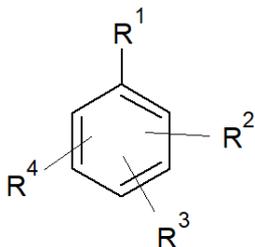


## Assessment of regulatory needs

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

**Group Name: Benzene and its derivatives with linear aliphatic substituents**

**General structure:**

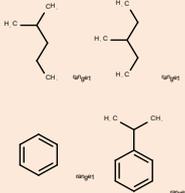
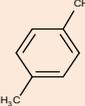
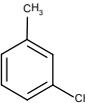
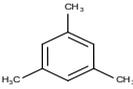
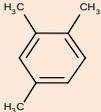


Where R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> = H, or linear alkyl group C<sub>1</sub>-C<sub>18</sub>, saturated and unsaturated

### Revision history

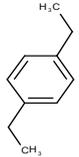
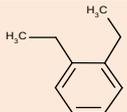
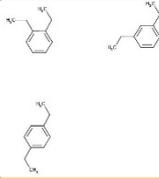
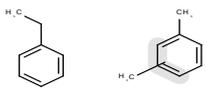
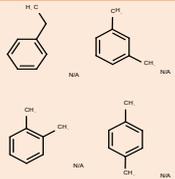
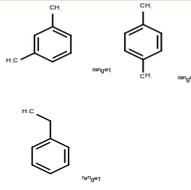
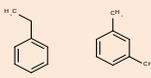
<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	25 September 2023	

## Substances within this group:

SG	EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
<b>Subgroup 1 - Benzene (and substances containing benzene &gt; 0.1 %)</b>					
1	200-753-7	71-43-2	benzene		Full, >1 000
	903-151-9	-	reaction mass of 2-methylpentane and 3-methylpentane and benzene and cumene		OSII or TII
<b>Subgroup 2 - Methylbenzenes</b>					
2a	203-625-9	108-88-3	toluene		Full, >1 000
2b	202-422-2	95-47-6	o-xylene		Full, >1 000
	203-396-5	106-42-3	p-xylene		Full, >1 000
	203-576-3	108-38-3	m-xylene		Full, >1 000
	215-535-7	1330-20-7	xylene		Full, >1 000
2c	203-604-4	108-67-8	mesitylene		Full, 10-100
	202-436-9	95-63-6	1,2,4-trimethylbenzene		Full, >1 000

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

ASSESSMENT OF REGULATORY NEEDS

SG	EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
<b>Subgroup 3 - Ethylbenzenes</b>					
3a	202-849-4	100-41-4	ethylbenzene		Full, >1 000
3b	203-265-2	105-05-5	1,4-diethylbenzene		Full, 100-1 000
	205-170-1	135-01-3	o-diethylbenzene		Not registered
	246-874-9	25340-17-4	diethylbenzene		Full, 100-1 000
<b>Subgroup 4 - Reaction masses of xylenes and ethylbenzene</b>					
4	292-694-9	90989-38-1	aromatic hydrocarbons, C8		Not registered
	905-213-0	-	reaction mass of ethylbenzene and o-xylene and p-xylene and m-xylene		Not registered
	905-562-9	-	reaction mass of ethylbenzene and m-xylene and p-xylene		Full, >1 000
	905-570-2	-	reaction mass of ethylbenzene and m-xylene		Full, >10 000

## ASSESSMENT OF REGULATORY NEEDS

SG	EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
	905-588-0	-	reaction mass of ethylbenzene and xylene		Full, >1 000
<b>Subgroup 5 (other linear alky benzenes, saturated or unsaturated)</b>					
5	203-132-9	103-65-1	propylbenzene		Not registered
	204-591-8	123-01-3	dodecylbenzene		Not registered
	208-645-1	536-74-3	phenylacetylene		OSII or TII
	224-684-7	4445-07-2	octadecylbenzene		OSII or TII
	229-806-2	6742-54-7	undecylbenzene		Not registered
	270-954-2	68512-02-7	benzene, (tetrapropenyl) derivs.		Not registered
	405-980-7*	768-56-9	4-phenylbut-1-ene		NONS
	626-527-1*	768-56-9	(but-3-en-1-yl)benzene		Not registered

## ASSESSMENT OF REGULATORY NEEDS

\*When a dossier is submitted without EC number, REACH-IT automatically assigns a List number to the dossier. Sometimes, due to IT technical limitations, duplicate List numbers are created. In this Group the following are considered duplicate entries: EC 405-980-7 and List nr 626-527-1. In general EC numbers take precedence over List numbers.

This table does not contain group members that are only notified under the CLP Regulation. However, the list is not necessarily exhaustive.

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## **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)<sup>2</sup>. 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<sup>3</sup>. 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.

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<sup>2</sup> [Working with Groups - ECHA \(europa.eu\)](https://echa.europa.eu/en/working-with-groups)

<sup>3</sup> 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<sup>4</sup>.

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

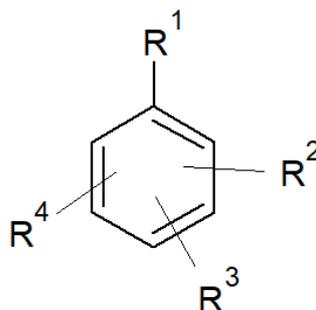
## Glossary

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
RCR	Risk characterisation ratio
RMM	Risk management measures
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 alkyl benzene moiety shown in the figure below.



Where R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> = H, or linear alkyl group C<sub>1</sub>-C<sub>18</sub>, saturated and unsaturated

There are 26 substances in the group of which 14 with full registration. The substances of this group are sorted to the following subgroups (SG) related to the chemical structure:

- SG 1: Benzene and substances containing benzene > 0.1 %
  - benzene
  - reaction mass of 2-methylpentane and 3-methylpentane and benzene and cumene
- SG 2: Methylbenzenes
  - 2a methylbenzene (toluene)
  - 2b dimethylbenzenes (o-, m-, p-xylenes)
  - 2c trimethylbenzenes
- SG 3: Ethylbenzenes
  - 3a ethylbenzene
  - 3b diethylbenzenes
- SG 4: Reaction masses of ethylbenzene and xylenes
- SG 5: Other benzene derivatives with linear aliphatic substituents, saturated or unsaturated.

Based on information reported in the REACH registration dossiers, the substances have the following main uses:

- **Benzene (SG 1)** is mainly used industrially as a solvent, or intermediate. Professional use is limited to laboratory use. Human occupational exposure is limited by the BOEL. Benzene is also used in fuel and fuel additives, which is regulated.
- All **methylbenzenes (SG 2a, 2b, 2c) and reaction masses of ethylbenzene and xylenes (SG 4)** have industrial, professional and consumer uses. Uses include among others explosives, fertiliser, plant protection products, de-icing products, washing and cleaning products,

biocidal products, air care products, polishes and wax blends, non-metal surface treatment products, lubricants, greases, fuel, adhesives and sealants, finger paints, fillers and putties, coatings and paints, thinners, paint removes, ink and toners, textile dyes and impregnating products, leather treatment products, welding and soldering products, and laboratory chemicals. Human occupational exposure is limited by the individual IOELs. There is a potential for professional, consumer and environmental exposure.

