Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

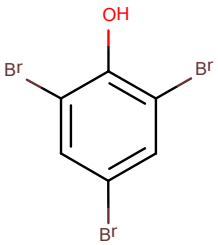
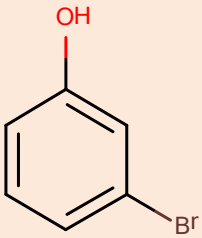
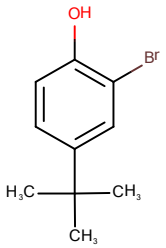
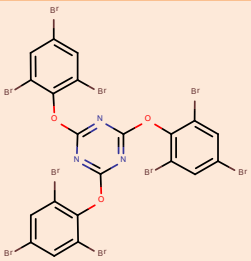
Date: 4 October 2021

Group Name: Brominated cycloalkanes, alcohols, phosphates, triazine triones, diphenyl ethers and diphenyl alkyls (flame retardants related substances)

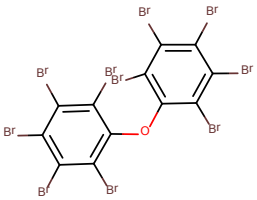
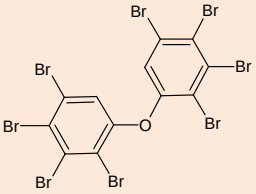
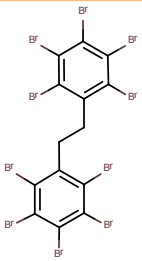
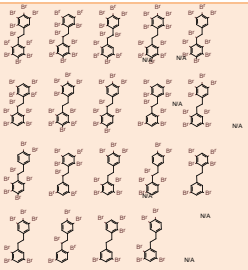
Revision history

Version	*Date*	*Description*
1	4 October 2021	

Substances within this group:

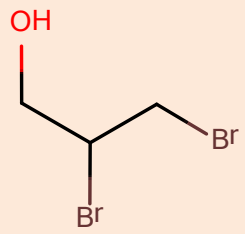
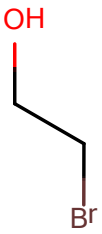
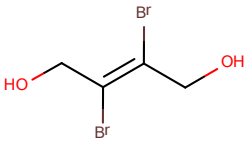
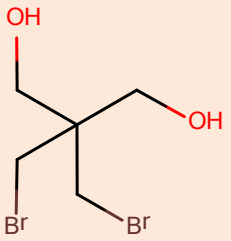
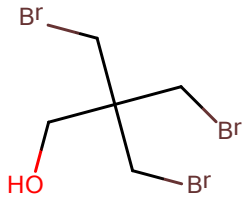
EC / List number	CAS number	Substance name and acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Subgroup 1: Bromophenols and related substances				
204-278-6	118-79-6	2,4,6-tribromophenol		Full, 10-100
209-706-5	591-20-8	3-bromophenol		OSII or TII
218-602-9	2198-66-5	2-bromo-4-*tert*-butylphenol		OSII or TII
426-040-2	25713-60-4	2,4,6-tris(2,4,6-tribromophenoxy)-1,3,5-triazine		Full, 100-1000
443-430-8	-	FIREGUARD FG-1500		NONS

[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

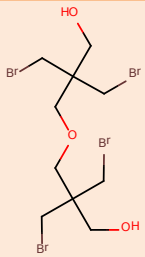
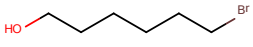
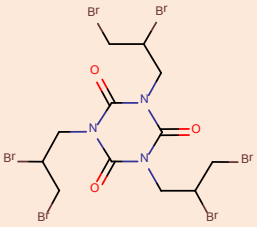
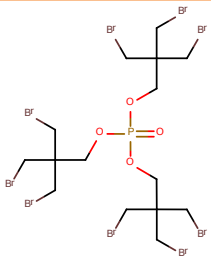
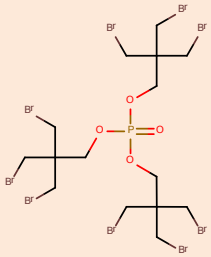
Subgroup 2: Brominated diphenyl ethers[2]				
214-604-9	1163-19-5	bis(pentabromophenyl) ether (decaBDE)		Full, 100-1000[3]
251-087-9	32536-52-0	diphenyl ether, octabromo derivative (octaBDE)	e.g. 	C&L notification
Substance with confidential identity		not publicly available		Full, not publicly available
Subgroup 3: Brominated diphenyl ethyls				
284-366-9	84852-53-9	1,1'-(ethane-1,2-diyl)bis[pentabromobenzene] (DBDPE)		Full, >1000
700-158-7	1092834-40-6	1,1'-ethan-1,2-diylbisbenzene, brominated		Full, 1-10
Subgroup 4: Brominated alcohols and related substances				

[2] Also referred to as polybrominated diphenyl ethers (PBDE) in RoHS.

[3] The manufacturing (with some derogations), placing on the market and use of this substance is prohibited under the POPs Regulation, and it is also included in Annex XIV of REACH. It is possible that registration dossiers are not updated to reflect correctly decreased tonnages or are not withdrawn in case a use ceases altogether.

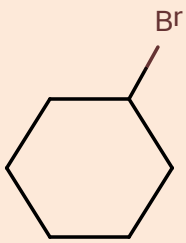
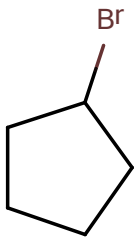
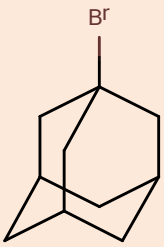
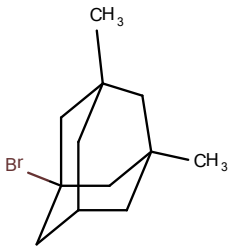
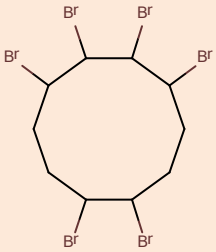
202-480-9	96-13-9	2,3-dibromopropan-1-ol (2,3-DBPA)		OSII or TII
208-748-1	540-51-2	2-bromoethanol		OSII or TII
216-554-3	1611-56-9	11-bromoundecanol		OSII or TII
221-779-5	3234-02-4	2,3-dibromo-2-butene-1,4-diol		Full, 1-10
221-967-7	3296-90-0	2,2-bis(bromomethyl)propane-1,3-diol (BMP)		Full, 100-1000
253-057-0	36483-57-5[4]	2,2-dimethylpropan-1-ol, tribromo derivative (TBNPA)		Full, 100-1000

