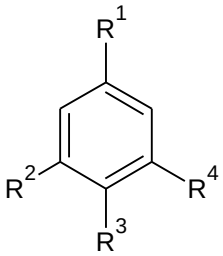
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Benzene derivatives with branched aliphatic substituents

General structure:

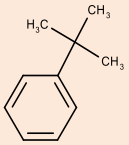
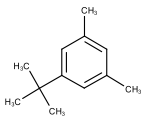
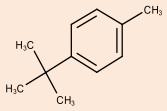
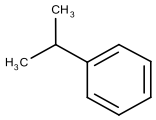
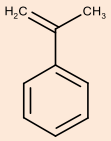
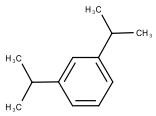
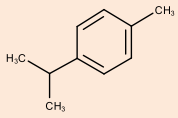
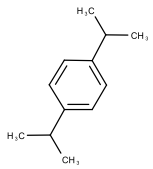


R1: isopropyl, isopropenyl, (iso)butyl, isopentyl, and longer saturated (iso)alkyl chains
R2: methyl, isopropyl, isopropenyl, (optional)

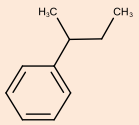
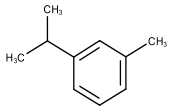
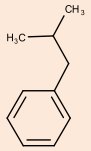
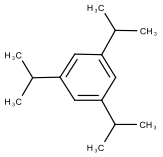
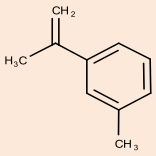
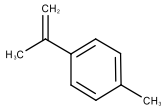
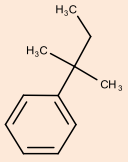
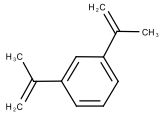
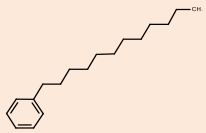
Revision history

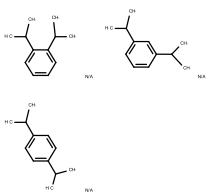
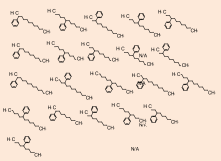
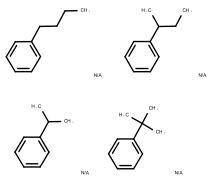
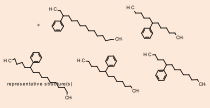
Version	*Date*	*Description*
1.0	29 February 2024	

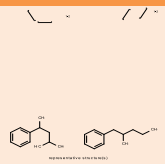
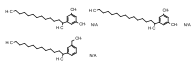
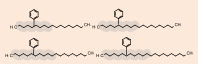
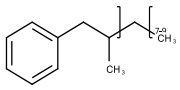
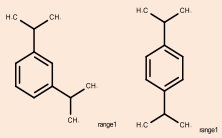
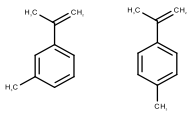
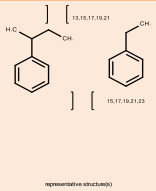
Substances within this group:

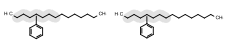
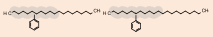
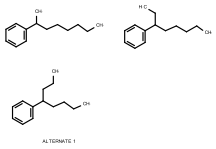
EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
202-632-4	98-06-6	tert-butylbenzene		Full, 10-100
202-647-6	98-19-1	5-tert-butyl-m-xylene		OSII or TII
202-675-9	98-51-1	4-tert-butyltoluene		OSII or TII
202-704-5	98-82-8	Cumene		Full, >1000
202-705-0	98-83-9	2-phenylpropene		Full, >1000
202-773-1	99-62-7	1,3-diisopropylbenzene		Full, not (publicly) available
202-796-7	99-87-6	p-cymene		Full, 10-100
202-826-9	100-18-5	1,4-diisopropylbenzene		Full, 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

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
205-227-0	135-98-8	sec-butylbenzene		C&L notification
208-617-9	535-77-3	m-cymene		C&L notification
208-706-2	538-93-2	Isobutylbenzene		OSII or TII
211-941-3	717-74-8	1,3,5-triisopropylbenzene		Full, not (publicly) available
214-394-9	1124-20-5	m,α-dimethylstyrene		C&L notification
214-795-9	1195-32-0	p,α-dimethylstyrene		C&L notification
218-076-0	2049-95-8	tert-pentylbenzene		Full, not (publicly) available
223-146-9	3748-13-8	m-bis(1-methylvinyl)benzene		Full, not (publicly) available
246-772-4	25265-78-5	Tetrapropylenebenzene		C&L notification