- **Ethylbenzene (SG 3)** main uses are industrial. It is also reported to be used professionally for coating and paints, thinners, paint removes. Human occupational exposure is limited by the IOEL.
- **The other benzene derivatives (SG 5)** do not have professional or consumer uses, they are either intermediates or not registered.

Substances of this group have, among others, the following harmonised classifications, which are relevant to Section 2, below:

- Benzene: Carc. 1A, Muta 1B, STOT RE 1 (haematopoietic system)
- Toluene: Repr. 2 (development), STOT RE 2 (neuropsychological effects, auditory dysfunction, and effects on colour vision),
- Ethylbenzene: STOR RE 2 (hearing organs).

In addition, further regulatory actions have been performed. Conclusions relevant for the current investigation are summarised as follows:

- Benzene (SG 1): Based on an EU Risk Assessment Report (EU RAR) performed by the German Federal Institute for Occupational Safety and Health (BAuA; 2000)<sup>5</sup>, the Commission Recommendation on results of the risk evaluation and risk reduction strategies for benzene (2008)<sup>6</sup> concluded on the need to review the OEL for workers. Recently, a revised BOEL<sup>7</sup> was published.
- Toluene (SG 2a):
  - Based on an EU RAR performed by the Danish Environmental Protection Agency (2003)<sup>8</sup> the Commission Recommendation (2004)<sup>9</sup> concluded on the need to consider a restriction on the marketing and use of toluene in adhesives and spray paints, which is now in place (REACH Annex VII, entry 48), and the need to review the IOEL. The IOEL of 50 ppm (Council Directive 2006/15/EC) was based on a proposal by SCOEL from 2001.
  - In the Substance Evaluation Report performed by the Finnish Safety and Chemicals Agency (2013)<sup>10</sup> it is noted that this IOEL does not consider reproductive and neurobehavioral effects of toluene and did not apply the assessment factor according to ECHA Guidance Document R.8.

<sup>5</sup> <https://echa.europa.eu/documents/10162/be2a96a7-40f6-40d7-81e5-b8c3f948efc2>

<sup>6</sup> <https://echa.europa.eu/documents/10162/750b16f3-a595-4b6e-bfe6-b880892ed69c>

<sup>7</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022L0431&cldee=a2JlY2h0b2xkQGFpaGFub3Jn&recipientid=lead-6cbdfcd4c0e0e71180fa005056952b31-247ab532d540459e97d4be705dfd6061&esid=d7c6a768-98aa-ec11-8136-005056952b31>

<sup>8</sup> <https://echa.europa.eu/documents/10162/24a34bd6-55cd-4e28-ae24-5bae281bf3c2>

<sup>9</sup> <https://echa.europa.eu/documents/10162/cc2186cb-191a-4d3b-816d-465b772b0e33>

<sup>10</sup> <https://echa.europa.eu/documents/10162/42f18c7c-d423-093e-c2ec-956ee4d37f69>

- Xylenes (SG 2b):
  - a RMOA including xylene isomers, o-, m-, and p-xylene and reaction masses of ethylbenzene and xylene or m-xylene and p-xylene is intended to be performed by the German BAuA (2020)<sup>11</sup>, particular for consumer products, articles and mixtures.
  - A Substance Evaluation Conclusion Report on p-, o-, and m-xylene performed by the German BAuA (2021)<sup>12</sup> concluded on the need to review the IOEL of 50 ppm (Council Directive 2000/39/EC).
- Ethylbenzene (SG 3):
  - A draft strategy for limiting risks for human health performed by the German BAuA (2008)<sup>13</sup> recommended to revise the IOEL (Dir 98/24), further technical and organisational occupational measures and to apply certain classifications. Harmonised classifications for ethylbenzene were published in 2008<sup>14</sup>.
  - A RMOA including reaction masses of ethylbenzene and xylene or m-xylene and p-xylene is intended to be performed by the German BAuA (2020)<sup>15</sup>, particular for consumer products, articles and mixtures.

Toluene (CAS no. 18-88-3), xylene (CAS no. 1330-20-7) and ethylbenzene (CAS no. 100-41-4) are listed in the German Printing Inks Ordinance, which amends the German Consumer Goods Ordinance, and in the Swiss Ordinance of the Federal Department of Home Affairs on materials and articles intended to come into contact with foodstuffs. All substances have been evaluated and are subject to a migration limit.

Several of the substances fall under the definition of aromatic mineral oil hydrocarbons (MOAH). EFSA has recently re-evaluated the risks linked to MOAH in food<sup>16</sup>. Therein, the main concern of MOAH (reproductive toxicity, carcinogenicity, genotoxicity) is linked to the substances with three or more aromatic rings. 1- and 2-ring MOAH are considered non-genotoxic and of less concern. However, EFSA still emphasises, that more data on the 1- and 2-ring MOAH are needed.

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<sup>11</sup> <https://echa.europa.eu/assessment-regulatory-needs/-/dislist/details/0b0236e184ff4ec9>

<sup>12</sup> <https://echa.europa.eu/documents/10162/2525f5e6-5f59-59bc-2f61-5efaeb4c700d>

<sup>13</sup>

[https://echa.europa.eu/documents/10162/17228/trd\\_rrs\\_germany\\_ethylbenzene\\_en.pdf/cfabd489-9234-49e5-aabd-644c8ef5d8b4](https://echa.europa.eu/documents/10162/17228/trd_rrs_germany_ethylbenzene_en.pdf/cfabd489-9234-49e5-aabd-644c8ef5d8b4)

<sup>14</sup> <https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/274>

<sup>15</sup> <https://echa.europa.eu/assessment-regulatory-needs/-/dislist/details/0b0236e184ff4ec9>

<sup>16</sup> <https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0109000006qqHf/pc0400>

## 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**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<b>SG 2a: Toluene</b> 203-625-9, toluene	Known or potential hazard for STOT RE 2 (neuropsychological effects, auditory dysfunction, and effects on colour vision)  for reproductive toxicity 2 (dev.)	Known or potential hazard for aquatic toxicity	Relevant industrial, and widespread professional and consumer uses	OEL <u>Justification:</u> OEL: IOEL 50 ppm to be lowered (Commission Recommendation 2004 and SEV conclusion 2013; worker DNEL ca. 20 ppm)  Other RRM in place: CLH: Harmonised classification Repr. 2, STOT RE 2 (CNS) expected to be followed by implementation of necessary RRMs should be sufficient to ensure safe use for humans and environment.  Restrictions (REACH Annex XVII): use in adhesives and spray paints (entry 48 of Annex XVII) and for tattooing purposes (entry 75).