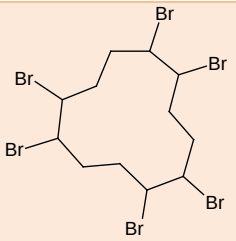
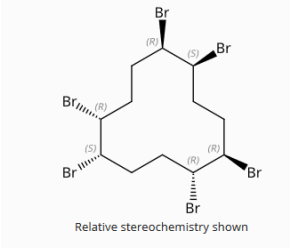
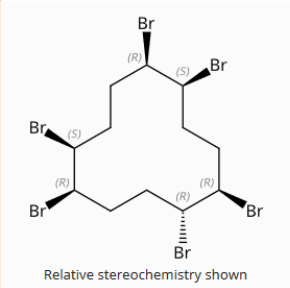
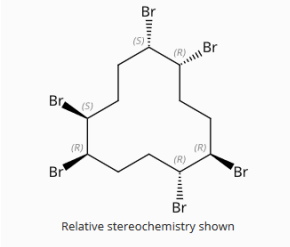
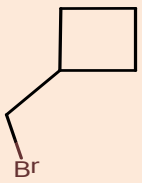
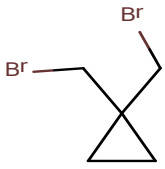
[4] The preferred CAS is 1522-92-5, CAS name: 1-Propanol, 3-bromo-2,2-bis(bromomethyl). This CAS number is associated to List 622-370-8. CAS 36483-57-5 is not specific with regard to the position of the Br atoms on the parent structure.

408-020-5	109678-33-3	2,2,6,6-tetrakis(bromomethyl)-4-oxaheptane-1,7-diol		NONS
610-072-0	4286-55-9	1-Hexanol, 6-bromo-		OSII or TII
257-913-4[5]	52434-90-9	1,3,5-tris(2,3-dibromopropyl)-1,3,5-triazine-2,4,6(1*H*,3*H*,5*H*)-trione		Full, 1-10
413-060-1	19186-97-1	tris[3-bromo-2,2-bis(bromomethyl)propyl] phosphate		Full, 10-100
606-254-4[6]	19186-97-1	1-Propanol, 3-bromo-2,2-bis(bromomethyl)-, 1,1′,1′′-phosphate		C&L notification
Subgroup 5: Brominated cycloalkanes				

[5] This substance is included in this subgroup because it has a brominated moiety similar to the substance described by EC 202-480-9

[6] This List number is associated to the same substance as the one described by EC 413-060-1. ECHA received a registration dossier associated with List 606-254-4 following the SID adaptation process the registration dossier was associated to EC 413-060-1.

203-622-2	108-85-0	bromocyclohexane		OSII or TII
205-294-6	137-43-9	bromocyclopentane		OSII or TII
212-200-7	768-90-1	1-bromotricyclo[3.3.1.13,7]decane		OSII or TII
213-378-9	941-37-7	1-bromo-3,5-dimethyltricyclo[3.3.1.13,7]decane		OSII or TII
221-695-9	3194-55-6	1,2,5,6,9,10-hexabromocyclodecane		C&L notification
230-331-8	7051-34-5	bromomethylcyclopropane		OSII or TII
247-148-4	25637-99-4	Hexabromocyclododecane (HBCDD)	e.g.	Full, >1000

				
603-801-9	134237-50-6	alpha-hexabromocyclododecane (α-HBCDD)		C&L notification
603-802-4	134237-51-7	beta-hexabromocyclododecane (β-HBCDD)		C&L notification
603-804-5	134237-52-8	gamma-hexabromocyclododecane (γ-HBCDD)		C&L notification
700-027-4	17247-58-4	(Bromomethyl)cyclobutane		OSII or TII
805-270-0	29086-41-7	1,1-bis(bromomethyl)cyclopropane		OSII or TII

This table contains also group members that are only notified under the CLP Regulation. However, the list is not necessarily exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

Contents

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Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on a different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, a more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[7].

[7] 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
POPs Regulation	Regulation (EU) No 2019/1021 on persistent organic pollutants
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

ECHA has grouped together structurally similar substances based on the presence of the bromine moiety of aliphatic and aromatic compounds with reported flame retardant uses. Additional substances were included due to their structural similarity with the selected flame retardants.

In addition to the presence of bromine, the substances within this group have hydroxyl, ether, phosphate and triazine/trione functionalities. Most are mono- or multi-constituent substances.

The group consists of 32 substances, of which 12 have full registrations, 13 are registered as intermediates only, 2 are NONs, and 5 are C&L notified substances.

The substances have been organized in five sub-groups based on their chemical structure:

Subgroup 1 - bromophenols and related substances;

Subgroup 2 - brominated diphenyl ethers;

Subgroup 3 - brominated diphenyl ethyls;

Subgroup 4 - brominated alcohols and related substances;

Subgroup 5 - brominated cycloalkanes.

Based on information reported in the REACH registration dossiers, the primary common use of the fully registered substances is as flame retardants in polymer preparation and compounds. In addition, uses in washing and cleaning products, biocides, cosmetics, fragrances, pharmaceuticals, polishes, lubricants, textile and leather treatment, coatings and paints, paper and board, ink and toner are also reported for three substances (ECs/List 214-604-9, substance with confidential identity, 284-366-9). For the fully registered substances, there is high potential for worker and consumer exposure as well as release in the environment due to many widespread uses (i.e., professional and industrial uses as well as article service life).

Thirteen substances in this group are already subject to regulatory actions:

- Identification as SVHC and inclusion in the Candidate List (on 8 July 2021) for three brominated alcohols (EC 221-967-7, BMP; EC 202-480-9, 2,3-DBPA; EC 253-057-0, TBNPA) due to Carc. 1B concern.

- Firstly, inclusion in Annex XIV to REACH. Currently, a ban applies under the POPs Regulation for five brominated cycloalkanes (ECs/Lists 247-148-4, 603-801-9, 603-802-4, 603-804-5, 221-695-9, HBCDD and diastereoisomers) due to PBT concern.

- Firstly, inclusion in Annex XIV to REACH. Currently, a ban applies under the POPs Regulation for two brominated diphenyl ethers (EC 214-604-9,

decaBDE and EC 251-087-9, octaBDE) due to PBT and Repr. 1B concern[8]. These substances are also restricted under RoHS.

- Substance evaluation (PBT assessment) for one brominated diphenyl ethyl (EC 284-366-9), one brominated triazine trione (EC 426-040-2) and one bromophenol (EC 204-278-6).

