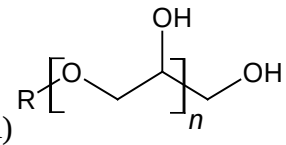
# Assessment of regulatory needs

**Authority: European Chemicals Agency (ECHA)**

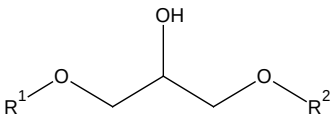
**Group Name: Glycerol Ethers**

**General structures:**

(A)




(B)




**Revision history**

| Version | Date | Description |
|---|---|---|
| **1.0** | 28 June 2024 | |
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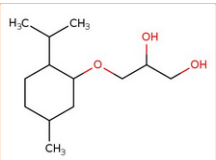
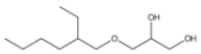
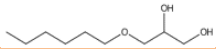
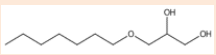
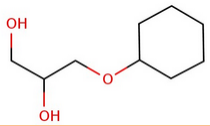
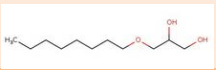
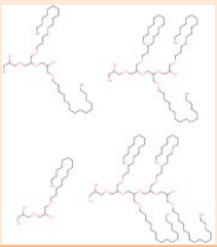
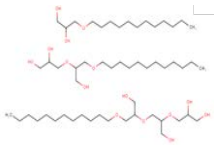
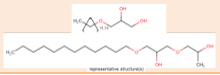
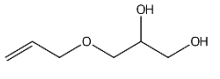
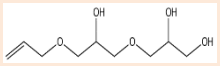
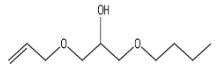
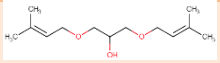
| | | |
| | | |

| EC/List number | CAS number | Substance name<br><br>[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 1a** | **Linear, branched alkyl and cyclic mono-glycerol ethers** | | | |
| **208-874-7** | 544-62-7 | batilol |  | Full<br>1-10 |
| **289-296-2** | 87061-04-9 | 3-[[5-methyl-2-(1-methylethyl)cyclohexyl]oxy]propane-1,2-diol |  | Full<br>100-1000 |
| **408-080-2** | 70445-33-9 | 3-(2-ethylhexyloxy)propane-1,2-diol |  | Full<br>100-1000 |
| **485-870-3** | Not (publicly) available | Not (publicly) available | Not (publicly) available | Not (publicly) available |
| **600-386-6** | 10305-38-1 | 3-(hexyloxy)-1,2-propanediol |  | Full<br>1-10 |
| **700-923-5** | 10305-39-2 | 3-(heptyloxy)propane-1,2-diol |  | Not (publicly) available |
| **805-622-3** | 10305-41-6 | 3-cyclohexyloxypropane-1,2-diol |  | Full<br>1-10 |
| **837-816-9** | 10438-94-5 | 3-(octyloxy)propane-1,2-diol |  | Not (publicly) available |
| **Subgroup 1b** | **Aliphatic poly-glycerol ethers** | | | |
| **411-450-6** | 143747-72-2 | 6,9-bis(hexadecyloxymethyl)-4,7-dioxanonane-1,2,9-triol |  | Not registered |
| **470-470-3** | 9022-75-7 | Poly[oxy[(hydroxymethyl)-1,2- | | Full<br>100-1000 |

[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<br><br>[and/ or Substance name acronyms] | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| | | ethanediyl]], .alpha.-dodecyl-.omega.-hydroxy- |  | |
| **618-509-7** | 9022-76-8 | Poly[oxy[(hydroxymethyl)-1,2-ethanediyl]], α-(9Z)-9-octadecenyl-ω-hydroxy- | Not (publicly) available | C&L notification |
| **691-853-3** | 9022-76-8 | Alpha.-9-octadecenyl-.omega.-hydroxy-poly[oxy[(hydroxymethyl) -1,2-ethanediyl]] (4 moles of glycerol) containing 20 % water | Not (publicly) available | C&L notification |
| **922-520-5** | | c12-16 alkyl, glycerol ether |  | Not (publicly) available |
| **939-727-1** | | Reaction mass of (Z)-3-(9-octadecenyloxy)propane-1,2-diol and alpha-(Z)-octadec-9-en-1-yl-omega-hydroxy-di[oxy[(hydroxymethyl)-1,2-ethanediyl]] and alpha-(Z)-octadec-9-en-1-yl-omega-hydroxy-tri[oxy[(hydroxymethyl)-1,2-ethanediyl]] |  | Full<br>100-1000 |
| **Subgroup 2 Alkenyl mono/di-glycerol ethers** | | | | |
| **204-620-4** | 123-34-2 | 3-(allyloxy)propane-1,2-diol |  | Full<br>1-10 |

