Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Organic hydroperoxides and aliphatic/cumyl peroxides

General structure:

R-O-O-R'

Revision history

Version	*Date*	*Description*
1.0	6 July 2023	

Substances within this group:

	EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Organic hydroperoxides	**200-915-7**	75-91-2	tert-butyl hydroperoxide *TBHP*	Full, >1000
	201-254-7	80-15-9	α,α-dimethylbenzyl hydroperoxide	Full, >1000
	221-341-3	3071-32-7	1-phenylethyl hydroperoxide	OSII or TII
	222-321-7	3425-61-4	tert-pentyl hydroperoxide	Full, 10-100
	227-369-2	5809-08-5	1,1,3,3-tetramethylbutyl hydroperoxide *TMBH*	Full, not (publicly) available
	247-987-6	26762-92-5	Menthane, monohydroperoxy derivative	Full, not (publicly) available
	247-988-1	26762-93-6	Diisopropylbenzene hydroperoxide	Full, 100-100
	911-929-4		Reaction mass of (1α,2β,5α)-2,6,6-trimethylbicyclo[3.1.1]heptane and pinanyl hydroperoxide	C&L notified
	918-860-9		Reaction mass of 3,7-Dimethyl-1,5-octadien-3-ol-7-hydroperoxid and 3,7-Dimethyl-1,7-octadien-3-ol-6-hydroperoxid	OSII or TII
	943-996-0		Reaction product of d-Limonene obtained by oxidation, UV-rays and rose bengale	OSII or TII
	944-113-1		Not (publicly) available	OSII or TII
	944-211-4		Reaction mass of (E)-7-hydroperoxy-3,7-dimethyl-oct-5-en-1-ol and isomer 1 of 6-hydroperoxy-3,7-dimethyl-oct-7-en-1-ol and isomer 2 of 6-hydroperoxy-3,7-dimethyl-oct-7-en-1-ol	OSII or TII
	944-285-8		Reaction mass of 1-isopropyl-4-methylenebicyclo[3.1.0]hexan-3-hydroperoxide and 4-hydroperoxy-1-isopropyl-4-methylbicyclo[3.1.0]hex-2-ene and pin-2(3)-ene	OSII or TII
Organic peroxides	**201-128-1**	78-63-7	Di-tert-butyl 1,1,4,4-tetramethyltetramethylene diperoxide *DMHBP*	Full, 100-1000
	201-279-3	80-43-3	Bis(α,α-dimethylbenzyl) peroxide	Full, >1000
	203-733-6	110-05-4	Di-tert-butyl peroxide *DTBP*	Full, >1000
	213-944-5	1068-27-5	Di-tert-butyl 1,1,4,4-tetramethylbut-2-yn-1,4-ylene diperoxide	Full, 10-100
	218-664-7	2212-81-9	[1,3-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide	Full, not (publicly) available
	220-479-1	2781-00-2	Di-tert-butyl α,α,α',α'-tetramethyl-(p-phenylenedimethylene) diperoxide	C&L notified
	222-389-8	3457-61-2	tert-butyl α,α-dimethylbenzyl peroxide	Full, 100-1000

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

	EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
	234-042-8	10508-09-5	Di-tert-pentyl peroxide	Full, not (publicly) available
	246-678-3	25155-25-3	[1,3(or 1,4)-phenylenebis(1-methylethylidene)] bis[tert-butyl] peroxide	Full, >1000
	410-840-3	71566-50-2	A mixture of: 1-methyl-1-(3-(1-methylethyl)phenyl)ethyl-1-methyl-1-phenylethylperoxide, 63% by weight; 1-methyl-1-(4-(1-methyl ethyl)phenyl)ethyl-1-methyl-1-phenylethylperoxide, 31% by weight	NONS
	412-140-3	32144-25-5	A mixture of: 2,2'-bis(tert-pentylperoxy)-p-diisopropylbenzene; 2,2'-bis(tert-pentylperoxy)-m-diisopropylbenzene	NONS

This table contains 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.

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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 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[2].

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

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the organic (hydro)peroxide moiety R–O–O–R′ where R and R' represent hydrogen, branched alkyl chains and/or cyclic and/or aromatic groups.