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
246-835-6	25321-09-9	Diisopropylbenzene		C&L notification
267-051-0	67774-74-7	Benzene, C10-13-alkyl derivs.		Full, >1000
270-126-0	68411-44-9	Benzene, butyl-, branched and linear		Not registered
270-486-9	68442-69-3	Benzene, mono-C10-14-alkyl derivs.	No Structure	C&L notification
272-007-9	68648-86-2	Benzene, C4-16-alkyl derivs.	No Structure	C&L notification
272-472-8	68855-24-3	Benzene, C14-30-alkyl derivs.		C&L notification
302-197-1	94094-94-7	Benzene, mono-C12-18-branched alkyl derivs.	No Structure	C&L notification

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
614-264-5	68081-77-6	Benzene, polypropene derivs.		OSII or TII
700-758-9	-	Benzene, dimethyl-, mono C14-16 (even numbered) sec alkyl derivs.		OSII or TII
701-016-7	-	Benzene, C20-24 (even numbered) sec-alkyl derivs.		OSII or TII
810-801-4	-	Benzene, mono-C11-C13-branched alkyl derivatives		Full, not (publicly) available
905-459-9	-	Reaction mass of 1,3-diisopropylbenzene and 1,4-diisopropylbenzene		Full, 100-1000
909-129-5	-	Reaction mass of m,alpha-dimethylstyrene and p,alpha-dimethylstyrene		Full, not (publicly) available
932-219-0				Not registered

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
940-786-0	-	Benzene, C15-16-alkyl derivs.		Full, not (publicly) available
943-152-1	2156592-66-2	Benzene, C20-22-alkyl derivs.		OSII or TII
950-576-0	-	Reaction mass of octan-2-ylbenzene, octan-3-ylbenzene and octan-4-ylbenzene		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.

Contents

DISCLAIMER

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

Foreword

The 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.

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.

[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).

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

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

Glossary

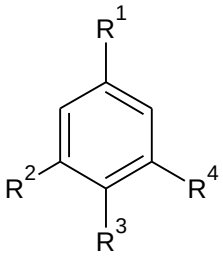
ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
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 34 structurally similar substances based on the presence of the benzene ring that is substituted with different saturated or unsaturated alkyl chains in one or more positions.

General structure:



R1: isopropyl, isopropenyl, (iso)butyl, isopentyl, and longer saturated (iso)alkyl chains
R2: methyl, isopropyl, isopropenyl, (optional)

The group consists of 12 mono-constituent, 3 multi-constituent and 7 UVCB registered substances. The registration status of the substances is the following: 15 full (Article 10) registrations, 7 intermediates, 10 C&L notified and 2 non-registered substances.

Based on information reported in the REACH registration dossiers, the use profile for the group is heterogenous – a broad range of product categories (PCs) and technical functions are reported whereas only a small subset of uses is common to multiple members within the group. A few substances in particular (EC 267-051-0, 202-704-5, 202-705-0) have many registrants (19-48) and overall report many product categories (up to 31) and technical functions. It is important to note that the use information provided for some registration dossiers is unclear and introduces uncertainties in terms of exposure potential. In particular, the description of some uses is very general with many associated product categories but little or contradictory supporting information; in addition, numerous technical functions are sometimes reported and are often not informative (e.g. "all technical functions"). Consequently, it is unclear whether all reported uses are relevant (or over-reported), whether the substance could be present in articles and whether there is a potential for release/exposure. Based on the provided information, the most common uses appear to be intermediate, polymer preparations and compounds, washing and cleaning products, and lubricants. The most common technical functions are as intermediate (precursor)/monomer, solvent, lubricating agent. Use as a fragrance has also been reported for one substance (EC 202-796-7). A detailed overview of all uses is shown in Annex 2.

Several members report widespread professional and/or consumer uses where there is a potential for release and exposure. Most group members report only industrial uses where there is generally a lower likelihood for release and exposure. However, industrial uses are potentially widespread for several substances (EC 267-051-0, 202-704-5, 202-705-0) with multiple registrants and high overall volumes (e.g. registered tonnage bands of 100 t/y or more) suggesting the industrial uses can occur across multiple sites and/or by many users. Exposure as

a result of release from articles cannot be excluded. Article service life (ASL) has been reported or assumed for uses in polymers (e.g. production of plastic and rubber articles), batteries and for applications of mixtures such as coatings and functional fluids leading to the inclusion in articles. However, based on a screening of the registration dossiers, it is not clear whether and to what extent releases of the substances from those articles could be expected.