| EC/List number | CAS number | Substance name<br><br>[and/ or Substance name acronyms] | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **301-230-7** | 93982-41-3 | 3-[3-(allyloxy)hydroxypropoxy]propane-1,2-diol |  | TII/OSII |
| **801-709-5** | 53146-45-5 | 1-(allyloxy)-3-butoxypropan-2-ol_pab |  | Full<br>10-100 |
| **858-735-5** | 2337348-25-9 | 2-Propanol, 1,3-bis[(3-methyl-2-buten-1-yl)oxy]- |  | Not (publicly) available |

[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

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

# Contents

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# Foreword

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

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

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

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

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

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

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

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

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

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

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

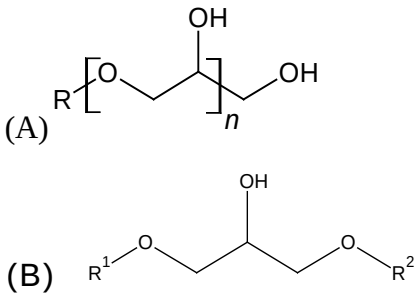
# Glossary

| | |
|---|---|
| ARN | Assessment of Regulatory Needs |
| CCH | Compliance Check |
| CLH | Harmonised classification and labelling |
| CMR | Carcinogenic, mutagenic and/or toxic to reproduction |
| DEv | Dossier evaluation |
| ED | Endocrine disruptor |
| NONS | Notified new substances |
| OEL | Occupational exposure limit |
| OSII or TII | On-site isolated intermediate or transported isolated intermediate |
| PBT/vPvB | Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative |
| PMT/vPvM | Persistent, mobile and toxic/very persistent and very mobile |
| 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

*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 reacted glycerol moieties shown in the figures A and B below.




Structure (A) represents a glycerol ether where R consists of a linear and/or branched alkyl and/or cyclic group where the repeating unit n is usually 1 or 2 (n=1,2,...).

Structure (B) represents a glycerol ether where R1 and R2 consist of linear and/or branched alkyl and/or linear and/or branched alkenyl groups.

Based on the different structures, the group is divided into three subgroups

- Linear, branched alkyl and cyclic mono-glycerol ethers (8 substances, subgroup 1a)
- Aliphatic poly-glycerol ethers (6 substances, subgroup 1b)
- Alkenyl mono/di-glycerol ethers (4 substances, subgroup 2)

In more detail, for subgroup 1a, whilst all substances are mono-glycerol ethers, there are some structural differences within the subgroup. The substances EC/List 600-386-6, 700-923-5, 837-816-9 and 208-874-7 all have a linear carbon chain of different lengths, whilst EC 408-080-2 has branched chain(s) and EC/Lists 805-622-3 and 289-296-2 are cyclic.

The group consists of 18 substances, out of which 13 have a full registration under REACH, one is an intermediate, one is a NONS, one is not registered and two are only C&L notified substances under CLP.

Based on information reported in the REACH registration dossiers, the main uses for subgroups 1a and 1b are in cosmetics and washing and cleaning products. One substance has additional uses in pharmaceuticals and metal working fluids. Subgroup 2 substances are not used in cosmetics, but as monomers in polymers, however, with List 858-735-5 having a different use profile, as it is used in products such as adhesives, coatings, and inks. This is also the only substance that has article service life indicated, covering a wide variety of articles.

The substances are, most commonly, used as skin conditioning agent (humectant, emollient), but some are clearly indicated as surfactants. List 858-735-5 is reported as a yellowing prevention agent.

Ten substances have consumer or professional uses, therefore, for those ten, high potential for exposure/release can be expected.

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

This group is divided into three structurally different subgroups, as described in Part 1 above. Based on the information currently available in the REACH registration dossiers, the hazard profiles of the subgroups are not similar enough to extrapolate between subgroups or to suggest they might be the same. Therefore, the structural subgrouping is retained.

**Subgroup 1a**

**Based on currently available information, the members of this subgroup may have potential for reproductive toxicity. However, it is not currently possible to assess the need for regulatory risk management** as information on the hazard is not sufficient to conclude on the reproductive toxicity hazards of any of the substances in subgroup 1a.