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is 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 table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

[8] The POPs entry for pentabromodiphenyl ether (pentaBDE) also contains the substance EC 251-084-2. This substance, however, has not been included in this group, as it is not produced in the EU (it is neither registered under REACH nor is it notified substance in the C&L inventory).

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

All 32 of the substances in this group are bromides and can potentially release bromide *in vivo*; hence they all have a potential for neuro- and reproductive toxicity. This assumption is based on the opinion of RAC on ammonium bromide[9] where it is concluded that the observed adverse effects of ammonium bromide on sexual function and fertility, on development or via lactation warrant its classification as Repr. 1B, H360 FD and H362. RAC also concluded that ammonium bromide warrants classification as STOT SE 3, H336 (narcotic effects) and STOT-RE 2; H372 (nervous system). These adverse effects are caused by the bromide ion. In the current assessment it is considered that the presence of bromine may indicate a potential for neurotoxicity, developmental neurotoxicity and reproductive toxicity either due to potential metabolism that would release bromide within the body or because of direct action of the substances passing the blood brain barrier. The uncertainty is whether and how fast Br is released under physiological conditions. Based on the general chemical knowledge, it is likely that alkyl bromides subgroups (i.e., subgroup 4, brominated alcohols, and subgroup 5, brominated cycloalkanes) are more labile than aromatic bromides (i.e., the other subgroups). The reproductive toxicity, already confirmed for some of the substances (CLH as Repro 1 B for EC 251-087-9, as Repro 2 for EC/Lists 202-480-9, 221-695-9, 247-148-4, 603-801-9, 603-802-4, 603-804-5), and neurotoxic hazards related to the potential release of bromide is tentatively extrapolated to all the substances of the group despite some data gaps for some of the substances. Seven substances have been confirmed as PBT/vPvB substances and are already banned under the POPs Regulation.

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for reproductive toxicity and STOT RE (neurotoxic) hazards due to the potential for release/ exposure of most substances in the group.

The proposed regulatory measure for these substances is restriction to limit their widespread uses mainly as flame retardants in polymers, but also in washing and cleaning products, cosmetics, polishes, lubricants, coatings, inks, textile and leather articles due to the risks resulting from the human health hazards[10]. In addition, a group restriction would avoid possible regrettable substitution of the substances with a large variety of widespread uses by substances that are currently used mainly for polymers. For the substances ending up in articles, a restriction is considered necessary to address risks arising from article use. Lastly, a restriction would allow for more flexibility in setting conditions and possible derogations in case some uses would already be adequately regulated under other EU legislation as a consequence of harmonised classification.

Before or in parallel to the restriction (to avoid unnecessary delay), it is proposed that CLH proposals are developed to confirm reproductive toxicity and repeated

[9] RAC opinion proposing harmonised classification of Ammonium bromide, 8 October 2020.

[10] Note that the use of halogenated flame retardants, such as these substances, is already restricted in the enclosure and stand of electronic displays (Annex II of the Commission Regulation (EU) 2019/2021 on ecodesign requirements for electronic displays).

dose toxicity (neurotoxicity) for all the substances in the group, except EC/Lists 214-604-9 (decaBDE), 251-087-9 (octaBDE), 202-480-9 (2,3-DBPA), 221-967-7 (BMP), 253-057-0 (TBNPA), 610-072-0, 216-554-3, 247-148-4 (HBCDD), 603-801-9 (α-HBCDD), 603-802-4 (β-HBCDD), 603-804-5 (γ-HBCDD),221-695-9 (1,2,5,6,9,10-HBCD), 212-200-7 and 213-378-9 (see the conclusions and actions summarised in the table in section 3).
When preparing the proposals, it may be considered what would be the best way to develop them, for instance whether to make a proposal for the group of substances, to submit them individually or jointly.

Although CLH is not a prerequisite for a restriction, a harmonised classification as Repr. 1B will require i) company level risk management measures (RMM) in workplaces to be implemented, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30.
For substances used in clothing, other textiles and footwear articles only, 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 CLH as Repr. 1B will trigger regulatory action under:

- the Cosmetic Products Regulation (EC) No 1223/2009, since CMR cat. 1 are restricted by this regulation;
- 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.

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[11] which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, restricting substances in articles used by professionals or consumers (e.g. plastic or rubber articles, coated articles, etc.) should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first.

Besides the common regulatory risk management measure identified for the group, additional human and/or environmental concerns apply per subgroup. The relevant proposed actions per subgroup are presented below.

Subgroup 1: bromophenols and related substances

All five subgroup members (EC 204-278-6, EC 209-706-5, EC 218-602-9, EC 443-430-8 and EC 426-040-2) are known/likely reprotoxic 1B and STOT RE (neurotoxic).

In addition to the CLH to confirm reproductive toxicity and neurotoxicity, it is proposed to clarify the ED potential for human health and the environment for EC

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

204-278-6, EC 443-430-8 and EC 426-040-2. EC 204-278-6 and EC 426-040-2 have potential for exposure from widespread uses as flame retardant or chain ending agent in polymer preparations.

As a first step, it is proposed to reactivate the substance evaluation process for EC 204-278-6 (a SEv due to ED concern by the Norwegian CA had been terminated previously due to ceasing of manufacture) and wait for the outcome to clarify the ED hazards. If hazard is confirmed, the next action would be SVHC identification for ED, followed by restriction for EC 204-278-6, EC 443-430-8 (which releases EC 204-278-6 on hydrolysis) and EC 426-040-2 (which contains EC 204-278-6).

Clarifying ED hazard is seen beneficial in parallel to the confirmation of reproductive toxicity as it may lead to non-threshold considerations in risk management and also in case the reproductive toxicity would not be confirmed for all three substances. Identification of a substance as environmental ED may result in increased scrutiny of the substances for regulation under environmental legislation such as the IPPC Directive and the EU Water Framework Directive.

These three substances are also potentially persistent/very persistent, mobile/very mobile. However, for the time being no action is proposed to clarify this additional concern, until there is clarity on the approach to persistent and mobile substances.

Due to data gaps on aquatic toxicity and bioaccumulation observed for EC 426-040-2 it is suggested to open a CCH to confirm PBT and Aquatic toxicity for this substance.

No mutagenicity hazard is expected. However, due to a data gap it is suggested to obtain further *in vitro* test data by opening a compliance check for EC 204-278-6 to confirm the assumption of no potential for mutagenicity.

