cosmetics, pharmaceuticals and polishes and wax blends.

- Two substances in subgroup 1 (EC 202-859-9/benzyl alcohol and 205-399-7/benzyl acetate) have additional uses, as e.g. solvent, in many other product categories such as (among others): pH-regulators and flocculants, plant protection products, lubricants, polymers, adhesives, fillers, coatings and paints, inks, textile dyes, leather treatment products laboratory chemicals and photo-chemicals. Both might be substitutable by other substances from subgroup 1.

For all substances in the group, except for the intermediates, the registrants indicate professional, consumer and industrial uses across several product categories. Article service life is also indicated for four of the substances, such as baby wipes, and scented articles as clothes and paper articles. So, there is a significant potential for exposure for humans and the environment for all the substances.

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 2: Conclusions and proposed actions

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
Subgroup 2 200-456-2 203-113-5 203-116-1 203-119-8 204-567-7 205-406-3 231-246-9 266-841-2 Subgroup 3 204-569-8 204-587-6	Known or potential hazard for reproductive toxicity (Subgroup 2- Repr. 1B; Subgroup 3 - Repr. 2)	Known or potential hazard for aquatic toxicity for ECs 203-113-5, 203-116-1, 205-406-3 (subgroup 2) and for subgroup 3 No hazard or unlikely hazard for PBT/vPvB for PMT/vPvM except for EC 205-406-3 Inconclusive hazard for PBT/vPvB or PMT/vPvM for EC 205-406-3	Uses in washing and cleaning products, biocidal products, perfumes, cosmetics, air care products, pharmaceuticals, polishes and laboratory chemicals. In addition, for EC 200-456-2, use in pH-regulators and laboratory chemicals. High potential for release to the environment and high potential for exposure for workers and consumers.	First step: CCH for ECs 200-456-2 and 203-113-5 Potential next steps (if hazard confirmed after data generation): CLH for ECs 200-456-2, 203-113-5, 203-116-1 (Repr. 1B) and 204-587-6 (Repr. 2). Potential last action: Restriction <u>Justification:</u> <u>Justification for substances in subgroup 2:</u> Harmonised classification as Repr. 1B would lead to generic restriction of the substances in consumer mixtures by means of restriction entry 30.

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				<p>The harmonised classification as Repr. 1B will also support regulatory action under the following legislation: Cosmetic Products Regulation (EC) No 1223/2009; Biocidal Products Regulation (EU) 528/2012.</p> <p>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.</p> <p>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.</p> <p>In addition, regarding EC 200-456-2: Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses.</p> <p><u>Justification for substances in subgroup 3:</u> Harmonised classification as Repr. 2 will support regulatory action under the following legislation: Cosmetic Products Regulation (EC) No 1223/2009; Directive 92/85/EEC; Directive 94/33/EC.</p> <p>Restriction for consumer use of washing and cleaning products, personal care products, polishes and wax blends, to be considered.</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<p>Subgroup 1 202-859-9 203-095-9 203-105-1 203-106-7 204-559-3 205-399-7 943-617-9</p>	<p>Known or potential hazard for skin sensitisation for EC 202-859-9</p>	<p>Known or potential hazard for aquatic toxicity only for EC 205-399-7</p> <p>No hazard or unlikely hazard for PBT/vPvB for PMT/vPvM</p>	<p>Uses in washing and cleaning products, biocidal products, perfumes, cosmetics, air care products, pharmaceuticals, polishes.</p> <p>In addition, for EC 202-859-9 and 205-399-7, uses in pH-regulators, plant protection products, lubricants, polymers, adhesives, finger paints, fillers, coatings and paints, inks, paper treatment products, textiles, leather, metal surface treatment, lab chemicals, photo-chemicals.</p> <p>High potential for release to the environment and high potential for exposure for workers and consumers.</p>	<p>No action</p> <p><u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the reported uses. Regarding EC 205-399-7 self classification followed by implementation of necessary RRM should be sufficient to ensure safe use for environment. The same applies for EC 202-859-9 and the harmonised classification as Skin Sensitiser 1.</p>
<p>Subgroup 4 222-128-8</p>	<p>Inconclusive hazard</p>	<p>Known or potential hazard for aquatic toxicity</p> <p>Inconclusive hazard for PBT/vPvB for PMT/vPvM</p>	<p>Industrial intermediate uses only. Limited potential for exposure.</p>	<p>No action</p> <p><u>Justification:</u> It is not possible to assess the needs for regulatory risk management for substance EC 222-128-8 as information on hazard is not sufficient to conclude on reproductive toxicity. The needs for regulatory risk management actions will be assessed if the registration status and/or uses change.</p>

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

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for reproductive toxicity hazards due to the potential for release/ exposure of the substances ECs 200-456-2, 203-113-5 and 203-116-1 in subgroup 2 and of the substance EC 204-587-6 in subgroup 3, possibly extended to all substances in subgroup 2 and subgroup 3.