Based on ECHA's assessment of hazard information currently available in the registration dossiers, the substances EC 289-296-2 and List 408-080-2 may have potential for reproductive toxicity. These hazards are identified based on the varied observed reproductive/developmental effects, ranging from early resorptions and post implantation losses (EC 289-296-2), to reduced reproductive performance, corpora lutea with unclear developmental effects on skeletal structures (EC 408-080-2). However, current data are considered inconclusive regarding a reproductive toxicity classification for these two substances. Generation of further reproductive information may determine whether a reproductive toxicity classification for these two substances is warranted.

Further, even though there is some key structural similarity within subgroup 1a, the findings from the toxicity studies of EC 289-296-2 and List 408-080-2 cannot be directly extrapolated to the whole subgroup, as the effects observed from the available data on the substances are too varied, and due to marked structural differences (branched moiety is common to EC 408-080-2 and 289-296-2, only). If further data is generated, it may determine how that data may be considered for the other substances within the subgroup for potential for reproductive toxicity.

Regarding EC 289-296-2 specifically, it is reported to have dose-dependent hepatotoxicity findings, but the available data is insufficient for the purpose of classification for STOT RE.

Based on ECHA's assessment of hazard information currently available in the registration dossiers, some of the substances in subgroup 1a have the following known/potential **environmental hazard**: aquatic toxicity for EC/List 408-080-2, 289-296-2, 837-816-9 and 208-874-7.

EC 408-080-2 has a harmonised classification as Aquatic Chronic 3, H412. EC 289-296-2 is self-classified also as Aquatic Chronic 3, whilst List 837-816-9 has no classification for environmental hazards indicated. EC 208-874-7 has a self-classification as Aquatic Acute 1, H400, Aquatic Chronic 1, H410, however, some data, is missing and so needs to be clarified... For EC/List 700-923-5, all data is based on read across. There were no observed effects for EC/List 600-386-6 and 805-622-3 and no information available for EC 485-870-3 (NONS). Due to the structural differences and the variation of results within the subgroup, it is proposed not to extrapolate the potential aquatic toxicity to the subgroup 1a member List

700-923-5.

Based on ECHA's assessment of currently available hazard information, no potential for endocrine disruption hazards was identified for either human health or the environment, and no potential for PBT/vPvB or PMT/vPvM hazards was identified.

Should the hazard of reproductive toxicity be clarified for any of the substances, the first step of the regulatory risk management is harmonised classification (CLH) as toxic to reproduction. When preparing a proposal for harmonised classification, it should be considered what would be the best way to go forward, for instance whether to make a proposal for the group of substances, to submit them individually or jointly.

As the main use for the majority of the substances in this subgroup is as cosmetic ingredient, it can be noted that harmonised classification as toxic to reproduction will trigger regulatory actions under the Cosmetic Products Regulation (EC) No 1223/2009. While Category 1 CMR substances are prohibited by that regulation (noting that they may be used in cosmetic products by way of exception where a number of expressly set conditions must be fulfilled), for category 2 CMR substances, exemptions may be granted for use in cosmetic products where the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in cosmetic products. For those substances that have other consumer uses than that in cosmetic products, further regulatory risk management would need to be considered once adequate data confirming reproductive toxicity is available.

Overall, for the aquatic toxicity hazard, it is expected that following data generation on aquatic toxicity, registrants would adequately self-classify the substances and implement the necessary risk management measures to ensure safe use from that perspective. Therefore, it is proposed that there is currently **no need for EU-wide regulatory risk management based on environmental hazards.**

The substance EC 485-870-3 is a NONS, and there is little information available. Therefore, no further actions are currently proposed, also due to low exposure potential. 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 of the substance.

**Subgroup 1b**

**Based on currently available information, there is a need for (further) EU regulatory risk management – CLH** for reproductive toxicity for all the substances in this subgroup.

Based on the indications of reproductive toxicity for subgroup 1b members EC 939-727-1 and 470-470-3, a reproductive toxicity hazard is likely for the whole subgroup 1b via extrapolation, considering the structural similarity within subgroup 1b, a common structural moiety (similar carbon chain range C12-C18 throughout subgroup 1b is expected to lead to similar bioavailability).