EC/List 202-773-1, 202-826-9, and 905-459-9 are currently on the CoRAP list, for a joint substance evaluation, to clarify (primarily) reproductive toxicity and PBT/vPvB properties. Due to ongoing enforcement (for List 905-459-9) after the follow-up of the compliance check decision, France is expected to start the substance evaluation work in 2025. Substance EC 202-704-5 has a harmonised classification as Carc. 1B, meanwhile other members have an ongoing CLH for Repr. 1B (EC 202-796-7, 202-675-9) or Carc. 2 (EC 202-705-0), among other hazard classes. Cumene (EC 202-704-5) and 2-phenylpropene (EC 202-705-0) also have an Indicative OEL (IOEL). Furthermore, cumene and benzene, C10-13-alkyl derivs. (EC 267-051-0) have been assessed under the Existing substances regulation and a Risk Assessment Report is available.

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 number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
202-773-1 **202-826-9** **905-459-9** **810-801-4**[5]	Known or potential hazard for reproductive toxicity	Known or potential hazard for PBT/vPvB and aquatic toxicity	Mainly industrial uses e.g. as solvent, chemical intermediate, in inks, lubricants, extraction agents, and polymer preparations. High aggregated tonnage for most substances. Release/exposure in the industrial setting (including from intermediate uses) is likely or cannot be excluded.	**First step:** Pending Action – SEV **Potential next steps (if hazard confirmed after data generation):** CLH **Potential last action** Restriction <u>Justification:</u> The harmonised classification as Repr. 1B or Carc. 1B would trigger the restriction entry 28 or 30 and by that ensure that the substances are not

[5] The substance EC 246-772-4 (tetrapropylenebenzene) currently does not have a registration dossier. The registration of this substance was changed to List 810-801-4 (Benzene, mono-C11-C13-branched alkyl derivatives), through a substance identity adaptation. Because of these circumstances, for the purposes of this screening exercise, the two substances are viewed as being the same.

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				included in consumer mixtures above the limits specified in that entry. Releases to the environment from consumer uses cannot be avoided. 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. In addition, these uses are typically non-contained and non-automated leading to releases to the environment and exposure to workers. 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. Industrial uses to be considered as part of the restriction. Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses.

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
202-704-5 **202-705-0** **202-796-7** **267-051-0** **940-786-0**	Known or potential hazard for reproductive toxicity for EC/List 202-705-0, 202-705-0, 202-796-7, 940-786-0 Known or potential hazard for carcinogenicity for EC 202-704-5, 202-705-0	No hazard or unlikely hazard for PBT/vPvB Inconclusive for PBT/vPvB and aquatic toxicity for 940-786-0 Known or potential hazard PMT/vPvM for 202-705-0	High tonnage with many registrants for most substances. Widespread professional and/or consumer uses in e.g. coatings, washing and cleaning products, lubricants with a high likelihood for exposure. Exposure of industrial workers and as result of release from articles cannot be excluded	**First step:** Potential restriction for 202-704-5 Pending Action – CLH for 202-796-7, 202-705-0 CCH in parallel for 202-705-0, 267-051-0, 940-786-0 **Potential next steps (if hazard confirmed after data generation)** CLH **Potential last action:** Restriction <u>Justification:</u> The harmonised classification as Repr. 1B or Carc. 1B would trigger the restriction entry 28 or 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				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. Potential exposure from articles and industrial uses needs further investigation; restriction for use in articles and industrial uses to be considered together with the restriction of professional uses.

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
202-632-4 **202-647-6** **202-675-9** **205-227-0** **208-617-9** **208-706-2** **211-941-3** **214-394-9** **214-795-9** **218-076-0** **223-146-9** **246-835-6** **270-126-0** **270-486-9** **272-007-9** **272-472-8** **302-197-1** **614-264-5**[6] **700-758-9** **701-016-7** **909-129-5** **932-219-0** **943-152-1** **950-576-0**	Known or potential hazard for reproductive toxicity for 202-632-4, 202-675-9, 950-576-0 Known or potential hazard for skin sensitisation for 211-941-3, 218-076-0, 223-146-9	Known or potential hazard for PBT/vPvB for 202-647-6, 202-675-9, 208-706-2, 218-076-0, 223-146-9 Known or potential hazard for PMT/vPvM for 202-632-4 Known or potential hazard for aquatic toxicity for 202-675-9, 205-227-0, 208-706-2, 214-795-9, 218-076-0, 223-146-9, 270-126-0, 270-486-9, 272-472-8, 302-197-1, 701-016-7, 909-129-5, 950-576-0	Low tonnage and mostly limited industrial uses for fully registered substances. Remaining substances have only intermediate registration (under SCC) or are not registered.	**First step:** CCH for 202-632-4, 211-941-3, 950-576-0 to clarify hazards **Potential next steps (if hazard confirmed after data generation):** No action Justification: According to the reported uses, low potential for exposure to both human health and environment is expected. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change. Harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace.