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<p><b>SG 2b: Xylenes</b>  <b>202-422-2, o-xylene</b>                      203-396-5, p-xylene                      203-576-3, m-xylene                      215-535-7, xylene</p>	<p>Known or potential hazard                      for reproductive toxicity</p>	<p>Known or potential hazard                      for aquatic toxicity</p>	<p>Relevant industrial, and widespread professional and consumer uses</p>	<p><b>First step:</b>                      Pending Action                      EOGRTS requested (ECs 202-422-2, 203-396-5, 203-576-3)</p> <p><b>Potential next steps and last action (if hazard confirmed after data generation):</b>                      OEL, CLH, Restriction (in case risk(s) for consumer uses)</p> <p><u>Justification:</u>                      OEL: IOEL 50 ppm to be lowered (SEV conclusion 2021; DNEL 2 ppm)                      CLH: Potential for reproductive toxicity (dev) to be considered in case hazard confirmed in EOGRTS; for p-xylene a potential for hearing loss (STOT RE) identified but threshold for classification not met.                      Restriction: DNEL for the general population to be lowered in case risk(s) identified for consumer uses (SEV conclusion 2021).</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<p><b>SG 2c:</b> <b>trimethylbenzenes</b> 203-604-4 mesitylene, 202-436-9 1,2,4- trimethylbenzene</p>	<p>Known or potential hazard for STOT RE</p>	<p>Known or potential hazard for aquatic toxicity</p>	<p>Industrial, and widespread professional and consumer uses</p>	<p><b>First steps:</b> CCH <b>Further first steps and last action:</b> OEL, CLH <u>Justification:</u> OEL: IOEL 20 ppm to be lowered (US ACGIH TLV value 10 ppm) CLH: STOT RE (CNS) concern (US EPA indicated lack of reversibility of neurological effects)</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<p><b>SG 3a: Ethylbenzene</b> 202-849-4 ethylbenzene</p>	<p>Known or potential hazard for STOT RE (hearing organs) for carcinogenicity</p>	<p>Known or potential hazard for aquatic toxicity</p>	<p>Mainly industrial uses; professional uses only for (PC 9a coatings, thinners, paint removals for 2/24 registrations)  But widespread professional and consumer uses for the reaction masses of ethylbenzene and xylenes (see SG 4)</p>	<p><b>First step:</b> OEL, CLH <u>Justification:</u> OEL: IOEL of 100 ppm to be lowered (German MAK values 20 ppm) CLH: IARC classification Group 2B (carcinogenicity; may resemble Carc. Cat 1B); MSCA considered carcinogenic risk for human unlikely; RAC did not evaluate yet</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action
<p><b>SG 4: Reaction masses of ethylbenzene and xylenes</b>                      905-562-9,                      905-570-2,                      905-588-0 (905-213-0)</p>	<p>Known or potential hazard                      for STOT RE 2 (hearing organs)                      for carcinogenicity                      for reproductive toxicity</p>	<p>Known or potential hazard                      for aquatic toxicity</p>	<p>Relevant industrial and widespread professional and consumer uses (except List 905-213-0 which is not registered)</p>	<p><b>First step:</b>                      Pending Action  <b>Potential last action (if hazard confirmed):</b>                      Restriction (in case of risk(s) for consumer uses)  <u>Justification:</u>                      Restriction: DNEL for the general population to be lowered in case of risk(s) for consumer uses (SEV conclusion 2021)                      CLH: Classifications for ethylbenzene (e.g., STOT RE 2) and xylenes apply for reaction masses of ethylbenzene and xylenes.</p>
<p>292-694-9                      Aromatic hydrocarbons, C8</p>	<p>Known or potential hazard                      for carcinogenicity 1B                      for mutagenicity 1B</p>	<p>Known or potential hazard                      for aquatic toxicity</p>	<p>Not registered</p>	<p>No action  <u>Justification:</u>                      Substance not registered; reason for harmonised classification Carc 1B and Muta 1B unclear, possibly due to impurities</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action
<p><b>SG 1: Benzene</b>            200-753-7, benzene            903-151-9, Reaction mass of 2-methyl-pentane and 3-methyl-pentane and benzene and cumene</p>	<p>Known or potential hazard            for carcinogenicity 1A            for mutagenicity 1B            for STOT RE 1 (haematopoietic system)            for reproductive toxicity (fertility)</p>	<p>Known or potential hazard            for aquatic toxicity</p>	<p>Mainly industrial uses and to a limited extend professional uses, e.g., as solvent, intermediate, fuel, fuel additive.             The maximum content of benzene in gasoline was limited in 1998 to 1% v/v (EU Directive 98/70/EC relating to the quality of petrol and diesel fuels).</p>	<p>No action  <u>Justification:</u>            CLH: Harmonised classification already in place and expected to be followed by implementation of necessary RREs should be sufficient to ensure safe use for humans and environment.            OEL: revised (2022);            Restrictions (REACH Annex XVII): in place on consumer use (entries 28-29), further restriction in toys (entry 5), clothes, textiles and footwear (entry 72), and tattoo inks (entry 75) are in place</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action
<p><b>SG 3b:</b> <b>Diethylbenzenes</b></p> <p>203-265-2 1,4-diethylbenzene</p> <p>205-170-1 o-diethylbenzene</p> <p>246-874-9 diethylbenzene</p>	<p>No hazard or unlikely hazard</p>	<p>Known or potential hazard for aquatic toxicity</p> <p>Known or potential hazard</p> <p>For PMT/vPvM for 203-265-2</p>	<p>Mainly industrial uses, 205-170-1 not registered</p>	<p><b>First step:</b> CCH for EC 203-265-2</p> <p><b>Potential last action:</b> <b>Currently no need for EU RRM</b></p> <p><u>Justification:</u> No indications for carcinogenicity (ethylbenzene not a metabolite of diethyl-benzenes), no indications for hearing loss, for neurological effects threshold for STOT RE not met; mainly industrial uses</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action
<p><b>SG 5: Other linear alkyl benzenes, saturated or unsaturated</b></p> <p>203-132-9 204-591-8 208-645-1 224-684-7 229-806-2 270-954-2 405-980-7 626-527-1</p>	<p>Inconclusive hazard</p>	<p>Known or potential hazard for aquatic toxicity</p>	<p>No relevant exposures:</p> <p>Not registered (ECs 203-132-9; 204-591-8; 229-806-2; 270-954-2; 626-527-1)</p> <p>Intermediates (ECs 208-645-1224-684-7)</p> <p>NONs (EC 405-980-7)</p>	<p>No action</p> <p><u>Justification:</u></p> <p>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</p>

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

**Suggested regulatory risk management action for toluene (SG 2a), xylenes (SG 2b), trimethylbenzenes (SG 2c), ethylbenzene (SG 3a), and reaction masses of ethylbenzene and xylenes (SG 4) if human health hazard(s) are confirmed**