There is a negative reproductive screening test for one group member in subgroup 2 (EC 801-709-5) and **with the data available there is no reproductive hazard identified for subgroup 2**. No Extrapolation of the reproductive toxicity findings in subgroup 1a or subgroup 1b is considered

possible due to the structural differences between the subgroups.

In **subgroup 1b**, for the substance List 939-727-1 a harmonised classification may be warranted as Repr. 2 due to a marked increase in pup mortality in a screening study and no further data is considered necessary. For EC 470-470-3, the reproductive/developmental toxicity screening study with reported reduced ovary weight and decreased pup weight does not seem to directly provide sufficient evidence for classification.

In subgroup 1b, the common structural moieties (including a carbon chain length in a range normally giving similar effects, i.e., C12-C18) would allow for extrapolation of the reproductive/developmental hazard. Therefore, all the substances in subgroup 1b are considered to have potential for reproductive toxicity (EC/List: 939-727-1, 470-470-3, 411-450-6, 922-520-5, 618-509-7, and 691-853-3), but currently List 939-727-1 is the only substance within subgroup 1b with sufficient evidence to trigger classification as Repr. 2.

Based on ECHA's assessment of hazard information currently available in the registration dossiers, the substances in the subgroup have the following known/potential **environmental hazard**: aquatic toxicity (EC/List 470-470-3, 922-520-5, 939-727-1, 411-450-6, 618-509-7 & 691-853-3).

EC 470-470-3 has a self-classification of Aquatic Acute 1, H400, Aquatic Chronic 2, H411, which is supported by the available data. Both List 922-520-5 and 939-727-1 have a self-classification of Aquatic Acute 1, H400, Aquatic Chronic 3, H412, which is also supported by the available data. No information is available for the remaining substances. EC/List 411-450-6 is not registered, and 618-509-7 and 691-853-3 have a C&L notification as Aquatic Acute 1, H400, Aquatic Chronic 2, H411. Due to the current available data and the structural similarity within the subgroup, it is proposed to extrapolate the potential aquatic toxicity to all subgroup 1b members.

Based on ECHA's assessment of currently available hazard information, no potential for endocrine disruption hazards was identified for either human health or the environment, and no potential for PBT/vPvB or PMT/vPvM hazards was identified.

Compliance checks to generate further data are proposed, where possible, to clarify reproductive toxicity and environmental hazards. Should the hazard be clarified via compliance check, as toxic to reproduction, harmonised classification (CLH) is proposed as first and final regulatory risk management action. When preparing the CLH proposals, it can be considered whether to make a proposal for the whole subgroup or whether to submit them individually.

As the substance List 939-727-1 is only used as a cosmetic ingredient, it can be noted that harmonised classification as Repr. 2 will trigger regulatory actions under the Cosmetic Products Regulation (EC) No 1223/2009. While Category 1 CMR substances are prohibited by that regulation (noting that they may be used in cosmetic products by way of exception where a number of expressly set conditions must be fulfilled), for category 2 CMR substances, exemptions may be granted for use in cosmetic products where the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in cosmetic products.

Overall, for the aquatic toxicity hazard, it is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances and implement necessary risk management measures to ensure safe use from that

perspective. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management based on environmental hazards.

**Subgroup 2**

**Based on currently available information, there is a need for EU regulatory risk management – CLH** for mutagenicity and skin sensitisation for all the substances in this subgroup.

The fully registered members of **subgroup 2** (EC/List: 204-620-4, 801-709-5 and 858-735-5) are potential or known skin sensitisers. Further, EC 204-620-4 and List 801-709-5 have potential or known mutagenicity hazards, based on *in vitro* data, only. Whilst List 801-709-5 has a self-classification as Muta 2, it is solely based on *in vitro* data, hence a harmonised classification cannot be based on this data, alone. EC 301-230-7 has a self-classification as Muta 2, but there is no information available as it is only used as an intermediate. The self-classifications are considered to be not supported by the evidence. Furthermore, currently, EC 204-620-4 and List 801-709-5 seem to have insufficient evidence for the purposes of harmonised classification for mutagenicity, because no *in vivo* data confirming positive *in vitro* results are available. However, it is proposed to extrapolate the mutagenicity and skin sensitising potential to all subgroup 2 members due to the available positive *in vitro* data and the presence of a double bond at the end of the carbon chain and the potential formation of an epoxide.

Based on ECHA's assessment of hazard information currently available in the registration dossiers, some of the substances in the group have the following known/potential **environmental hazard**: aquatic toxicity for EC/List 858-735-5.