[6] The substance List 614-264-5 (Benzene, poly(propene) derivatives) presumably has a similar composition as the substance List 810-801-4 (Benzene, mono-C11-C13-branched alkyl derivatives). However, there are remaining uncertainties related to this aspect of composition and compositional similarity. This is because the level of detail available on the composition in the registration dossier of List 614-264-5 is very limited. The ongoing Substance evaluation process on List 810-801-4 (Benzene, mono-C11-C13-branched alkyl derivatives) may further elucidate this aspect.

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

Whilst the substances in the group share some similarities in terms of structure, hazards and uses, they also have significant differences. In particular, based on the data currently available, no clear trends were observed to allow for hazard extrapolation at the group level and no clear link was identified to the driver of toxicity (e.g. specific metabolite, constituent). The substances in the group are generally prone to oxidation and have the potential to form reactive metabolites (e.g. epoxide), however a common mode of action could not be identified for human health. It was also not possible to assess potential for substitution due to a heterogenous use profile; while some substances have the same PCs reported, they often have different or multiple technical functions. Therefore, it was generally not feasible to extrapolate amongst group members and the following conclusions are primarily based on data provided for individual substances.

Suggested regulatory risk management action for substances EC/List 202-796-7, 940-786-0, 202-773-1, 202-826-9, 267-051-0, 905-459-9, 202-704-5, 202-705-0, 810-801-4 if potential carcinogenicity, reproductive toxicity and/or PBT/vPvB hazards are confirmed.

Based on ECHA's assessment of currently available hazard information, potential hazards were identified for human health. The available information indicates potential for reproductive toxicity for most of these substances due to observed adverse effects on male fertility in experimental studies (for EC 202-796-7, List 810-801-4), a submitted CLH intention for Repr. 1B (for EC 202-796-7) or planned/ongoing activities under substance evaluation to clarify repro concerns (for EC/List 202-773-1, 202-826-9, 905-459-9, 810-801-4). Furthermore, benzene, C10-13-alkyl derivs. (EC 267-051-0) and benzene, C15-16-alkyl derivs. (List 940-786-0) are flagged as potential reproductive toxicants due to a read-across adaptation with the source substance EC 272-008-4 which has a notified classification as Repr. 2 H361 (44 notifiers). In addition, there is potential for carcinogenicity for two substances due to a harmonised classification for Carc. 1B (EC 202-704-5) and an ongoing CLH for Carc. 2 (for EC 202-705-0).

Based on ECHA's assessment of currently available hazard information primarily from the registration dossiers, several members (EC/List 905-459-9, 202-826-9, 202-773-1, 810-801-4) fulfil the PBT/vPvB screening criteria[7]. These substances:

- are potentially persistent or very persistent (P/vP) as they are not readily or inherently biodegradable based on screening tests;
- are potentially bioaccumulative or very bioaccumulative (B/vB) as they have experimental bioaccumulation data showing a high potential for bioaccumulation, or a high potential to partition to lipid storage (*e.g.,* log K_{ow} > 4.5).
- potentially fulfil the T criteria set out in Annex XIII, based on (future) classification as Carc. 1B, Repro. 1B or 2.

EC 202-705-0 is also potentially persistent, is expected to be mobile in the

[7] As defined in REACH Annex XIII and R11 Guidance on PBT assessment (https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f)

environment and is potentially toxic.

In addition, most of the substances are toxic to the aquatic environment based on available experimental data or (self) classification.

As a first step, it is proposed to wait for the ongoing activities under substance evaluation and CLH. In parallel, a compliance check will be opened to further clarify the potential reproductive toxicity hazard (for EC/List 267-051-0, 940-786-0), unlikely PBT properties (for List 940-786-0) and potential PMT properties (for EC 202-705-0).