Based on ECHA's assessment of currently available hazard information all the substances in the group have known or potential **aquatic toxicity**. They have been registered at various tonnages but most of the registered substances are at high tonnage bands and as indicated for some subgroups, releases to the environment are possible. 1,4-Diethylbenzene (EC 203-265-2, SG 3b is potentially (very) persistent, (very) mobile and potentially toxic (acute toxicity in fish is observed and therefore due to lack of long-term data it is difficult to exclude potential T hazards). A Compliance check and if needed substance evaluation is proposed to be used to clarify persistency, mobility, and toxicity for potential future regulatory action. If such property exists after generation of data, these properties will need to be considered as well and may be confirmed via SVHC identification and inclusion in the Candidate list. From a first step, a compliance check (CCH) is proposed to clarify the long-term fish which is missing, persistency and mobility of the substance. It is expected that following data generation for aquatic toxicity, registrants would adequately adjust the aquatic toxicity self-classification of the substance if needed and implement necessary RMMs to ensure safe use from that perspective. For the time being no EU regulatory risk management is proposed for this substance until there is clarity on the approach to persistent and mobile substances. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

However, in general and in addition to the above CCH, due to the extensive use of read-across, following the follow up evaluation of the currently requested/ on-going data generation, several CCHs are proposed to clarify/investigate the following parameters: read-across, persistency, bioaccumulation, aquatic toxicity, and mobility for subgroup 2c, Trimethylbenzenes (ECs 203-604-4, 202-436-9).

Based on ECHA's assessment of currently available hazard information, known/potential **hazards were identified for human health**. The available information indicates the following known or potential hazards:

- for **toluene** (SG 2a) harmonised classifications for reproductive (developmental) toxicity (Category 2), neuropsychological effects, auditory dysfunction and effects on colour vision (STOT RE 2) and STOT SE 3 (drowsiness or dizziness);
- for the individual o-, m-, and p-**xylene** isomers and the mixture of isomers (SG 2b) potential reproductive (developmental) toxicity (to be clarified by an extended-one-generation reproductive toxicity study (EOGRTS) which are being requested) and respiratory tract irritation and drowsiness or dizziness (STOT SE 3), based on human and animal data available in the dossier and as indicated during substance evaluation;
- for the **trimethylbenzenes** (1,2,4-trimethylbenzene and mesitylene; SG 2c) harmonised classification for respiratory tract irritation (STOT SE 3) and potential irreversible neurological effects (STOT RE) as identified during a screening based on data in the dossier and evaluated by US EPA;
- for **ethylbenzene** (SG 3a) a harmonised classification for hearing loss (STOT RE 2) and potential for carcinogenicity based on IARC classification Carc 2B.

For all substances, indicative occupational exposure limits (IOELs) exist and there are indications that those IOELs might not be sufficient protective (see further justification below). Therefore, a review of the IOELs for toluene, xylenes, trimethylbenzene and ethylbenzene should be considered, given the high production volumes of such substances and relevant occupational exposure. The substances are (highly) volatile with irritating and/or neurological and/or ototoxic potentials. In addition, for toluene, p-xylene and ethylbenzene co-exposure is frequently reported. Due to their ototoxic potential, which could be an additive effect, the individual IOELs might not be sufficiently protective to prevent this irreversible effect. Therefore, a maximum summary IOEL for ototoxic substances (with frequent co-exposure) might be considered or individual IOELs taking into account potential co-exposure.

### ***Toluene (SG 2a)***

The only step of the regulatory risk management action plan proposed for toluene (EC 203-625-9) is the **revision of the existing IOEL**.

For toluene the IOEL is 50 ppm (192 mg/m<sup>3</sup>). The Finnish competent Authority (FI-CA) noted in their Substance Evaluation Conclusion report<sup>17</sup> (2013) that the EU risk assessment<sup>18</sup> conducted under Regulation (EEC) No 793/93 concluded on a 2-fold lower reference value (~20 ppm) for toluene and that it should be reviewed if there would be a need to update the IOEL.

Toluene is manufactured in and/or imported to the European Economic Area, at more than one million tonnes per annum. Even if this substance is used by consumers and professional workers, the concern identified in the Substance Evaluation Conclusion report was related to occupational settings.

### ***Xylenes (SG 2b) and reaction masses of ethylbenzene and xylenes (SG 4)***

The first step of the regulatory risk management actions proposed is the **revision of the existing IOELs** for xylene (mixed isomers), o-, m-, and p-xylene (ECs 215-535-7, 202-422-2, 203-576-3, 203-396-5).

The IOELs for the individual o-, m-, and p-xylene isomers and for the mixture of isomers are 50 ppm (221 mg/m<sup>3</sup>). The German competent Authority (DE-CA) indicated in their Substance Evaluation Conclusion report<sup>19</sup> the need to lower the IOELs (and consequently the DNEL for workers) to 2 ppm.

Another step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via **harmonised classification (CLH)** as reproductive (developmental) toxicity for xylenes (SG 2b), which would also apply to reaction masses of ethylbenzene and xylenes (SG 4).

In the Substance Evaluation Conclusion report (2021) the concern for reproductive toxicity was unresolved and extended-one-generation reproduction toxicity studies are requested. Developmental neurotoxicity cohorts were included in the request based on available evidence for a concern on developmental (neuro-)toxicity. Based on the results of those studies, the need for a harmonised classification with regards to reproductive toxicity would need to be evaluated.

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<sup>17</sup> <https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/Ob0236e1807e45ba>

<sup>18</sup> <https://publications.jrc.ec.europa.eu/repository/handle/JRC24380>

<sup>19</sup> <https://echa.europa.eu/documents/10162/4e04518b-5cd8-11a6-04e3-982bada1763e>

All xylenes (SG 2b) as well as the reaction masses of ethylbenzene and xylenes (SG 4) are produced in very high quantities and have multiple industrial, professional and consumer uses, which supports the need for appropriate harmonised classifications.

A RMOA including all xylenes (SG 2b) and reaction masses of ethylbenzene and xylene or m-xylene and p-xylene (SG 4) is intended to be performed by Germany (2020)<sup>20</sup>, particular for consumer products, articles and mixtures. In the Substance Evaluation Conclusion report (2021) the following was concluded with regards to consumer exposure to o-, m-, and p-xylenes (SG 2b):

It can be assumed that xylenes are present in consumer products and consumer exposure is likely. On the other hand, consumer uses for the xylene isomers subject to substance evaluation have been removed by most registrants. However, these uses may still be relevant for isomeric mixtures of xylenes which are registered separately. A new, lower DNEL has been derived by the eMSCA which can be adjusted for shorter exposure duration over a day and/or infrequent use over a year (instead of averaging out the event exposure over a year). As a result, the eMSCA concludes that for a series of previously registered uses, risks to consumers may not be excluded (anticipated RCRs >1). The eMSCA considers that this DNEL should be applied for future exposure assessments by the registrants of the pure xylene isomers subject to substance evaluation as well as isomeric mixtures of xylenes which so far have not been subject to formal substance evaluation.

Industry should update their registration dossiers and clarify whether the uses reported for this substance are supported. In the next iteration to this assessment of regulatory needs, if no update of the registration dossiers has been submitted, those uses will be considered to be of relevance and if the potential hazard properties confirmed, then further regulatory risk management will be considered.