Subgroups 2-3: brominated diphenyl ethers and brominated diphenyl ethyls

One brominated diphenyl ether (confidential identity) and the two brominated diphenyl ethyls (EC 284-366-9, DBDPE and List 700-158-7) are known/potential reprotoxic 1B, STOT RE (neurotoxic) and vPvB.

These substances have potential for exposure/releases due to uses as flame retardants in polymer preparations and compounds by industrial and professional workers, by consumers and from the presence in articles , Confidential EC, EC 284-366-9), or only from industrial uses and article service life (List 700-158-7). EC 284-366-9 (DBDPE) is registered at high tonnages (>1000 ton/y) and along with the substance with confidential identity, it has widespread uses also in washing and cleaning products, cosmetics, lubricants, adhesives, inks, textile dyes and leather treatment.

In order to clarify the hazards, it is suggested as a first step to obtain further data:

- A compliance check is proposed for the brominated diphenyl ether with confidential identity to clarify the potential reproductive toxicity and vPvB hazard, and to generate data on repeated dose toxicity.
- Testing for reproductive toxicity is already ongoing for one brominated diphenyl ethyl (EC 284-366-9) as part of a testing proposal evaluation. The study results are expected to confirm potential reproductive toxicity. A fish bioaccumulation study was requested in the substance evaluation to clarify the (v)B potential. For the other brominated diphenyl ethyl (List 700-158-7 closely structurally related to EC 284-366-9), no compliance check is

proposed because there are no data gaps, but we suggest following the same regulatory hypothesis as for the other substances in the subgroup if the hazards are confirmed.

After confirmation of reproductive toxicity through CLH, the confirmation of hazards via SVHC identification and inclusion in the Candidate List as PBT/vPvB followed by restriction is proposed.

Due to presence in articles for all the three substances in the subgroup, a restriction is preferred to authorisation which would not cover imported articles. A CLH as Repr. 1B would already imply a certain level of consumer protection under other EU legislation. However, professional workers would still be exposed, and releases from articles (e.g., containing polymers) and from industrial uses would still occur. Due to potential PBT/vPvB hazards, releases to the environment should be minimised via a restriction.

In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold.

Subgroup 4: brominated alcohols and related substances

In addition to neuro- and reproductive toxicity hazards for all the substances in this sub-group, known/likely human health and/or environmental hazards are mentioned below.

Three substances in this subgroup (EC 202-480-9 (2,3-DBPA), EC 221-967-7 (BMP), and EC 253-057-0 (TBNPA)) are known carcinogen and/or mutagen, and one of these three (2,3-DBPA, EC 202-480-9) has also harmonised classification as Repr. 2. These three substances are identified as SVHCs and included in the Candidate List since July 2021. All three substances are likely (v)P and are expected to be mobile in the environment, and one substance (TBNPA) is likely toxic for the environment. Also in this case, no action is proposed to confirm the potential for persistency and mobility (as for Subgroup 1).

Two substances (BMP and TBNPA) have potential for exposure/releases due to uses as flame retardants by industrial and professional workers, by consumers (TBNPA), or from the presence in articles, whereas 2,3-DBPA is used as intermediate.

Data generation would be needed for BMP to clarify the reproductive toxicity and environmental hazards. However, because the substance has a harmonised classification as Muta. 1B and Carc. 1B and has been included in the Candidate List, no further regulatory risk management is needed.

Due to the presence in articles for BMP and TBNPA, it is suggested to include these three substances in the restriction proposed for the entire group.

Four substances in this subgroup (EC 221-779-5, EC 408-020-5, EC 413-060-1, EC 257-913-4) are known/likely CMRs, persistent, and are expected to be mobile in the environment. One substance (EC 408-020-5) is also toxic for the environment.

EC 413-060-1 and EC 257-913-4 have widespread uses by consumers and/or in articles article service life, whereas EC 408-020-5 is a NONS that with potential for

substitution since it is used as a flame retardant in paints, textiles and plastics outside of the EU[12].

One intermediate substance (EC 208-748-1) does not screen for other human health hazards in addition to the potential repro. and STOT RE (neurotoxic) and has an inconclusive environmental hazard assessment. The available information on uses does not indicate that the substance would function as flame retardant. However, it has a bromine content of ≥ 50 %, which can be considered as a desired property for brominated flame retardants. Indeed, brominated flame retardants currently on the market mainly have a bromine content of ≥ 50 %. For this reason, it is assumed that it could be potentially used as substitute.

In parallel to the CLH process for reproductive toxicity and neurotoxicity, a compliance check is proposed for two substances (EC 413-060-1 and 257-913-4) to clarify the mutagenicity hazard. If the mutagenicity hazard is confirmed, it is proposed to cover in the CLH also mutagenicity for all the substances in the sub-group, except for EC 221-779-5 that does not screen as potentially carcinogenic or mutagenic.

The last foreseen action is a restriction for all the substances in order to address the potential for human health exposure and releases to the environment. The substances have widespread uses by industrial workers (all substances) and consumers (one substance) as flame retardants in polymer preparations and compounds[13] and related article service life or could possibly become regrettable substitutes. We propose to include also the substance EC 408-020-5 (NONS, used as flame retardant outside the EU) and the intermediate (EC 208-748-1) in the restriction to avoid possible regrettable substitution. Restriction of substances in articles is the preferred over authorisation as it is considered the best measure to introduce controls at the level of placing on the market of (imported) articles.

Subgroup 5: brominated cycloalkanes

Five brominated cycloalkanes (EC/Lists 203-622-2, 205-294-6, 230-331-8, 700-027-4, 805-270-0) have been registered as intermediates. These substances are mainly used in the manufacturing of other chemicals, including pharmaceuticals. With the information available at this level of assessment, there is no indication that the substances would function as flame retardants.

These substances do, however, have a bromine content of ≥ 50 %, similar to brominated flame retardants currently on the market, and this can be considered as an indication of substitution potential. Due to their bromine content, reproductive toxicity and neurotoxicity are likely to apply to these substances as well and therefore their inclusion in the proposed CLH and restriction is suggested.

The substances differ structurally from the other subgroup members (HBCDD, α-, β- and γ-HBCDD and 1,2,5,6,9,10-HBCD) that are known POPs. Due to the limited amount of registration data for intermediates and the observed differences in structure, it is not possible to extrapolate the environmental hazard to these intermediates. Therefore, these five substances remain inconclusive for environmental hazard.

[12] https://pubchem.ncbi.nlm.nih.gov/compound/15708903

[13] Although no other product categories are referred to in the current registration dossiers, the use in a wider range of products (for which currently other brominated flame retardants are used) cannot be excluded.