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via CLH as PBT/vPvB and Repro. 1B. It is important to highlight that an additional CLH for EC 202-705-0 may be warranted for Repro. 1B if RAC adopts the currently proposed CLH for Carc. 2, in order to benefit from the more stringent regulatory obligations that would result from a category 1 classification.

CLH is highly recommended as a step prior to restriction. CLH as Repro. 1B or Carc. 1B i) will require company level risk management measures (RMM) for workers, to be in place, and ii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 28 and 30.

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

CLH will also support regulatory action under other regulations. 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 for uses as fragrance, since CMR cat. 1 are restricted by this regulation.

- harmonised classification as CMR cat. 1 will trigger regulatory action under the biocidal product regulation (EU) 528/2012, which does not allow the use by the general public of a product containing substances above the concentration limit leading to classification of the mixture as CMR cat 1.

Confirmation of the hazard properties via CLH is not considered sufficient to minimise potential releases of the substances in the environment and prevent potential exposure of workers.

The professional uses particularly in polymer preparations for adhesives, fillers or coatings, in washing and cleaning products, ink and toners, polishes and wax blends, lubricants, and non-metal surface treatment products are expected to be widespread (at many sites and by many users) and typically non-contained and non-automated leading to releases to the environment and with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration leading to potential workers' exposure. In addition, professional users may be self-employed and therefore not covered by OSH legislation.

Consumers may be co-exposed to the substances used by professionals (polymer preparations for adhesives or coatings, in washing and cleaning products, lubricants*)*.

Therefore, a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers, industrial and professional workers is suggested after SVHC identification and CLH, with the aim to minimise exposures and emissions to humans and the environment.

In addition, the use of the most harmful substances (e.g. PBT/vPvB, CMR) by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[8].

Moreover, **restricting substances in articles** used by professionals or consumers should be considered in the context of the restriction as potential exposure from articles (e.g. where the substances are used as adhesives, coatings, textile dyes, leather treatment products, plasticisers in plastic or rubber articles) needs further investigation first.

Substances EC/List 202-773-1, 905-459-9, 202-826-9 and 810-801-4 are only used in industrial settings (or equivalent)[9] as a chemical intermediate, lubricant, in ink and toners, or polymer preparations, however, they are also proposed to be included in the restriction if the PBT hazard is confirmed to minimise release to the environment.

For the substances with potential CMR properties only (EC 202-796-7, 267-051-0, 202-704-5, 202-705-0), restriction of certain industrial uses such as washing and cleaning products, polymer preparations, adhesives, lubricants, coatings, surface treatment products, leather and textile treatment products (including dyes), and as solvent could be considered in the context of the restriction for professional uses. Most of these substances have many registrants (19-48), high aggregated tonnage and numerous applications suggesting that the industrial uses are widespread. In addition, based on Process categories (PROCs)[10] reported in the registration dossiers for activities that occur in the industrial setting and supported by the existing IOELs in place for some of the substances, there is a preliminary indication that there is potential for exposure of industrial workers. For EC 202-705-0, the restriction should also take into account the potential PMT properties.

Alternatively, or as a complementary measure to a restriction of industrial uses, an IOEL[11] could be considered to reflect the new hazard classifications and ensure adequate protection of workers. Furthermore, the need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

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

[9] Use as a laboratory chemical by skilled professionals

[10] PROCs for industrial uses preliminarily suggest potential for exposure due to e.g. manual processes (PROC 28) and air dispersive techniques (PROC 10, 11, 7)

[11] EC 202-704-5 (Flam. Liq. 3; STOT SE 3; Asp. Tox. 1; Aquatic Chronic 2) and EC 202-705-0 (Flam. Liq. 3; Eye Irrit. 2; STOT SE 3; Aquatic Chronic 2) already have IOELs; however they have both since been proposed for additional classification for carcinogenicity

Currently no need to suggest (further) regulatory risk management actions for the remaining group members due to low potential for release and exposure.

Based on ECHA's assessment of currently available hazard information, the remaining substances have a diverse hazard profile: several substances[12] fulfil the PBT/vPvB screening criteria; substances EC 202-632-4 and 202-705-0 screen as a potential PMT/vPvM; most substances are (potentially) toxic to the aquatic environment; a few (EC 211-941-3, 218-076-0, 223-146-9) are self-classified as skin sensitisers; and a few (EC/List 202-632-4, 202-675-9, 950-576-0) are potential reproductive toxicants. In addition, a CLH intention has been submitted for EC 202-675-9 for Repro. 1B.