Therefore, a **restriction of the substances as such or in mixtures (concentration limit in mixtures)** might be suggested in case the evaluating MSCA would identify a risk for consumer uses.

### ***Trimethylbenzenes (SG 2c)***

The first step of the regulatory risk management actions proposed is the revision of the existing IOELs for 1,2,4-trimethylbenzene (EC 202-436-9) and mesitylene (EC 203-604-4).

The IOELs for 1,2,4-trimethylbenzene and mesitylene are 20 ppm (100 mg/m<sup>3</sup>). According to US OSHA information<sup>21</sup>, the TVL was recently set by the US ACGIH to 10 ppm.

1,2,4-trimethylbenzene is manufactured and/or imported in the European Economic Area at > 10 000 tonnes per annum, mesitylene only at > 10 tonnes per annum. Those substances are used by consumers, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

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<sup>20</sup> <https://echa.europa.eu/assessment-regulatory-needs/-/dislist/details/0b0236e184ff4ec9>

<sup>21</sup> <https://www.osha.gov/chemicaldata/326>

Another step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) STOT RE (CNS) for trimethylbenzenes (SG 2c).

Based on the conclusion from US EPA (Toxicological Review of Trimethylbenzenes, 2016)<sup>22</sup> there is a strong indication for a lack of reversibility of trimethylbenzene-induced neurotoxicity. Therefore, ECHA is proposing to consider harmonised classification STOT RE (CNS) for trimethylbenzenes.

Especially the high volume of 1,2,4-trimethylbenzene and its multiple consumer uses (such as adhesives and sealants, anti-freeze products, biocides, coating products, fillers, putties, plasters, modelling clay, finger paints, non-metal-surface treatment products, inks and toners, leather treatment products, lubricants and greases, polishes and waxes and textile treatment products and dyes) support the need for appropriate harmonised classification.

### ***Ethylbenzene (SG 3a) and reaction masses of ethylbenzene and xylenes (SG 4)***

The first step of the regulatory risk management action proposed is the revision of the existing IOEL for ethylbenzene (EC 202-849-4).

The IOEL for ethylbenzene is 100 ppm (442 mg/m<sup>3</sup>). The German MAK Commission recommended in 2011 an OEL of 20 ppm (88 mg/m<sup>3</sup>).<sup>23</sup>

Ethylbenzene is manufactured in and/or imported to the European Economic Area at more than one million tonnes per annum. The use is mainly industrial (e.g., as intermediate, in polymer preparations and compounds, and ink and toners), supporting the concern related to occupational settings. Reaction masses of ethylbenzene and xylenes (SG 4), are also produced in high quantities (above 10 000, 100 000 and 1 000 000 tonnes per annum for List numbers 905-562-9, 905-570-2, and 905-588-0, respectively), and have widespread professional and consumer uses such as fertilisers, plant protection product, biocidal product, cosmetic products, air care products, polishes and waxes, adhesives, sealants, coatings, ink, and toners.

Another step of the regulatory risk management action proposed, should the hazard exist, could be the confirmation of hazard via harmonised classification (CLH) as carcinogenicity for ethylbenzene.

In the year 2000, IARC classified ethylbenzene as IARC Group 2B (the agent is possibly carcinogenic to humans)<sup>24</sup>. In a draft strategy for limiting risks for human health (2008)<sup>25</sup> the evaluating MSCA noted that, although the detailed mechanisms underlying the increases in tumour rates are presently not clarified, it appears unlikely from the data available that ethylbenzene poses a carcinogenic risk for humans exposed<sup>26</sup>. In the RAC opinion proposing a harmonised classification for

<sup>22</sup> <https://iris.epa.gov/static/pdfs/1037tr.pdf>

<sup>23</sup> <https://onlinelibrary.wiley.com/doi/epdf/10.1002/3527600418.mb10041e5214>

<sup>24</sup> <https://incem.org/documents/iarc/vol77/77-05.html>

<sup>25</sup>

[https://echa.europa.eu/documents/10162/17228/trd\\_rrs\\_germany\\_ethylbenzene\\_en.pdf/cfabd489-9234-49e5-aabd-644c8ef5d8b4](https://echa.europa.eu/documents/10162/17228/trd_rrs_germany_ethylbenzene_en.pdf/cfabd489-9234-49e5-aabd-644c8ef5d8b4)

<sup>26</sup>

[https://echa.europa.eu/documents/10162/17228/trd\\_rrs\\_germany\\_ethylbenzene\\_en.pdf/cfabd489-9234-49e5-aabd-644c8ef5d8b4](https://echa.europa.eu/documents/10162/17228/trd_rrs_germany_ethylbenzene_en.pdf/cfabd489-9234-49e5-aabd-644c8ef5d8b4)

STOT RE 2 (hearing organ) (2012)<sup>27</sup>, carcinogenicity was explicitly not evaluated. The lead registrant has provided a detailed justification why they consider a self-classification with regards to carcinogenicity not necessary. The process of harmonized classification would clarify if the data would fulfill criteria for harmonized classification as carcinogen.

The widespread professional and consumer uses of reaction masses of ethylbenzene and xylenes (SG 4) would support the need for harmonised classification, even if it is less likely that the process of harmonised classification would result in a classification Carc. 1B. CLH will require company level risk management measures (RMM) under the OSH legislation for workers to be in place. In addition, a potential harmonised classification as Carc. 2 for ethylbenzene will

- prohibit the substance(s) under the Cosmetic Products Regulation (EC) No 1223/2009 unless an exemption is granted upon assessment of safe use of the substances in cosmetic products by the Scientific Committee on Consumer Safety (SCCS).
- restrict the use of these substances in toys. According to the safety requirements set for chemicals in toys under the Toy Safety Directive (2009/48/EC), substances or mixtures that are classified as CMR category 2 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys unless they meet the criteria for a derogation. In addition, harmonised classification will facilitate conformity assessment and declaration, particularly when the toy manufacturer bearing obligations is located outside the EU and therefore self-classification in registration
- require that the necessary safety measures are in place for specific sensitive workers, i.e. pregnant women in accordance with Directive 92/85/EEC and young people in accordance with Directive 94/33/EC.

The potential classification for ethylbenzene with regards to carcinogenicity would not be applicable for diethylbenzenes, because ethylbenzene is not a metabolite of diethylbenzenes.

**Currently no need to suggest (further) regulatory risk management actions for members of subgroups 1 (benzene), 3b (diethylbenzenes) and 5 (other benzene derivatives with linear aliphatic substituents, saturated or unsaturated)**

***Benzene (and substances containing benzene > 0.1 %) (SG 1)***

Benzene (EC 200-753-7) has harmonized classifications inter alia for Carc. 1A, Muta. 1B, and STOT RE 1 (hematopoietic system). Substances containing benzene at concentrations higher than 0.1 % need to be classified for carcinogenicity and mutagenicity accordingly. For example, Reaction mass of 2-methylpentane and 3-methylpentane and benzene and cumene (EC 903-151-9) is self-classified as Carc. 1A and Muta. 1B. Benzene is further self-classified for aquatic chronic 3.