Based on ECHA's assessment of currently available hazard information, potential hazards were identified for human health. The available information indicates potential for reproductive and developmental toxicity for ECs 200-456-2, 203-113-5 and 203-116-1 in subgroup 2 and potential for developmental toxicity for EC 204-587-6 in subgroup 3.

For EC 200-456-2 (2-phenylethanol), there are developmental toxicity effects (various malformations) in a pre-natal developmental toxicity study in rabbits that were also observed in rat studies. Some of the effects are observed in the presence of severe maternal toxicity and dermal application. However, the effects may warrant classification as Repr. 1B or 2.

For EC 203-116-1 (Phenethyl isobutyrate), developmental toxicity (mortality, post-implantation loss) and fertility effects (changes in gestation length and sperm/testis parameters) have been observed, that, with some uncertainties, may warrant classification as Repr. 1B.

The same toxicity concern exists also for esters of the subgroups 2 and 3, as they hydrolyse to alcohols and acids. The alcohols (but not the organic acids, C1-C5 linear and branched) are considered drivers of toxicity, based on the assessment of chemical structures and hazard information currently available in the registration dossiers. Therefore, further data generation may clarify if similar reproductive toxicity concern could also be relevant for all other substances in subgroup 2 (esters of phenylethanol) and for the ester in subgroup 3 (3-phenylpropyl acetate/EC 204-569-8).

The substances EC 203-113-5 and EC 205-406-3 from subgroup 2 are both self-classified as Aquatic Chronic 2 and the substance EC 203-116-1 is self-classified as Aquatic Chronic 3. The substances EC 204-569-8 and EC 204-587-6 from subgroup 3 show aquatic toxicity and are self-classified as Aquatic Chronic 2. Based on aquatic toxicity data, the T criterion is not triggered. However, based on human health data, EC 200-456-2 and EC 203-116-1 trigger T criterion, as they may warrant classification as Repr. 1B.

Based on ECHA's assessment of currently available hazard information for subgroup 2 and 3, no potential for endocrine disruption hazards was identified for either human health or the environment and no potential for PBT/vPvB or PMT/vPvM or aquatic toxicity (for the remaining substances) hazards was identified for the environment, except for EC 205-406-3 from subgroup 2, which is considered as inconclusive for PBT/vPvB or PMT/vPvM as no reliable data on P.

Should the hazards be confirmed through newly generated data for substance EC 203-113-5 (toxicity to reproduction and development) and for EC 200-456-2 (toxicity to reproduction), the first step of the regulatory risk management is the confirmation of hazard via harmonised classification (CLH) as Repr. 1B for the

ASSESSMENT OF REGULATORY NEEDS

substances ECs 200-456-2, 203-113-5 and 203-116-1, from subgroup 2. For EC 204-587-6 from subgroup 3 the first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repr. 2.

When preparing the proposals for the substances from subgroup 2, 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.

If the CLH process confirms the substances from subgroup 2 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; and 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 legislation. 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 Products Regulation (EU) 528/2012.

The following professional uses are expected to be widespread (at many sites and by many users): washing and cleaning, cosmetics and personal care products, polishes and wax blends. 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. cleaning personnel. 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 Sustainability⁵ which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, **restricting substances in articles** used by consumers (scented articles such as clothes, erasers, and paper articles, reported for substance EC 200-456-2) is proposed as potential for exposure from articles is likely.

Regarding substance EC 204-587-6 (subgroup 3), the first step of the proposed regulatory risk management action is to confirm the potential as Repr. 2 via harmonised classification (CLH).

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>

ASSESSMENT OF REGULATORY NEEDS

If the CLH process confirms the substance as Repr. 2 will require company level risk management measures (RMM) for workers to be in place. In addition, the harmonised classification as Repr. 2 will:

- prohibit the substance(s) under the Cosmetic Products Regulation (EC) No 1223/2009 unless an exemption is granted upon assessment of safe use of the substances in cosmetic products by the Scientific Committee on Consumer Safety (SCCS).
- require that the necessary safety measures are in place for specific sensitive workers, i.e. pregnant women in accordance with Directive 92/85/EEC and young people in accordance with Directive 94/33/EC.

The second step of the regulatory risk management action proposed is restriction as the uses for subgroup 3 are similar to those of subgroup 2, and the uses are widespread.