Due to the poor data availability and the limited potential for extrapolation, the vast majority of substances are inconclusive for most endpoints. Furthermore, due to the low tonnage band, registration status as intermediate or lack of a registration, there is limited potential for further data generation under REACH to clarify the inconclusive hazards. Nevertheless, a CCH will be opened where possible to further clarify the potential hazards.

There is a low potential for release and exposure for all of these substances albeit with some uncertainty. Most of the substances are either not registered or registered only as intermediates where uses are expected to occur under strictly controlled conditions (SCC). Substance EC 202-675-9 is also registered only as an intermediate however it is mentioned in the registration dossier that *"the substance is contained in consumer products".* Nevertheless, the proposed CLH for Repro. 1B should ensure adequate protection of human health. The remaining substances have a full registration however most have a low tonnage band of 1-10 tpa or (a minority) with 10-100 tpa, and have the following limited uses:

- EC 202-632-4 is only used in formulations however no PCs or additional information on the use (e.g. types of products, technical function) is provided.

- EC 211-941-3 is only used as a functional fluid; while the registrant reports ASL, the substance is physically encapsulated within medical equipment and is presumably handled by highly skilled medical professionals – therefore release and exposure as a result of ASL are considered unlikely.

- EC 218-076-0 is only used in formulation of electrolytes for batteries and as a chemical intermediate; while ASL might be relevant due to use in batteries, exposure as a result of release from the article is considered unlikely.

- EC 223-146-9 is only used as an intermediate for the manufacture of chemicals and rubber products; however no additional information is provided to support a conclusion on whether exposure as a result of ASL (due to rubber articles) could be relevant.

- List 909-129-5 is imported as part of a polymer and therefore no use information is provided; although it is generally assumed that release of a substance from a polymer (when covalently bound) is low, due to lack of

[12] EC/List 202-647-6, 202-675-9, 208-706-2, 223-146-9, 246-772-4, 218-076-0

information it is not clear whether residual amounts of the substance could be present in the polymer or could be released via degradation.

- List 950-576-0 is only used in compressors where release from the article is not intended.

Furthermore, the reported PROCs and Environmental release categories (ERCs)[13], while only indicative, generally support the low likelihood of release and exposure.

For industrial uses of substances with skin sensitisation properties, sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation.

Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances 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 for any of these substances.

[13] For example PROCs 1,2 and 3 indicate use in a closed system without likelihood of exposure or with occasional controlled exposure; ERCs 6a, 6c and 7 are associated with relatively low (2-5%) default worst-case release factors to air and water (before STP)

Annex 1: Overview of classifications

Data extracted on 02/11/2022

EC Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
202-632-4	*98-06-6*	*tert-butylbenzene*	*-*	*Flam. Liquid 3 H226* *Skin Irrit. 2 H315* *Eye Irrit. 2 H319 [intermediate (active)]*
202-647-6	*98-19-1*	*5-tert-butyl-m-xylene*	*-*	*Skin Irrit. 2 H315 [intermediate (active)]* *Eye Irrit. 2 H319 [intermediate (active)]* *STOT Single Exp. 3 H335 [intermediate (active)]*
202-675-9	*98-51-1*	*4-tert-butyltoluene*	*-*	*Aquatic Acute 2 H401 [intermediate (active)]* *Acute Tox. 4 H302 [intermediate (active)]* *Acute Tox. 2 H330 [intermediate (active)]* *STOT Single Exp. 1 H370, affected organs: central nervous system [intermediate (active)]* *Eye Irrit. 2A H319 [intermediate (active)]* *Repr. 2 H361, specific effect:fertility [intermediate (active)]* *Aquatic Chronic 2 H411 [intermediate (active)]*
202-704-5	*98-82-8*	*cumene*	*Index number: 601-024-00-X* *Flam. Liq. 3 Hazard Statement: H226* *Notes: C* *STOT SE 3 Hazard Statement: H335* *Notes: C* *Asp. Tox. 1 Hazard Statement: H304* *Notes: C* *Aquatic Chronic 2 Statement: H411* *Additional Info: C*	*Flam. Liquid 3 H226* *Asp. Tox. 1 H304* *STOT Single Exp. 3 H335, affected organs: upper respiratory tract* *Aquatic Chronic 3 H412* *Aquatic Chronic 2 H411*