None of the substances have a harmonised or self-classification for environmental hazards. For List 858-735-5, there is some observed aquatic acute toxicity data between 10 – 100 mg/L, but for List 204-620-4 and 801-709-5, no toxicity was observed. There is no information available for EC 301-230-7 as it is only used as an intermediate. As List 858-735-5 is the only one with potential aquatic toxicity, and EC/Lists 204-620-4 and 801-709-5 have no observed effects, then despite the structural similarity within the subgroup, with the variation of results, it is proposed not to extrapolate the potential aquatic toxicity to all the subgroup 2 members.

Regarding vPvM, List 801-709-5 is not readily biodegradable, has a log10 Pow in the range 2.43 to 3.60 (OECD 117) and a Log Koc value < 2, and thus is potentially P/vP and M/vM, based on the screening criteria in Annex XIII to REACH. No further data generation (under dossier evaluation) for persistency and mobility is proposed for List 801-709-5. List 858-735-5 is considered as inconclusive for P but has potential for M and EC 204-620-4 is considered as potential P but unlikely M. So, both are not vPvM. There is no information available for EC 301-230-7. However, as List 801-709-5 is the only one with potential for the **vPvM hazard** and EC/Lists 858-735-5 or 204-620-4 have different observed effects, despite the structural similarity within the subgroup, due to the variation of effects, it is proposed not to extrapolate the **vPvM hazard** to all subgroup 2 members.

Based on ECHA's assessment of currently available hazard information, no potential for endocrine disruption hazards was identified for either human health or Environment and no potential for PBT/vPvB hazards was identified.

Compliance check is proposed to generate further data, where possible, to confirm the skin sensitisation and mutagenicity hazards.

Should the hazards be confirmed, harmonised classification (CLH) as mutagenic and skin sensitising is proposed as first and final regulatory risk management action. 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 subgroup, or to submit them individually.

The substance List 858-735-5 is reported to be used in several types of mixtures used by professionals as well as in industry. These professional uses may potentially need to be considered for restriction, in addition to CLH, should the mutagenicity hazard be confirmed. The substance is also used in the production of a variety of articles. However, the substance is used as an oxygen or radiation scavenger and a chemical reaction takes place in the process. It is not possible to assess in the context of this report whether the substance would be subject to releases from any or some the article-types during their life cycle. Therefore, as use in textiles is not indicated (that article category would suggest potential use in direct, prolonged contact with the skin), and the volumes used are low, at present no further regulatory risk management in terms of restriction for use in articles is proposed.

CLH will also support regulatory action for substances containing any of the substances in this group as an impurity or constituent. This could be of relevance since some of the substances are exclusively used as monomers in the production of polymers.

Overall, for the aquatic toxicity hazard, it is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances and implement necessary risk management measures to ensure safe use from that perspective. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management based on aquatic toxicity.

Regarding the **vPvM hazard**, for List 801-709-5, for the time being, no EU regulatory risk management is proposed to address this specific hazard until there is clarity on the approach to persistent and mobile substances. Due to its use as a monomer, its exposure potential is considered moderate to low. It is worth noting, however, that the strategy may need to be revisited and the need for further regulatory action reconsidered if there is a change in the registration status or reported uses of the substance.

# 3 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**

| Subgroup | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| **Subgroup 1a**<br><br>208-874-7<br>289-296-2<br>408-080-2<br>600-386-6<br>700-923-5<br>805-622-3<br>837-816-9<br><br>485-870-3 | Inconclusive hazard for reproductive toxicity<br><br>Known or potential hazard<br>for STOT RE<br>For 289-296-2 | Known or potential hazard<br>for aquatic toxicity<br>for 208-874-7, 289-296-2, 408-080-2 and 837-816-9<br><br>Inconclusive hazard<br>for aquatic toxicity<br>for 700-923-5<br><br>Inconclusive hazard<br>for PBT/PMT<br>600-386-6, 700-923-5, 805-622-3 and 837-816-9 | Cosmetic ingredients<br><br>Use in washing and cleaning products (408-080-2, 600-386-6, 805-622-3)<br><br>High potential for exposure<br><br>No use information, low exposure potential: 485-870-3 | **First step:**<br>CCH<br>for<br>289-296-2<br>408-080-2<br>805-622-3<br>208-874-7<br>837-816-9<br>700-923-5<br>600-386-6<br><br>**Potential next steps (if hazard confirmed after data generation):** CLH<br><br><u>Justification:</u><br>Where hazard is confirmed (repro) CLH may suffice for those substances |