The use in cosmetics is already covered by the Cosmetic Products Regulation and it would be appropriate to consider restriction of uses with a relatively similar exposure profile. Therefore, a restriction may be considered for consumer use of washing and cleaning products, personal care products, and polishes and wax blends. The use as co-formulants in biocidal products (with consumer uses) of substances in this subgroup 3 is covered by the Biocidal Products Regulation.

Based on currently available information, there is no need for (further) EU regulatory risk management of the substances in subgroup 1 (EC/List 202-859-9, 203-095-9, 203-105-1, 203-106-7, 204-559-3, 205-399-7 and 943-617-9).

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health for the substances in subgroup 1. These conclusions are based on negative findings in in vitro mutagenicity studies in bacterial and mammalian cells, repeated dose sub-chronic and screening studies, and reprotoxicity studies. These studies determine the high dose groups as NOAELs (500-1000 mg/kg bw/d depending on the exact study), or are based on the outcome of substance evaluation:

SEv (Germany) concluded in 2021 that *"based on the available database the eMSCA agrees with the registrants' conclusion that there is no concern regarding reproductive toxicity (fertility) of benzyl alcohol and that classification of benzyl alcohol for reproductive toxicity (fertility) is currently not warranted.*

Based on the results of the available studies, the eMSCA concludes that there is no concern regarding developmental toxicity of benzyl alcohol. Hence, the eMSCA considers classification of benzyl alcohol for reproductive toxicity (developmental toxicity) not warranted."

The substance EC 205-399-7 shows aquatic toxicity and is self-classified as Aquatic Chronic 3. Based on available data, no other member of subgroup 1 triggers any environmental classification criteria. Based on ECHA's assessment of currently available hazard information for subgroup 1, no potential for endocrine disruption hazards was identified for either human health or the environment and no potential for PBT/vPvB or PMT/vPvM or aquatic toxicity (for the remaining substances) hazards was identified for the environment. Overall, there is no or unlikely hazard that would lead to concern for the reported uses.

Regarding substance EC 205-399-7, it is expected that based on the self-classification registrants have implemented necessary RMMs to ensure safe use. The same applies for substance EC 202-859-9 (benzyl alcohol) and the harmonised classification as skin sensitiser (RAC 2021, not yet included in CLP A.VI via ATP). Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

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 reproductive toxicity hazard of the substance EC 222-128-8 in subgroup 4 (only substance in this subgroup).

No data is available for the substance EC 222-128-8 and conclusions to potential concern depend on outcomes of data generation for SG 2 and SG 3.

The substance EC 222-128-8 is self-classified as Aquatic Chronic 3, however as no data is available and due to its use as an intermediate, classification cannot be confirmed.

The substance EC 222-128-8 is only registered as intermediate. Therefore, the exposure potential is expected to be low. Furthermore, information on hazard is not sufficient to conclude on reproductive toxicity. Therefore, no EU regulatory risk management action is currently proposed for this substance. It is worth noting however that the strategy may need to be revisited and need for further regulatory action reconsidered if there is a change in the registration status or reported uses for this substance.

If future results from data generation for substances in subgroup 3 are available, this may allow combining subgroup 4 with subgroup 3 if such results allow extrapolation of a hazard from subgroup 3 to subgroup 4. If such an extrapolation indicates an absence of hazards, subgroup 4 could be combined with subgroup 1.

Annex 1: Overview of classifications

Data extracted on 15/03/2023.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ⁶
200-456-2	60-12-8	2-phenylethanol	-	Acute Tox. 4 H312 [intermediate (inactive)] Acute Tox. 4 H302 Eye Irrit. 2 H319
202-859-9	100-51-6	benzyl alcohol	Index number: 603-057-00-5 Acute Tox. 4 Hazard Statement: H302 (Minimum classification) Skin Sensitisation 1 Hazard Statement: H317 (RAC 2021) Acute Tox. 4 Hazard Statement: H332 (Minimum classification)	Acute Tox. 4 H302 Acute Tox. 4 H332 Eye Irrit. 2 H319
203-095-9	103-28-6	benzyl isobutyrate	-	Eye Irrit. 2 H319
203-105-1	103-37-7	benzyl butyrate	-	-
203-106-7	103-38-8	benzyl isovalerate	-	Eye Irrit. 2 H319
203-113-5	103-45-7	phenethyl acetate	-	Eye Damage 1 H318
203-116-1	103-48-0	phenethyl isobutyrate	-	Aquatic Chronic 3 H412
203-119-8	103-52-6	phenethyl butyrate	-	-
204-559-3	122-63-4	benzyl propionate	-	-
204-567-7	122-70-3	phenethyl propionate	-	-
204-569-8	122-72-5	3-phenylpropyl acetate	-	-
204-587-6	122-97-4	3-phenylpropan-1-ol	-	Skin Corr. 1B H314 Eye Damage 1 H318
205-399-7	140-11-4	benzyl acetate	-	Aquatic Chronic 3 H412
205-406-3	140-26-1	phenethyl isovalerate	-	Aquatic Chronic 2 H411
222-128-8	3360-41-6	4-phenylbutan-1-ol	-	Aquatic Chronic 3 H412 [intermediate (active)]
231-246-9	7460-74-4	phenethyl valerate	-	-
266-841-2	67662-96-8	phenethyl pivalate	-	-
943-617-9	15082-42-5	Benzenemethanol, lithium salt (1:1)	-	Carc. 2 H351 [intermediate (active)] Eye Irrit. 2 H319, specific concentration: >=25 [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory tracts, specific concentration: >=25 [intermediate (active)]