EC Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
202-705-0	*98-83-9*	*2-phenylpropene*	*Index number: 601-027-00-6 Flam. Liq. 3 Hazard Statement: H226 Hazard Category: Eye Irrit. 2 Hazard Statement: H319 STOT SE 3 Hazard Statement: H335 Aquatic Chronic 2 Statement: H411 Category: STOT SE 3 Class: Specific Target Organ Toxicity - Single Exposure Statement: H335: C>=25%*	*Repr. 2 H361 Flam. Liquid 3 H226 Eye Irrit. 2 H319 Skin Sens. 1B H317 Asp. Tox. 1 H304 STOT Single Exp. 3 H335, affected organs: upper respiratory tract, specific concentration: >=25 Aquatic Chronic 2 H411*
202-773-1	*99-62-7*	*1,3-diisopropylbenzene*	*-*	*-*
202-796-7	*99-87-6*	*p-cymene*	*Inhalation ATE 3 mg/L (vapour, 601-094-00-1) Index number: 601-094-00-1 Flam. Liq. 3 Hazard Statement: H226 Asp. Tox. 1 Hazard Statement: H304 Acute Tox. 3 Hazard Statement: H331 Aquatic Chronic 2 Statement: H411*	*STOT Single Exp. 3 H335, affected organs: Lung [intermediate (active)] Repr. 2 H361 Flam. Liquid 3 H226 Acute Tox. 3 H331 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Asp. Tox. 1 H304 Aquatic Chronic 2 H411*
202-826-9	*100-18-5*	*1,4-diisopropylbenzene*	*-*	*Skin Irrit. 2 H315*
205-227-0	*135-98-8*	*sec-butylbenzene*	*-*	*-*
208-617-9	*535-77-3*	*m-cymene*	*-*	*-*

EC Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
208-706-2	*538-93-2*	*isobutylbenzene*	*-*	*Flam. Liquid 3 H226 [intermediate (active)] Aquatic Chronic 1 H410 [intermediate (active)] Aquatic Acute 1 H400 [intermediate (active)]*
211-941-3	*717-74-8*	*1,3,5-triisopropylbenzene*	*-*	*Skin Sens. 1B H317*
214-394-9	*1124-20-5*	*m,a-dimethylstyrene*	*-*	*-*
214-795-9	*1195-32-0*	*p,a-dimethylstyrene*	*-*	*-*
218-076-0	*2049-95-8*	*tert-pentylbenzene*	*-*	*Flam. Liquid 3 H226 Skin Sens. 1B H317 Aquatic Chronic 2 H411*
223-146-9	*3748-13-8*	*m-bis(1-methylvinyl)benzene*	*-*	*Skin Sens. 1B H317 Aquatic Chronic 2 H411*
246-772-4	*25265-78-5*	*tetrapropylenebenzene*	*-*	*-*
246-835-6	*25321-09-9*	*diisopropylbenzene*	*-*	*-*

EC Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
267-051-0	*67774-74-7*	*Benzene, C10-13-alkyl derivs.*	-	*Asp. Tox. 1 H304*
270-486-9	*68442-69-3*	*Benzene, mono-C10-14-alkyl derivs.*	-	-
272-007-9	*68648-86-2*	*Benzene, C4-16-alkyl derivs.*	-	-
272-472-8	*68855-24-3*	*Benzene, C14-30-alkyl derivs.*	-	-
302-197-1	*94094-94-7*	*Benzene, mono-C12-18-branched alkyl derivs.*	-	-
614-264-5	*68081-77-6*	*Benzene, polypropene derivs.*	-	*Aquatic Chronic 4 H413 [intermediate (active)]* *Asp. Tox. 1 H304 [intermediate (active)]*
700-758-9	-	*C14-C16 (even numbered and branched) alkyl-dimethylbenzene*	-	*Asp. Tox. 1 H304 [intermediate (active)]*
701-016-7	-	*Benzene, C20-24 (even numbered) sec-alkyl derivs.*	-	*Aquatic Chronic 4 H413 [intermediate (active)]* *Asp. Tox. 1 H304 [intermediate (active)]*
-	*2156592-70-8*	*Benzene, mono-C11-C13-branched alkyl derivatives*	-	*Repr. 2 H361* *Asp. Tox. 1 H304* *Aquatic Chronic 4 H413*
905-459-9	-	*Reaction mass of 1,3-diisopropylbenzene and 1,4-diisopropylbenzene*	-	*Skin Irrit. 2 H315 [intermediate (active)]* *Eye Irrit. 2 H319 [intermediate (active)]* *Aquatic Chronic 2 H411 [intermediate (active)]* *STOT Single Exp. 3 H335, affected organs: lung*