| Subgroup | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| | | | | CLH for reproductive toxicity will trigger regulatory actions under the Cosmetic Products Regulation<br><br>No action is currently possible for 485-870-3 |
| **Subgroup 1b**<br><br>411-450-6<br>470-470-3<br>618-509-7<br>691-853-3<br>922-520-5<br>939-727-1 | Known or potential hazard<br>for reproductive toxicity | Known or potential hazard<br>for aquatic toxicity | Cosmetic ingredients:<br>470-470-3<br>939-727-1<br>618-509-7<br><br>Industrial intermediate:<br>922-520-5<br>Low potential for exposure | **First step:**<br>**CCH**<br>for<br>470-470-3<br>922-520-5<br>939-727-1 (targeted for Env only)<br><br>**Potential next steps (if hazard confirmed after data generation):** CLH for 939-727-1<br><br><u>Justification:</u><br>If hazard is confirmed (repro), CLH should suffice, noting that REACH restrictions on cosmetic ingredients are not possible based on health hazards (Article 67(2) REACH) |
| **Subgroup 2**<br><br>204-620-4<br>801-709-5<br>858-735-5<br>301-230-7 | Known or potential hazard<br>for skin sensitisation<br>for mutagenicity | Known or potential hazard<br>Aquatic toxicity for 858-735-5<br><br>Inconclusive hazard | 858-735-5 is an O2 absorber in a variety of articles (not textiles)<br><br>Exposure potential is moderate to low | **First step:**<br>CCH<br>for<br>204-620-4<br>801-709-5<br>858-735-5 |

| Subgroup | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| | | Aquatic toxicity for 301-230-7<br><br>vPvM for 801-709-5<br><br>Inconclusive hazard vPvM for 301-230-7 | Monomers: 204-620-4, 801-709-5<br><br>Intermediate: 301-230-7 | **Potential next steps (if hazard confirmed after data generation):** CLH<br><br><u>Justification:</u><br>If hazards are confirmed, CLH should suffice and no restriction is currently proposed, though the professional uses of 858-735-5 may merit further examination if the Muta hazard is confirmed |

# Annex 1: Overview of classifications

Data extracted on 1 February 2023

| EC / List No | CAS number | Substance name | Harmonised classification | Classification in registrations[5] |
|---|---|---|---|---|
| | | | | |
| **204-620-4** | 123-34-2 | 3-(allyloxy)propane-1,2-diol | - | Eye Irrit. 2 H319 |
| **208-874-7** | 544-62-7 | Batilol | - | Aquatic Acute 1 H400, M-factor: 100.00<br>Aquatic Chronic 1 H410, M-factor: 10.00 |
| **289-296-2** | 87061-04-9 | 3-[[5-methyl-2-(1-methylethyl)cyclohexyl]oxy]propane-1,2-diol | - | Skin Irrit. 2 H315<br>Eye Damage 1 H318<br>Aquatic Chronic 3 H412 |
| **301-230-7** | 93982-41-3 | 3-[3-(allyloxy)hydroxypropoxy]propane-1,2-diol | - | Skin Sens. 1 H317 [intermediate (active)]<br>Acute Tox. 4 H312 [intermediate (active)]<br>Eye Damage 1 H318 [intermediate (active)]<br>Acute Tox. 4 H302 [intermediate (active)]<br>Muta. 2 H341 [intermediate (active)]<br>Skin Corr. 1 H314 [intermediate (active)] |
| **408-080-2** | 70445-33-9 | 3-(2-ethylhexyloxy)propane-1,2-diol | Index number: 603-168-00-9<br>Hazard Category: Eye Dam. 1 Hazard Statement: H318<br>Aquatic Chronic 3 | Acute Tox. 4 H332<br>Eye Damage 1 H318<br>Aquatic Chronic 3 H412 |

[5] 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).