⁶ The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

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

Data extracted on 30.01.2023

Subgroup	EC/List number	PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	PC 36: Water softeners	PC 37: Water treatment chemicals	PC 2: Adsorbents	PC 12: Fertilisers	PC 27: Plant protection products	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 8: Biocidal products (e.g. disinfectants, pest control)	PC 28: Perfumes, fragrances	PC 3: Air care products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 38: Welding and soldering products, flux products	PC 21: Laboratory chemicals	PC 19: Intermediate	PC 30: Photo-chemicals
1	202-859-9	F, I, P, C				I	F, I, P	F, I	F, I, P, C	F, I, P, C	F, I, P, C, A	F, I, P, C	F, I, P, C, A	F, I, P	F, I, P, C	F, I, P	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, A	F, I, P, C	F, I, P, C	F, I, P, C		F, I, P, C	F, I, P, C	F, I, P	
1	203-095-9								C	I, C	C	C	I, P, C, A	I, C	C														I	F, I		
1	203-105-1								I, P, C	C	F, C	C	C		P, C														I, A	F, I		
1	203-106-7								C	I, C	C	C	I, P, C, A	I, C	C													I	F, I			
1	204-559-3								F, I, P, C	F, I, P, C	F, I, P, C	F, C	F, I, P, C		F, P, C												I					

ASSESSMENT OF REGULATORY NEEDS

Subgroup	EC/List number	PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	PC 36: Water softeners	PC 37: Water treatment chemicals	PC 2: Adsorbents	PC 12: Fertilisers	PC 27: Plant protection products	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 8: Biocidal products (e.g. disinfectants, pest control)	PC 28: Perfumes, fragrances	PC 3: Air care products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 38: Welding and soldering products, flux products	PC 21: Laboratory chemicals	PC 19: Intermediate	PC 30: Photo-chemicals		
1	205-399-7	I, P, C	C	P, C	C	C	F, P, C	C	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	C	F, I, P, C	C	C	C	I, C	I, C		C	C	C		C	C		C	I, P, C		C		
1	943-617-9																															I		
2	200-456-2	I, P							I, P, C	C	F, I, C, A	I, C	P, C	C	P, C															F, I, P	I			
2	203-113-5								I, P, C	C	F, C	C	C		P, C																			
2	203-116-1								I, P, C	C	F, C	C	P, C		P, C																			
2	203-119-8								C		I, C	C	I, P, C	I, C	C															I	F, I			
2	204-567-7								C		I, C	C	C, P, C	I, C	C															I	F, I			
2	205-406-3																													I	F, I			
2	231-246-9								I, P	C	F, C	C	C		P, C																			
2	266-841-2								F, I, P, C	F, C	F, C	F, C	F, C		F, P, C																			
3	204-569-8								C		I, C	C	I, P, C	I, C	C															I	F, I			

ASSESSMENT OF REGULATORY NEEDS

Subgroup	EC/List number	PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	PC 36: Water softeners	PC 37: Water treatment chemicals	PC 2: Adsorbents	PC 12: Fertilisers	PC 27: Plant protection products	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 8: Biocidal products (e.g. disinfectants, pest control)	PC 28: Perfumes, fragrances	PC 3: Air care products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 13: Fuels	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 14: Metal surface treatment products	PC 38: Welding and soldering products, flux products	PC 21: Laboratory chemicals	PC 19: Intermediate	PC 30: Photo-chemicals	
3	204-587-6								I, P, C	C	F, I, C	C	F, I, C	F, I, C	P, C																		
4	222-128-8										C		F, I, C	F, I, C																	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

Data extracted on 02/02/2023

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate List	Annex XIV	Annex XVII	Annex VI (CLP)	
202-859-9	YES				YES	AS approval (Biocides), Cosmetics

*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, 40 and 75).

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

ASSESSMENT OF REGULATORY NEEDS