Benzene has mainly industrial uses and to a limited extend professional uses, e.g. as solvent, intermediate, fuel, fuel additive. A revised OEL for benzene has recently been published in the Official Journal of the EU<sup>28</sup> requiring from April 2024 0.5 ppm and from April 2026 0.2 ppm.

<sup>27</sup> <https://echa.europa.eu/documents/10162/d01123d0-a4d5-3bd3-6c33-9cdcc1cdf8ce>

<sup>28</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022L0431&cldee=a2JIY2h0b2xkOGFpaGEub3Jn&recipienti>

It is expected that based on the harmonised classification Carc. 1A and Muta. 1B registrants have implemented necessary RMMs to ensure safe use.

The maximum content of benzene in gasoline was limited in 1998 to 1% v/v (EU Directive 98/70/EC relating to the quality of petrol and diesel fuels).

Consumer use of benzene is restricted via entries 28-29 of Annex XVII, for use in toys (entry 5), for use in clothes, textiles and footwear, and for tattooing purposes (entry 75).

Based on ECHA's assessment of currently available hazard information all the substances in the group have known or potential **aquatic toxicity**. They have been registered at various tonnages but most of the registered substances are at high tonnage bands and as indicated for some subgroups, releases to the environment are possible. For aquatic toxicity, registrants have a harmonised classification for the aquatic toxicity.

Therefore, it is proposed that there is currently no need for further EU-wide regulatory risk management.

In the Commission Recommendation on results of the risk evaluation and risk reduction strategies for benzene (2008)<sup>29</sup>, no further measures than revision of the IOEL were identified that would be relevant for the current investigation.

### ***Diethylbenzenes (SG 3b)***

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health. These conclusions are based on an available screening study conducted in rats with 1,4-diethylbenzene (EC 203-265-2) that did not show adverse effects on reproductive/developmental parameters at doses up to 750 mg/kg bw/day. The result of this study was used to read-across to diethylbenzene mixed isomers (EC 246-874-9).

Based on ECHA's assessment of currently available hazard information all the substances in the subgroup have known or potential **aquatic toxicity**. They have been registered at various tonnages but most of the registered substances are at high tonnage bands and as indicated for some subgroups, releases to the environment are possible. 1,4-Diethylbenzene (EC 203-265-2, SG 3b is potentially (very) persistent, (very) mobile and potentially toxic (acute toxicity in fish is observed and therefore due to lack of long-term data it is difficult to exclude potential T hazards). A Compliance check and if needed substance evaluation is proposed to be used to clarify persistency, mobility, and toxicity for potential future regulatory action. If such property exists after generation of data, these properties will need to be considered as well and may be confirmed via SVHC identification and inclusion in the Candidate list. From a first step, a compliance check (CCH) is proposed to clarify the long-term fish which is missing, persistency and mobility of the substance. It is expected that following data generation for aquatic toxicity, registrants would adequately adjust the aquatic toxicity self-classification of the substance if needed and implement necessary RMMs to ensure safe use from that perspective. For the time being no EU regulatory risk management is proposed for this substance until there is clarity on the approach to persistent and mobile

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<sup>29</sup> <https://echa.europa.eu/documents/10162/750b16f3-a595-4b6e-bfe6-b880892ed69c>

substances. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

***Other benzene derivatives with linear aliphatic substituents, saturated or unsaturated (SG 5)***

The substances of this sub-group are either intermediates or not registered and there is no information on toxicity of such substances. Accordingly, 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.

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.

## Annex 1: Overview of classifications

Data extracted on 08 June 2022

SG	EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>30</sup>
<b>1</b>	<b>Benzene</b>				
	200-753-7	71-43-2	benzene	Index number: 601-020-00-8 Skin Irrit. 2 H315 Flam. Liq. 2 H225 <b>STOT RE 1</b> H372 (No information to prove exclusion of certain routes of exposure) Eye Irrit. 2 H319 <b>Muta. 1B</b> H340 <b>Carc. 1A</b> H350 Asp. Tox. 1 H304 Notes: E	<b>Carc. 1A H350</b> [intermediate (active)] <b>STOT Rep. Exp. 1</b> H372 Skin Irrit. 2 H315 <b>Aquatic Chronic 3</b> H412 Flam. Liquid 2 H225 Asp. Tox. 1 H304 <b>Muta. 1B</b> H340 <b>STOT Rep. Exp. 1</b> H372, affected organs: other: Haematopoietic system Eye Irrit. 2 H319
	903-151-9		Reaction mass of 2-methylpentane and 3-methylpentane and benzene and cumene	-	Skin Irrit. 2 H315 <b>Repr. 2</b> H361 Asp. Tox. 1 H304 <b>Carc. 1A H350</b> Eye Irrit. 2 H319 <b>Aquatic Chronic 2</b> H411 <b>Muta. 1B H340</b> <b>STOT Single Exp. 3</b> H336, affected organs: Central nervous system <b>STOT Rep. Exp. 1</b> H372 Flam. Liquid 2 H225
<b>2</b>	<b>Methyl-benzenes</b>				

<sup>30</sup> 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).

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SG	EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>30</sup>
2a	203-625-9	108-88-3	toluene	Index number: 601-021-00-3 Skin Irrit. 2 H315 Flam. Liq. 2 H225 <b>Repr. 2</b> H361d; <b>STOT RE 2</b> H373 (hearing) <b>STOT SE 3</b> H336 Asp. Tox. 1 H304	<b>Repr. 2</b> H361, specific effect: suspected of damaging the unborn child Flam. Liquid 2 H225 Skin Irrit. 2 H315 Asp. Tox. 1 H304 <b>STOT Rep. Exp. 2</b> H373, affected organs: Neurologic: other (neuropsychological effects, auditory dysfunction and effects on colour vision) <b>Aquatic Chronic 3</b> H412 Eye Irrit. 2 H319 [intermediate (active)] <b>STOT Single Exp. 3</b> H336, affected organs: nervous system  <u>Toluene grade B (JS Member) (opt out)</u> Carc. 1A H350 Muta. 1B H340
2b	202-422-2	95-47-6	o-xylene	Index number: 601-022-00-9 Acute Tox. 4 H312 Skin Irrit. 2 H315 Flam. Liq. 3 H226 Acute Tox. 4 H332 Notes: C (Minimum classification)	STOT Single Exp. 3 H335, affected organs: Respiratory tract Flam. Liquid 3 H226 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Asp. Tox. 1 H304 Aquatic Chronic 3 H412
2b	203-396-5	106-42-3	p-xylene	Index number: 601-022-00-9 Acute Tox. 4 H312 Skin Irrit. 2 H315 Notes: C Flam. Liq. 3 Hazard Statement: H226 Notes: C Acute Tox. 4 Hazard Statement: H332 Notes: C (Minimum classification)	Flam. Liquid 3 H226 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Asp. Tox. 1 H304 STOT Single Exp. 3 H335, affected organs: other: Respiratory tract Aquatic Chronic 3 H412
2b	203-576-3	108-38-3	m-xylene	Index number: 601-022-00-9 Acute Tox. 4 Hazard Statement: H312 Notes: C (Minimum classification) Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Notes: C Flam. Liq. 3 Hazard Statement: H226 Notes: C Acute Tox. 4 Hazard Statement: H332 Notes: C (Minimum classification)	Flam. Liquid 3 H226 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Asp. Tox. 1 H304 STOT Single Exp. 3 H335, affected organs: other: Respiratory tract Aquatic Chronic 3 H412