EC Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
				[intermediate (active)] *Asp. Tox. 1 H304*
909-129-5	-	*Reaction mass of m,α-dimethylstyrene and p,α-dimethylstyrene*	-	*Skin Irrit. 2 H315* *Aquatic Acute 1 H400* *Aquatic Chronic 1 H410*
940-786-0	-	*Benzene, C15-16-alkyl derivs.*	-	*Asp. Tox. 1 H304*
943-152-1	-	*Benzene, C20-22 (even numbered) alkyl derivs.*	-	*Asp. Tox. 1 H304 [intermediate (active)]*
950-576-0	-	*Reaction mass of octan-2-ylbenzene, octan-3-ylbenzene and octan-4-ylbenzene*	-	*Aquatic Chronic 4 H413*

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

Data extracted on 02/11/2022

Main types of applications structured by product or article types	267-051-0	202-704-5	202-705-0[14]	940-786-0	202-773-1	810-801-4	905-459-9	202-796-7	202-826-9[15]	202-632-4	211-941-3	950-576-0[16]	218-076-0	223-146-9	909-129-5[17]
PC 19: Intermediate	F, I, **P**	I, **P**	I, **P**	I	I	I	I		I	I			I	I	
PC 32: Polymer preparations and compounds	F, I, **P**, **A**	I	F, I, **P**, **C**	I			F, I								
PC 35: Washing and cleaning products	F, I, **P**, **C**	F, I, **P**	I, **P**					I, **P**, **C**							
PC 24: Lubricants, greases, release products	F, I, **P**, **C**			F, I, **P**, **C**		F, I					I				
PC 31: Polishes and wax blends	F, I, **P**, **C**			I, **P**				**P**, **C**							
PC 16: Heat transfer fluids	F, I, **P**			**P**		F, I									
PC 17: Hydraulic fluids	F, I, **P**			I, **P**							I, **A**				
PC 1: Adhesives, sealants	F, I, **P**, **A**	I, **P**		I, **P**											
PC 9a: Coatings and paints, thinners, paint removes	F, I, **P**, **A**	F, I, **P**	I, **P**, **C**, **A**												
PC 18: Ink and toners	F, I, **P**	I, **P**							I						
PC 34: Textile dyes, and impregnating products	F, I, **P**, **A**	I	I												
PC 21: Laboratory chemicals		F, I, **P**	F, I, **P**						**P**						
PC 8: Biocidal products (e.g. disinfectants, pest control)	**P**							**C**							

[14] Consumer uses only reported by specific members of the joint registration.
[15] Detailed description of uses not provided – only generic use in formulations indicated.
[16] No product categories identified – used as a solvent in refrigerator compressors.
[17] No use information provided – imported as part of a polymer.

Main types of applications structured by product or article types	267-051-0	202-704-5	202-705-0[14]	940-786-0	202-773-1	810-801-4	905-459-9	202-796-7	202-826-9[15]	202-632-4	211-941-3	950-576-0[16]	218-076-0	223-146-9	909-129-5[17]
PC 28: Perfumes, fragrances	**P**, **C**							F, I, **C**							
PC 3: Air care products	F, I, **P**							**C**							
PC 39: Cosmetics, personal care products	I, **C**							**C**							
PC 29: Pharmaceuticals	I		I												
PC 25: Metal working fluids	F, I, **P**			F, **P**											
PC 9b: Fillers, putties, plasters, modelling clay	**P**		I, **P**, **C**												
PC 26: Paper and board treatment products	F, I, **P**		I												
PC 23: Leather treatment products	F, I, **P**, **A**		I												
PC 7: Base metals and alloys	F, I			**P**											
PC 40: Extraction agents		F, I, **P**					F, I								
PC 15: Non-metal-surface treatment products	F, I, **P**														
PC 13: Fuels	F, I, **C**														
PC 14: Metal surface treatment products	F, I														
PC42: Electrolytes for batteries													F		
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	**P**		F												
PC 37: Water treatment chemicals	**P**														
PC 2: Adsorbents	F, I														
PC 30: Photo-chemicals		F, I, **P**													

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 16/11/2022

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP	OEL
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
202-675-9					YES		
202-704-5					YES	ESR	YES (IOEL)
202-705-0					YES		YES (IOEL)
202-796-7					YES		
267-051-0						ESR	

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

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