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on reproductive toxicity and STOT RE (neurotoxicity) hazards of EC 216-554-3 and List 610-072-0 in subgroup 4 - brominated alcohols and related substances, and EC 212-200-7 and EC 213-378-9 in subgroup 5 - brominated cycloalkanes.

Alike all substances in this group, four substances registered as intermediates are potential neuro- and reproductive toxicants due to their bromine content. However, based on the available information on uses, there are no obvious reasons to assume that these intermediates would become potential substitutes for the restricted substances. This is also supported by the fact that they do not have a bromine content of ≥ 50 %, which can be considered as a desired property for brominated flame retardants.

EC 216-554-3 and EC 212-200-7 have not been classified by the registrants, whereas List 610-072-0 and EC 213-378-9 have been self-classified for eye and skin irritation. Although adequate exposure controls and personal protection measures related to these hazards can be assumed to be in place for the latter two substances, these measures would not suffice for reproductive hazards if these were to be confirmed.

No conclusions can be drawn on the environmental hazards because they are not closely structurally related to the other subgroup members.

Due to the above, it is not currently possible to conclude on the regulatory need. However, once additional information on potential reproductive toxicity and STOT RE (neurotoxicity) hazards for the other substances in this group, the assessment for these substances will be revisited and a group CLH could be considered as well.

Based on currently available information, there is no need for (further) EU regulatory risk management for the substances ECs/Lists 214-604-9, 251-087-9, 247-148-4, 603-801-9, 603-802-4, 603-804-5 and 221-695-9.

Seven of the substances in this group have already been adequately regulated due to risks arising from PBT/vPvB properties and therefore, no further EU regulatory risk management is proposed:

- **Subgroup 2 - brominated diphenyl ethers:** decaBDE (EC 214-604-9) and octaBDE (EC 251-087-9) have been included in Annex XVII of the REACH Regulation. In 2019, decaBDE was banned under the POPs Regulation alongside tetra-, penta-, hexa-, heptaBDE[14].
- **Subgroup 5 - brominated cycloalkanes:** HBCDD and its major diastereoisomers (EC 247-148-4, List 603-801-9, List 603-802-4, List 603-804-5 and EC 221-695-9) have been included in Annex XIV of the REACH Regulation and then banned under the POPs Regulation.

[14] Entry 45 for diphenylether, octabromo derivative (octaBDE) is still in force. Commercial octaBDE will de facto be prohibited as it contains BDE-congeners meeting the POP criteria, e.g. heptaBDE.
However, the specific octaBDE congener does not meet the POPs criteria in its own right. OctaBDE will continue to stay in REACH Annex XVII as it meets the PBT criteria (https://ec.europa.eu/environment/archives/pops/pdf/questions_answers.pdf).
Entries 44 and 67 of Annex XVII regarding pentaBDE (diphenylether, pentabromo derivative) and decaBDE, respectively, were repealed due to the more stringent restrictions under POPs of these substances.

Uncertainties

The main uncertainties for the regulatory strategy presented in section 3.2 concern the following points.

- Some substances in the group screen as potentially mobile. However, since there is currently no agreed approach at EU level for identifying and addressing substances which are persistent and mobile for the time being no data generation is proposed for them.
- Neuro- and reproductive toxicity hazards are less likely for subgroups 1, 2 and 3 compared to subgroups 4 and 5 since bromide is less likely to be released, based on their chemical structure. Even if neuro- and reproductive toxicity are not confirmed for the substances in the group, potential ED or vPvB properties might warrant EU regulatory risk management for subgroups 1, 2 and 3.
- One substance in subgroup 4 (EC 221-779-5) is currently not used as flame retardant, and there is no indication that could be used as a potential regrettable substitute. Moreover, it is less likely compared to the other brominated alcohols to release bromide because it is a vinyl bromide. Nevertheless, CLH to confirm the potential reproductive toxicity and STOT RE neurotoxicity is proposed. If these human health hazards are not confirmed, no further regulatory action should be taken.
- No regulatory risk management is proposed to address skin sensitising properties (potential/known hazard for ECs 204-278-6, 221-779-5, 408-020-5) as the substances had appropriate classifications (self/harmonised) in place or because the risks related to potential exposure to these substances would be addressed with the proposed harmonised classification as Repr. 1B and restriction.
- The brominated flame retardants that are currently registered with a narrow use in polymer compounds and preparations could become potential substitutes for substances with a wider scope of uses once the latter would become regulated. This is one of the reasons underpinning the choice of a group restriction for the substances in this group sharing similar human health hazards.
- Some intermediates in the group are considered to have a potential for substitution (see subgroup 5). However, the available information did not strongly support this conclusion.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. 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 will be updated and conclusions and actions revisited.

As indicated in the Restrictions Roadmap[15] ECHA will prepare an overall strategy on flame retardants by 2022, which will support the Commission when it decides to request ECHA to prepare (a) restriction dossier(s). The substances in scope are in principle all flame retardants, and there will be particular focus on brominated flame retardants and their prioritisation for restrictions.

The overall strategy on flame retardants may bring new perspectives and may result in a need to revise some of the conclusions in this ARN.

Subgroup name, EC/List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 1 - Bromophenols and related substances 204-278-6 209-706-5 218-602-9 426-040-2 443-430-8	Known or potential hazard for reproductive toxicity and for STOT RE (neurotoxicity) (all 5 substances) for ED (ECs 204-278-6, 443-430-8, 426-040-2) for skin sensitisation (EC 204-278-6)	Known or potential hazard for ED, PBT and expected to be mobile in the environment (ECs 204-278-6, 443-430-8,) Inclonclusive hazard for ED (EC 426-040-2), for PBT and Aquatic toxicity (ECs 209-706-5, 218-602-92 and 426-040-2)	Potential for exposure from widespread uses in polymer preparations as a flame retardant or chain ending agent. ECs 443-430-8, 209-706-5 and 218-602-9 have limited exposure potential due to use only as intermediates.	**Need for EU RRM: Restriction** Justification: Restriction is proposed to limit exposure to these substances following release from plastic and other polymer preparations, or to prevent regrettable substitution.	**First step:** Reactivate substance evaluation and initiate CCH for EC 204-278-6 and EC 426-040-2 **Next steps (if hazard confirmed):** CLH SVHC identification Restriction