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SG	EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>30</sup>
2b	215-535-7	1330-20-7	xylene	Index number: 601-022-00-9 Acute Tox. 4 Hazard Statement: H312 Notes: C (Minimum classification) Skin Irrit. 2 Hazard Statement: H315 Notes: C Flam. Liq. 3 Hazard Statement: H226 Notes: C Acute Tox. 4 Hazard Statement: H332 Notes: C (Minimum classification)	Asp. Tox. 1 H304 [intermediate (inactive)] STOT Single Exp. 3 H335, affected organs: Respiratory System [intermediate (inactive)] Skin Irrit. 2 H315 [intermediate (inactive)] Aquatic Chronic 3 H412 [intermediate (inactive)] Acute Tox. 4 H332 [intermediate (inactive)] <b>STOT Rep. Exp. 2</b> H373, affected organs: All gross lesions and masses [intermediate (inactive)] Flam. Liquid 3 H226 [intermediate (inactive)] Acute Tox. 4 H312 [intermediate (inactive)] Eye Irrit. 2 H320 [intermediate (inactive)]
2c	203-604-4	108-67-8	mesitylene	Index number: 601-025-00-5 Flam. Liq. 3 Hazard Statement: H226 <b>STOT SE 3</b> Hazard Statement: H335 <b>Aquatic Chronic 2</b> Statement: H411	Flam. Liquid 3 H226 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Asp. Tox. 1 H304 STOT Single Exp. 3 H335, affected organs: Respiratory tract, specific concentration: >=25 Aquatic Chronic 2 H411 STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (active)]
2c	202-436-9	95-63-6	1,2,4-trimethylbenzene	Index number: 601-043-00-3 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Flam. Liq. 3 Hazard Statement: H226 Hazard Category: Eye Irrit. 2 Hazard Statement: H319 <b>STOT SE 3</b> Hazard Statement: H335 Acute Tox. 4 Hazard Statement: H332 (Minimum classification) <b>Aquatic Chronic 2 Statement:</b> H411	Flam. Liquid 3 H226 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Asp. Tox. 1 H304 STOT Single Exp. 3 H335, affected organs: respiratory tract Aquatic Chronic 2 H411
3	Ethylbenzenes				
3a	202-849-4	100-41-4	ethylbenzene	Index number: 601-023-00-4 Flam. Liq. 2 Hazard Statement: H225 <b>STOT RE 2</b> Hazard Statement: H373 [hearing organs] Asp. Tox. 1 Hazard Statement: H304 Acute Tox. 4 Hazard Statement: H332 (Minimum classification)	Flam. Liquid 2 H225 Acute Tox. 4 H302 Acute Tox. 4 H332 Asp. Tox. 1 H304 STOT Rep. Exp. 2 H373, affected organs: hearing organs STOT Rep. Exp. 2 H373, affected organs: Hearing organs Aquatic Chronic 3 H412  <u>Ethylbenzene containing benzene ≤0.3% (opt-out)</u> Carc. 1A H350 Muta. 1B H340

ASSESSMENT OF REGULATORY NEEDS

SG	EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>30</sup>
3b	203-265-2	105-05-5	1,4-diethylbenzene	-	Flam. Liquid 3 H226 Skin Irrit. 2 H315 Eye Damage 1 H318 Asp. Tox. 1 H304 Aquatic Chronic 2 H411
3b	205-170-1	135-01-3	o-diethylbenzene	-	-
3b	246-874-9	25340-17-4	Diethylbenzene		Flam. Liquid 3 H226 Skin Irrit. 2 H315 Asp. Tox. 1 H304 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
4	<b>Reaction masses of ethylbenzene and xylenes</b>				
	292-694-9	90989-38-1		Index number: 648-010-00-X Muta. 1B Hazard Statement: H340 Notes: J Carc. 1B Hazard Statement: H350 Notes: J	-
	905-213-0			-	-
	905-562-9		Reaction mass of ethylbenzene and m-xylene and p-xylene	-	Flam. Liquid 3 H226 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Asp. Tox. 1 H304 <b>STOT Rep. Exp. 2</b> H373, affected organs: ototoxicity, specific concentration: >=10 <b>STOT Single Exp. 3</b> H335, affected organs: Upper respiratory tract
	905-570-2		Reaction mass of ethylbenzene and m-xylene	-	Flam. Liquid 3 H226 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Asp. Tox. 1 H304 <b>STOT Rep. Exp. 2</b> H373, affected organs: other: ototoxicity, specific concentration: >=10 <b>STOT Single Exp. 3</b> H335, affected organs: other: Upper respiratory tract <b>Aquatic Chronic 3</b> H412

ASSESSMENT OF REGULATORY NEEDS

SG	EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations <sup>30</sup>
	905-588-0		Reaction mass of ethylbenzene and xylene	-	Flam. Liquid 3 H226 Acute Tox. 4 H312 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Asp. Tox. 1 H304 <b>STOT Rep. Exp. 2</b> H373, affected organs: ototoxicity, specific concentration: >=10 <b>STOT Single Exp. 3</b> H335, affected organs: Upper respiratory tract
<b>5</b>	<b>Other</b>				
	203-132-9	103-65-1	propylbenzene	Index number: 601-024-00-X Flam. Liq. 3 Hazard Statement: H226 Notes: C <b>STOT SE 3</b> Hazard Statement: H335 Notes: C Asp. Tox. 1 Hazard Statement: H304 Notes: C <b>Aquatic Chronic 2</b> Statement: H411 Additional Info: C	-
	204-591-8	123-01-3	dodecylbenzene	-	-
	208-645-1	536-74-3	phenylacetyle ne	-	Eye Irrit. 2 H319 [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)] Asp. Tox. 1 H304 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]
	224-684-7	4445-07-2	octadecylbenzene	-	Aquatic Chronic 4 H413 [intermediate (active)]
	229-806-2	6742-54-7	undecylbenzene	-	-
	270-954-2	68512-02-7	Benzene, (tetrapropenyl) derivs.	-	-
	405-980-7		4-phenylbut- 1-ene	-	-
	626-527-1	768-56-9	(but-3-en-1- yl)benzene	Index number: 601-051-00-7 Skin Irrit. 2 Hazard Statement: H315 <b>Aquatic Chronic 2</b> Statement: H411	-