| | | | | |
|---|---|---|---|---|
| | | | Statement: H412 | |
| **470-470-3** | 9022-75-7 | 470-470-3 | - | Skin Corr. 1C H314<br>Eye Damage 1 H318<br>Aquatic Acute 1 H400<br>Aquatic Chronic 2 H411 |
| **600-386-6** | 10305-38-1 | 3-(hexyloxy)propane-1,2-diol | - | Eye Irrit. 2 H319 |
| **618-509-7** | 9022-76-8 | 618-509-7 | - | - |
| **691-853-3** | 90227-68- | 691-853-3 | - | - |
| **700-923-5** | 10305-39-2 | 3-(heptyloxy)propane-1,2-diol | - | Eye Damage 1 H318 |
| **801-709-5** | 53146-45-5 | 1-(allyloxy)-3-butoxypropan-2-ol | - | Muta. 2 H341<br>Acute Tox. 4 H302<br>Skin Corr. 1C H314<br>Skin Sens. 1B H317 |
| **805-622-3** | 10305-41-6 | 3-(cyclohexyloxy)propane-1,2-diol | - | Eye Damage 1 H318 |
| **837-816-9** | 10438-94-5 | 3-(octyloxy)propane-1,2-diol | - | Skin Irrit. 2 H315<br>Eye Damage 1 H318 |
| **858-735-5** | 2337348-25-9 | 1,3-bis[(3-methylbut-2-en-1-yl)oxy]propan-2-ol | - | Skin Irrit. 2 H315<br>Eye Irrit. 2 H319<br>Skin Sens. 1B H317 |
| **922-520-5** | - | C12-16 alkyl, glycerol ether | - | Aquatic Acute 1 H400<br>Aquatic Chronic 3 H412 |

| | | | | |
|---|---|---|---|---|
| **939-727-1** | - | Reaction mass of (Z)-3-(9-octadecenyloxy)propane-1,2-diol and alpha-(Z)-octadec-9-en-1-yl-omega-hydroxy-di[oxy[(hydroxymethyl)-1,2-ethanediyl]] and alpha-(Z)-octadec-9-en-1-yl-omega-hydroxy-tri[oxy[(hydroxymethyl)-1,2-ethanediyl]] | - | Skin Irrit. 2 H315<br>Eye Irrit. 2 H319<br>Aquatic Acute 1 H400<br>Aquatic Chronic 3 H412 |

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

Data extracted on 16/12/2022

Columns marked in grey indicate no use information available.

| Main types of applications structured by product or article types | 204-620-4 | 208-874-7 | 289-296-2 | 301-230-7 | 408-080-2 | 411-450-6 | 470-470-3 | 485-870-3 | 600-386-6 | 618-509-7 | 691-853-3 | 700-923-5 | 801-709-5 | 805-622-3 | 837-816-9 | 858-735-5 | 922-520-5 | 939-727-1 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 Adhesives, etc | | | | | | | | | | | | | | | | FIP | | |
| 2 Adsorbents | | | | | | | | | | | | | | | | I | | |
| 3 Air care products | | | | | | | C | | | | | | | | | | | |
| 8 Biocidal products | | | | | FI | | | | | | | | | | | | | |
| 9a Coatings etc | | | | | | | | | | | | | | | | FIP | | |
| 14 Metal surface treatment | | | | | | | | | I | | | | | I | | | | |
| 18 Ink and toners | | | | | | | | | | | | | | | | FIP | | |
| 19 Intermediate | | | | | | | | | | | | | | | | I | I | |
| 21 Laboratory chemicals | | | | (I) | F | | | | | | | | | | | I | | |
| 24 Lubricants, etc | | | | | | | | | I | | | | | I | | | | |
| 25 Metal working fluids | | | | | FIPC | | | | I | | | | | I | | | | |

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 28 Perfumes, fragrances | | | F | | | | C | | | | | | | | | | C |
| 29 Pharmaceuticals | | | | | FIPC | | | | | | | | | | | | |
| 31 Polishes and wax blends | | | | | | | | | | | | | | | | | |
| 32 Polymers | I | | | | | | | | | | | | (I) | | | FI**A** | | |
| 35 Washing and cleaning products | | | | | FPC | | | | FIC | | | | | FIC | | | | |
| 39 Cosmetics, PC products | | FPC | C | | FIPC | | FC | | FIC | | | FPC | | FIC | FC | | | FC |

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 9/1/2023

| EC / List number | RMOA | Authorisation | | Restriction* | CLH | Actions not under REACH / CLP |
|---|---|---|---|---|---|---|
| | | Candidate list | Annex XIV | Annex XVII | Annex VI (CLP) | |
| 408-080-2 | | | | YES | YES | |
| 411-450-6 | | | | | 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).

EC 408-080-2 has a harmonised classification as Eye Dam 1 and based on this is covered by entry 75 of REACH Annex XVII, on tattoo inks.

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