[15] https://ec.europa.eu/docsroom/documents/49734

Subgroup name, EC/List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 2 - Brominated diphenyl ethers Substance with confidential identity	Known or potential hazard for reproductive toxicity for STOT RE (neurotoxicity)	Known or potential hazard for PBT/vPvB	Widespread use as flame retardant in several products (polymers, coatings, inks, textiles, washing & cleaning etc.)	**Need for EU RRM: Restriction** Justification: Potential for exposure due to professional and consumer uses but also use in articles; authorisation would not cover imported articles. vPvB hazards better addressed via a restriction.	**First step:** CCH **Next steps (if hazard confirmed):** CLH SVHC identification Restriction
Subgroup 2 - Brominated diphenyl ethers 214-604-9 (decaBDE) 251-087-9 (octaBDE)	Known or potential hazard for reproductive toxicity for STOT RE (neurotoxicity)	Known or potential hazard for PBT/vPvB	Widespread use as flame retardant (among other functions)	**Currently no need for EU RRM** Justification: Already regulated under POPs Regulation.	**First step:** No action
Subgroup 3 - Brominated diphenyl ethyls 284-366-9 700-158-7	Known or potential hazard for reproductive toxicity for STOT RE (neurotoxicity)	Known or potential hazard for PBT/vPvB	Widespread use as flame retardant in several products (polymers, coatings, inks, textiles, washing & cleaning etc.) Only industrial use and use in articles as flame retardants in polymers for list 700-158-7 – but possible regrettable substitute.	**Need for EU RRM: Restriction** Justification: Potential for HH exposure due to professional and consumer uses but also use in articles; authorisation would not cover imported articles. vPvB hazards better	**First step:** Await for CCH for the substance with confidential identity and ongoing TPE for EC 284-366-9 **Next steps (if hazard confirmed):** CLH SVHC identification Restriction

Subgroup name, EC/List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				addressed via a restriction.	
Subgroup 4 - Brominated alcohols and related substances 202-480-9 (2,3-DBPA) 221-967-7 (BMP) 253-057-0 (TBNPA)	Known or potential hazard for carcinogenicity for mutagenicity for reproductive toxicity for STOT RE (neurotoxicity)	Known or potential hazard for PBT and expected to be mobile in the environment (ecotoxicity for TBNPA)	Widespread uses as flame retardant in polymers (except for 2,3-DBPA) and intermediate uses.	**Need for EU RRM: Restriction** <u>Justification:</u> Substances identified as SVHC and included in the candidate list. Confirmed carc. with use by professionals, BMP also present in article service life.	**First step:** Restriction
Subgroup 4 - Brominated alcohols and related substances 221-779-5 413-060-1 (corresponding to 606-254-4) 257-913-4 408-020-5 (NONS) 208-748-1	Known or potential hazard for carcinogenicity for mutagenicity for reproductive toxicity for STOT RE (neurotoxicity) for skin sensitisation (EC 221-779-5 and EC 408-020-5)	Known or potential hazard for PBT and expected to be mobile in the environment (ecotoxicity for EC 408-020-5)	Formulation and industrial use as adhesion promotor in polymers, cosmetics, coatings, metals. TF as flame retardant possible (EC 221-779-5). Wide dispersive uses as flame retardant in polymers. Intermediate use in polymers but TF as flame retardant possible (EC 408-020-5, EC 208-748-1).	**Need for EU RRM: Restriction** <u>Justification:</u> Potential for regrettable substitution for two substances + consumer exposure potential and presence in articles.	**First step:** CCH for EC 257-913-4 and EC 413-060-1 **Next steps (if hazard confirmed):** Group CLH potentially followed by Restriction

Subgroup name, EC/List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 4 - Brominated alcohols and related substances 610-072-0 216-554-3	Known or potential hazard for reproductive toxicity for STOT RE (neurotoxicity)	Inconclusive hazard for PBT and Aqua tox	Intermediate uses	**Currently not possible to assess the regulatory needs** Justification: Currently used only as transported isolated intermediates, no clear indication for regrettable substitution.	**First step:** No action
Subgroup 5 - Brominated cycloalkanes 203-622-2 205-294-6 230-331-8 700-027-4 805-270-0	Known or potential hazard for reproductive toxicity for STOT RE (neurotoxicity)	Inconclusive hazard for PBT and Aqua tox	Limited exposure potential with uses only as intermediates.	**Need for EU RRM: Restriction** Justification: To avoid possible regrettable substitution.	**First step:** CLH **Next steps (if hazard confirmed):** Restriction
Subgroup 5 - Brominated cycloalkanes 247-148-4 (HBCDD) 603-801-9 (α-HBCDD) 603-802-4 (β-HBCDD) 603-804-5 (γ-HBCDD) 221-695-9 (1,2,5,6,9,10-HBCD)	Known or potential hazard for reproductive toxicity for STOT RE (neurotoxicity)	Known or potential hazard for PBT/vPvB	The manufacturing, placing on the market and use of these substances is prohibited under the POPs Regulation.	**Currently no need for EU RRM** Justification: Already regulated under POPs Reg and REACH Annex XIV due to PBT properties (& CLH for Repro 2).	No action

Subgroup name, EC / List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 5 - Brominated cycloalkanes 212-200-7 213-378-9	Known or potential hazard for reproductive toxicity for STOT RE (neurotoxicity)	Inconclusive hazard for PBT and Aqua tox	Intermediate uses	**Currently not possible to assess the regulatory needs** <u>Justification:</u> Currently used only as transported isolated intermediates, no clear indication for regrettable substitution.	No action

Annex 1: Overview of classifications

Data extracted on 20.04.2021

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
Sub-group 1: Bromophenols and related substances				
204-278-6	2,4,6-tribromophenol	-	Acute Tox. 4 H302 Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Repr. 2 H361[1 out of 13] Skin Irrit. 2 H315[2 out of 13] STOT Single Exp. 3 H335, affected organs: Respiratory system[2 out of 13] Acute Tox. 4 H332[2 out of 13] STOT Rep. Exp. 2 H373, affected organs: Liver, Kidney[1 out of 13] Acute Tox. 4 H312[2 out of 13] STOT Single Exp. 2 H371, affected organs: Nervous System[1 out of 13] Acute Tox. 3 H301[3 out of 13] Aquatic Chronic 2 H411[2 out of 13]
209-706-5	3-bromophenol	-	STOT Single Exp. 3 H335, affected organs: high respiratory tract [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)]	Acute Tox. 4 H302[4 out of 7] Acute Tox. 4 H312[1 out of 7] STOT Single Exp. 3 H335, affected organs: lungs[1 out of 7] Eye Irrit. 2A H319[1 out of 7] STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 7] STOT Single Exp. 3 H335, affected organs: [1 out of 7] STOT Single Exp. 3 H335[1 out of 7] STOT Single Exp. 3 H335, affected organs: Respiratory system[1 out of 7]
218-602-9	2-bromo-4-*tert*-butylphenol	-	Acute Tox. 4 H302 [intermediate (active)]	Skin Irrit. 2 H315[3 out of 4] Acute Tox. 4 H312[2 out of 4]