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

Data extracted on 08 June 2022

Main types of applications structured by product or article types	EC/List number, substance name and/or acronym, subgroup													
	200-753-7	203-625-9	215-535-7	202-422-2	203-576-3	203-396-5	203-604-4	202-436-9	905-562-9	905-570-2	905-588-0	202-849-4	203-265-2	246-874-9
	Benzene B	Toluene MB	Xylene DMB	o-xylene 1,2-DMB	m-xylene 1,3-DMB	p-xylene 1,4-DMB	Mesitylene 1,2,3-TMB	1,2,4-TMB	EB + 1,3-DMB + 1,4-DMB	EB + 1,3-DMB	EB + DMB	EB	1,4-DEB	DEB
	1	2	2	2	2	2	2	2	3	3	4	4	4	
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	I, P	I, P	I, P	I, P	I, P	I, P	I, P				I			
PC 37: Water treatment chemicals			F, I											
PC 2: Adsorbents													I	
PC 11: Explosives			F, I, P						F	F	F, I, P			
PC 12: Fertilisers		C	C	C		C		C	C	C	F, I, P, C			
PC 27: Plant Protection Products		C	F, I, P, C	C	P	P, C		C	C	C	F, I, P, C			
PC 4: Anti-freeze and de-icing Products		F, I, C	C	C		C	C	C	C	C	F, I, P, C			
PC 35: Washing and cleaning Products		I,13, P, C	I, P, C	F, I, P, C	I, P	I, P, C	I, C		C	I, P, C	F, I, P, C			
PC 8: Biocidal Products (e.g. disinfectants, Pest control)		C	C	C		C	C	C	C	C	F, I, P, C, A			
PC 28: Perfumes, fragrances													I	
PC 3: Air care Products		F, I	C	C		C			C	C	F, I, P, C			
PC 31: Polishes and wax blends		F, I, C	C	C		C	C	C	C	C	F, I, P, C			
PC 15: Non-metal-surface treatment Products	F, I	F, I, P, C	F, I, P, C	C		C	C	C	C	C	F, I, P, C			

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	EC/List number, substance name and/or acronym, subgroup													
	200-753-7	203-625-9	215-535-7	202-422-2	203-576-3	203-396-5	203-604-4	202-436-9	905-562-9	905-570-2	905-588-0	202-849-4	203-265-2	246-874-9
	Benzene B	Toluene MB	Xylene DMB	o-xylene 1,2-DMB	m-xylene 1,3-DMB	p-xylene 1,4-DMB	Mesitylene 1,2,3-TMB	1,2,4-TMB	EB + 1,3-DMB + 1,4-DMB	EB + 1,3-DMB	EB + DMB	EB	1,4-DEB	DEB
	1	2	2	2	2	2	2	2	3	3	3	4	4	4
PC 24: Lubricants, greases, release Products		F, I, C	I, P, C	F, I, P, C		C	C	C	I, P, C	I, P, C	F, I, P, C			
PC 25: Metal working fluids											I, P			
PC 16: Heat transfer fluids		I	C						C	C	F, I, P, C			I
PC 17: Hydraulic fluids		I, P	I, P, C	I			I, P		I, P, C	I, P, C	F, I, P, C			
PC 13: Fuels		F, I, P, C	I, P, C	I, P, C	F, I, P	I, P, C	I, P, C	I	I, P, C	I, P, C	F, I, P, C			
PC 32: Polymer Preparations and compounds	I	F, I,04, P	F, I, P	I	I	I, C		I	I, P	I, P	F, I, P, A	F, I		
PC 1: Adhesives, sealants		F, I, P, C	F, I, P, C	C	I	C	C	C	C	C	F, I, P, C, A			
PC 9c: Finger Paint		C	F, I, P, C	C		C		C			F, I, C)			
PC 9b: Fillers, Putties, Plasters, modelling clay	F, I	F, I, P, C	F, I, P, C	C	I, P	C		C			F, I, P, C			
PC 9a: Coatings and Paints, thinners, Paint removes	F, I	F, I,20, P,08, C	F, I, P, C	I, P, C	I, P	I, P, C	I, P, C	I, P, C	I, P, C	I, P, C	F, I,21, P, C, A	F, I, P		
PC 18: Ink and toners		F, I, P, C	F, I, P, C	C		C	C	C	C	C	F, I, P, C, A	F, I		
PC 26: Paper and board treatment Products											F			
PC 34: Textile dyes, and impregnating Products		F, I, C	C	C		C	C	C	C		F, I, P, C			
PC 23: Leather treatment Products		F, I, C	C	C		C	C	C	C	C	F, I, P, C			
PC 14: Metal surface treatment Products		F, I, P	F, I, P, C								F, I, P			
PC 38: Welding and soldering Products, flux Products			C	C		C			C	C	F, I, P, C			

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	EC/List number, substance name and/or acronym, subgroup													
	200-753-7 Benzene B	203-625-9 Toluene MB	215-535-7 Xylene DMB	202-422-2 o-xylene 1,2-DMB	203-576-3 m-xylene 1,3-DMB	203-396-5 p-xylene 1,4-DMB	203-604-4 Mesitylene 1,2,3-TMB	202-436-9 1,2,4-TMB	905-562-9 EB + 1,3-DMB + 1,4-DMB	905-570-2 EB + 1,3-DMB	905-588-0 EB + DMB	202-849-4 EB	203-265-2 1,4-DEB	246-874-9 DEB
	1	2	2	2	2	2	2	2	3	3	3	4	4	4
PC 33: Semiconductors		F, I					I					F, I		
PC 21: Laboratory chemicals	F, I, P	F, I, P, C	F, I, P	I, P	F, I, P	F, I, P	F, I, P	F, I, P	F, I, P	F, I, P	F, I, P			
PC 19: Intermediate	F, I	I	I	I	F, I	I	I	I	I	I	I	I		I
PC 40: Extraction agents		I												
PC41: Oil and gas exploration or Production Products		F, I	F, I	I, P	I, P	I, P								
PC 30: Photo-chemicals											I			

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

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

Data extracted on 30 May 2022

SG	EC/List number	Name	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/CLP*
				Candidate List	Annex XIV	Annex XVII	Annex VI (CLP)	
1	200-753-7	Benzene	YES			YES		RAR
2a	203-625-9	Toluene	YES			YES		RAR
2b	202-422-2	o-Xylene	YES			YES		
2b	203-396-5	p-Xylene	YES			YES		
2b	203-576-3	m-Xylene	YES			YES		
2b	215-535-7	Xylene	YES			YES		
2c	202-436-9	1,2,4-Trimethylbenzene				YES		
3a	202-849-4	Ethylbenzene					YES	RAR
4	905-562-9	Reaction mass of ethylbenzene and m-xylene and p-xylene	YES					
4	905-588-0	Reaction mass of ethylbenzene and xylene	YES					
4	292-694-9	Aromatic hydrocarbons, C8				YES		
5	405-980-7	4-Phenylbut-1-ene						NONS, claimed, inactive
5	626-527-1	(But-3-en-1-yl)benzene				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).