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
			Eye Irrit. 2A H319 [intermediate (active)] Aquatic Chronic 2 H411 [intermediate (active)]	Eye Irrit. 2 H319[3 out of 4] Acute Tox. 4 H332[2 out of 4]
426-040-2	2,4,6-tris(2,4,6-tribromophenoxy)-1,3,5-triazine	-	-	-
443-430-8	*FIREGUARD FG-1500*	-		
Sub-group 2: Brominated diphenyl ethers				
214-604-9	bis(pentabromophenyl) ether (decaBDE)	-	-	STOT Rep. Exp. 2 H373, affected organs: liver, kidney[2 out of 57] Skin Irrit. 2 H315[1 out of 57] Repr. 1B H360, specific effect:D, specific concentration: >=5[1 out of 57] Acute Tox. 4 H312[4 out of 57] Acute Tox. 4 H302[5 out of 57] Aquatic Chronic 4 H413[15 out of 57] Eye Irrit. 2 H319[6 out of 57] STOT Single Exp. 3 H335, affected organs: , specific concentration: >=10[1 out of 57] Acute Tox. 4 H332[1 out of 57] Muta. 2 H341[3 out of 57]
251-087-9	diphenyl ether, octabromo derivative (octaBDE)	Repr. 1B	-	Repr. 1B H360, specific effect:Df[1 out of 2] Repr. 1B H360[1 out of 2]
Substance with confidenti	*Confidential*	-	-	-

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
al identity				
Sub-group 3: Brominated diphenyl ethyls				
284-366-9	1,1'-(ethane-1,2-diyl)bis[pentabromobenzene]	-	-	Aquatic Chronic 4 H413[1 out of 44]
700-158-7	1,1'-ethan-1,2-diylbisbenzene, brominated	-	Aquatic Chronic 4 H413	-
Sub-group 4: Brominated alcohols and related substances				
202-480-9	2,3-dibromopropan-1-ol (2,3-DBPA)	Carc 1B H350 Repr 2 H361f Acute Tox 3 H311 Acute Tox 4 H302, H332 Aquatic Chronic 3 H412	Acute Tox. 3 H311 [intermediate (active)] Repr. 2 H361 [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Carc. 1B H350 [intermediate (active)]	Repr. 2 H361, specific effect:f[4 out of 5]
208-748-1	2-bromoethanol	-	Acute Tox. 3 H301 [intermediate (active)] Acute Tox. 3 H311 [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)]	Acute Tox. 2 H300[3 out of 14] Acute Tox. 1 H310[2 out of 14] Acute Tox. 2 H330[1 out of 14] Eye Damage 1 H318[1 out of 14] Acute Tox. 2 H310[1 out of 14] Acute Tox. 1 H330[2 out of 14]

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
			Skin Corr. 1B H314 [intermediate (active)]	
216-554-3	11-bromoundecanol	-	-	-
221-779-5	2,3-dibromo-2-butene-1,4-diol	-	Acute Tox. 3 H301 Eye Irrit. 2 H319	Skin Sens. 1B H317[2 out of 3]
221-967-7	2,2-bis(bromomethyl)propane-1,3-diol (BMP)	Carc 1B Muta 1B	Carc. 2 H351 Muta. 2 H341	Carc. 1B H350[3 out of 15] STOT Single Exp. 3 H335, affected organs: [1 out of 15] Eye Irrit. 2 H319[9 out of 15] Acute Tox. 4 H302[6 out of 15] Aquatic Chronic 4 H413[2 out of 15] Skin Irrit. 2 H315[5 out of 15] STOT Single Exp. 3 H335, affected organs: respiratory system[3 out of 15] STOT Rep. Exp. 2 H373, affected organs: Kidney, Bladder[2 out of 15] Muta. 1B H340[3 out of 15]
253-057-0	2,2-dimethylpropan-1-ol, tribromo derivative (TBNPA)	Carc 1B Muta 2	Eye Irrit. 2 H319	Acute Tox. 4 H302[1 out of 7] Aquatic Chronic 3 H412[1 out of 7] Muta. 1B H340[1 out of 7] Carc. 1B H350[1 out of 7] Muta. 2 H341[1 out of 7]
408-020-5	2,2,6,6-tetrakis(bromomethyl)-4-oxaheptane-1,7-diol	Skin Sens. 1, Aquatic Chronic 2	-	Skin Sens. 1 H317[1 out of 1]
610-072-0	1-Hexanol, 6-bromo		Skin Irrit. 2 H315 [intermediate (active)]	STOT Single Exp. 3 H335, affected organs: [1 out of 6]

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
			Eye Irrit. 2 H319 [intermediate (active)]	STOT Single Exp. 3 H335, affected organs: lungs[3 out of 6]
257-913-4	1,3,5-tris(2,3-dibromopropyl)-1,3,5-triazine-2,4,6(1*H*,3*H*,5*H*)-trione	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: respiratory tract	Aquatic Chronic 4 H413[1 out of 7] STOT Single Exp. 3 H335, affected organs: [1 out of 7]
413-060-1	tris[3-bromo-2,2-bis(bromomethyl)propyl] phosphate	-	-	-
606-254-4	1-Propanol, 3-bromo-2,2-bis(bromomethyl)-, 1,1′,1′′-phosphate	-	-	-
Sub-group 5: Brominated cycloalkanes				
203-622-2	bromocyclohexane	-	-	Skin Irrit. 2 H315 STOT SE 3 H335 Aquatic Chronic 2 H411 Flam.Liq. 4 H227 Eye Irrit. 2A, 2
205-294-6	bromocyclopentane	-	Flam. Liquid 3 H226 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]	Muta. 2 H341[1 out of 14]
212-200-7	1-bromotricyclo[3.3.1.13,7]decane	-	-	Eye Irrit. 2A H319[1 out of 2] Skin Irrit. 2 H315[1 out of 2]

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
				STOT Single Exp. 3 H335, affected organs: Respiratory tract[1 out of 2]
213-378-9	1-bromo-3,5-dimethyltricyclo[3.3.1.13,7]decane	-	Eye Irrit. 2 H319 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]	STOT Single Exp. 3 H335, affected organs: Unknown[1 out of 5]
221-695-9	1,2,5,6,9,10-hexabromocyclodecane	Repr. 2, Lact H362	-	STOT Single Exp. 3 H335, affected organs: respiratory tract[15 out of 41] Effect on or via lactation H362[11 out of 41] Skin Irrit. 2 H315[15 out of 41] Aquatic Acute 1 H400[17 out of 41] Acute Tox. 4 H302[1 out of 41] Aquatic Acute 1 H400, M-factor: 10.00[1 out of 41] Repr. 2 H361, specific effect:fertility[1 out of 41] Repr. 2 H361, specific effect:May damage the unborn child. Suspected of damaging fertility.[1 out of 41] Aquatic Chronic 1 H410, M-factor: 10.00[1 out of 41] Aquatic Chronic 1 H410[30 out of 41] Skin Sens. 1 H317[1 out of 41] Repr. 2 H361[9 out of 41]

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
				Acute Tox. 4 H312[1 out of 41] Eye Irrit. 2 H319[15 out of 41] Acute Tox. 4 H332[1 out of 41]
230-331-8	bromomethylcyclopropane		Acute Tox. 4 H302 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory system. [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)]	STOT Single Exp. 3 H335, affected organs: lungs[1 out of 18] Acute Tox. 4 H332[1 out of 18] Acute Tox. 4 H312[1 out of 18] STOT Single Exp. 3 H335, affected organs: respiratory system[1 out of 18] Aquatic Chronic 2 H411[1 out of 18] STOT Single Exp. 3 H335[1 out of 18]
247-148-4	Hexabromocyclododecane (HBCDD)	Repr. 2, Lact H362	Effect on or via lactation H362 [Article 10 (inactive)] Aquatic Chronic 1 H410, M-factor: 10.00 [Article 10 (inactive)] Repr. 2 H361 [Article 10 (inactive)]	Aquatic Acute 1, M-factor: 10.00[12 out of 30] Aquatic Acute 1 H400[8 out of 30] Aquatic Acute 1 H400, M-factor: 10.00[5 out of 30] Repr. 2 H361, specific effect:fertility[1 out of 30] Aquatic Chronic 1 H410[11 out of 30]
603-801-9	alpha-hexabromocyclododec	Repr. 2, Lact H362		Repr 2 H361 Lact. H362

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
	ane (α-HBCDD)			Aquatic Acute 1 H400 Aquatic Chronic 1 H410
603-802-4	beta-hexabromocyclododecane (β-HBCDD)	Repr. 2, Lact H362		Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335(lungs)
603-804-5	gamma-hexabromocyclododecane (γ-HBCDD)	Repr. 2, Lact H362		Repr 2 H361 Lact. H362 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
700-027-4	(Bromomethyl)cyclobutane		Flam. Liquid 3 H226 [intermediate (inactive)]	STOT Single Exp. 3 H335, affected organs: [5 out of 8] Eye Irrit. 2 H319[6 out of 8] Skin Irrit. 2 H315[6 out of 8]
805-270-0	1,1-bis(bromomethyl)cyclopropane		Repr. 1B H360, specific effect: Development [intermediate (active)]	Repr. 1B H360d Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2A H319 STOT SE 3 H335(inhalation)

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifier

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

Data extracted on 20.04.2021

EC number	Sub-group	Ph-reg, flocculants, etc.	Wash & cleaning prod.	Biocides	Perfume, fragrance	Cosmetics, personal care	Pharma.	Polishes & waxes	Lubric, grease	Polymer prep. & compounds	Adhesives, sealants	Fillers, putties	Coatings & paints	Ink & toners	Paper & board treat.	Textile dyes, impreg prod/ leather treat.	Metal surface treat.	Welding, flux	Lab/ photo chem.	Vehicles/ machinery
221-779-5	**Br. alcohols & related subst.**					F, I	I			F, I	I		F, I				F, I	F, I	F, I	A
221-967-7										I, P, A	I									
253-057-0										F, I, P, C, A										
257-913-4										F, I, A										
413-060-1										F, I, C, A										
247-148-4 [16]	**Br. cycloalk.**									F, I, P, C, A						F, I, P, C, A				

[16] Substance EC 247-148-4 is included in Annex XIV of REACH and prohibited under the POPs Regulation, with some derogations for manufacturing. Hence, limited use and manufacturing is expected despite the registration data.

EC number	Sub-group	Ph-reg, flocculants, etc.	Wash & cleaning prod.	Biocides	Perfume, fragrance	Cosmetics, personal care	Pharma.	Polishes & waxes	Lubric, grease	Polymer prep. & compounds	Adhesives, sealants	Fillers, putties	Coatings & paints	Ink & toners	Paper & board treat.	Textile dyes, impreg prod/ leather treat.	Metal surface treat.	Welding, flux	Lab/ photo chem.	Vehicles/ machinery
214-604-9 [17]	**Br. diphenyl ethers**	F, I	F, I, P, C	F, I	F, I	F, I, P, C		F, I, P, C	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I	F, I, P, C, A				
Substance with confidential identity		F, I	F, I, P, C	F, I	F, I	F, I, P, C		F, I, P, C	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I	F, I, P, C, A				
284-366-9	**Br. diphenyl ethyls**	F, I, P	F, I, P, C	F, I, P	F, I, P	F, I, P, C		F, I, P, C	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P	F, I, P, C, A				
700-158-7										I, A										
426-040-2	**Bromophenols & related susbst.**									F, I, P, C, A										
204-278-6										I, A										

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 30.04.2021

[17] Substance EC 214-604-9 is included in Annex XIV of REACH and prohibited under the POPs Regulation. Hence, limited use and manufacturing is expected despite the registration data.

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
214-604-9	Yes	Yes (PBT, vPvB)		Yes		POP
202-480-9		yes (Carc 1 B)			Yes	
221-967-7		yes (Carc 1 B)			Yes	
253-057-0		yes (Carc 1 B)			Pending**	
408-020-5					Yes	
221-695-9		Yes (PBT)	Yes		Yes	POP
247-148-4		Yes (PBT)	Yes		Yes	POP
603-801-9		Yes (PBT)	Yes		Yes	POP
603-802-4		Yes (PBT)	Yes		Yes	POP
603-804-5		Yes (PBT)	Yes		Yes	POP

*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).

**RAC opinion adopted on 11 June 2020, proposed classification Muta. 1B, Carc. 1B

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