The group consists of 24 substances of which 10 contain mono-aromatic group(s) and two contain cyclic groups. Based on the different structures as well as physico-chemical properties and reactivity of the substances, the group is sub-divided into 'organic hydroperoxides' (R-O-O-H) (13 substances) and 'organic peroxides' *(aliphatic/cumyl peroxides,* R-O-O-R'*)* (11 substances).

14 of the substances have a full registration whereas six are registered as a transported isolated intermediate (TII) or as an on-site isolated intermediate (OSII). Four of the substances are not registered.

Based on information reported in the REACH registration dossiers, the substances in the group are mainly used in polymers with different functions. Nine of the substances (seven organic hydroperoxides and two organic peroxides) are only used as intermediate or monomer in polymer production. The potential for exposure to workers and the environment of these substances is expected to be low.

The other substances (six organic hydroperoxides and nine organic peroxides) are used as processing aid in the production of plastic and rubber articles. Of these, 12 with active registrations are also used as cross-linker in polymers (four organic hydroperoxides and eight organic peroxides), and one organic peroxide additionally also as flame retardant in polymers and other products (e.g. stone, plaster, and wood articles). From these uses, exposure to consumers and the environment via articles cannot be excluded. For the use as processing aid, the exposure to environment is most likely. Four of the substances have use as processing aid also registered for professional and/or consumer uses in sealants, coatings, paints, inks, air care products, biocides or similar. However, there is uncertainty on whether the substances are present in these products as such or if they have reacted during the manufacturing of the products.

'Dimethylbenzyl peroxides' bis(α,α-dimethylbenzyl) peroxide (EC 201-279-3), [1,3-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (EC 218-664-7) and [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (EC 246-678-3) are under substance evaluation due to in particular their PBT concern. In addition, EC 201-279-3 has a CLH for Repr. 1B.
Furthermore, the regulatory needs of some other peroxides have been assessed already by ECHA. These include 'dibenzoyl peroxide derivatives', 'peroxide anhydrides (non-cyclic)' and 'peroxydicarbonic acids' (being 'aliphatic peroxydicarbonates') and are therefore not addressed in this group.

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.

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

Based on currently available information, there is a need for (further) EU regulatory risk management – CLH followed up by OEL for potential carcinogenicity, mutagenicity, skin sensitising, STOT RE hazards and reproductive toxicity (only for di-tert-butyl peroxide, EC 203-733-6) due to the potential for release/ exposure of all the substances in the organic hydroperoxides group and for di-tert-butyl peroxide.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety all the substances in the organic hydroperoxide subgroup have (potentially) STOT RE (inhalation) and carcinogenicity (inhalation).

Hyperplasia have been observed in the sub-chronic inhalation studies for three substances (ECs 200-915-7, 201-254-7 and 247-987-6, substances are self-classified as STOT RE 2, target organ lung). One substance has positive findings in an inhalation carcinogenicity study (EC 200-915-7). One additional substance has the same hazard for carcinogenicity based on read-across in the dossier (EC 247-987-6). Given the intrinsic properties of the substances, i.e., the reactive group, local effects in the lung can be presumed for all members of the group. Given the inconsistent mutagenicity data a conclusion on whether this is a threshold effect or not remains open.

There is a need to generate additional information before proceeding with a harmonised classification for the group. Compliance check and/or substance evaluation is needed to generate the data to confirm the inhalation hazard.

In addition, all the organic hydroxyperoxides have (potential) skin sensitisation

properties. Most have positive results in skin sensitisation studies conducted on the respective substance and self-classifications have been applied (EC 200-915-7, EC 222-321-7, EC 227-369-2, EC 247-988-1, List 943-996-0 and List 944-285-8). Two substances have a self-classification for *Muta.* 2 (EC 222-321-7 and List 911-929-4). Based on the information available, classification for mutagenicity appears to be warranted for the substances EC 201-254-7 and EC 247-987-6. Such classification is however not reported in the registration dossiers. Registrants are invited to consider the information available, self-classify the substance(s), and update their registration dossiers and Safety Data Sheets accordingly. Mutagenicity needs further investigation and data generation for the other substances and compliance check is also needed to clarify reproductive toxicity as there is not enough information to conclude on the potential reproductive toxicity.

There are no other potential human health hazards for substances in this subgroup based on information available in the registration dossiers.

From an environmental hazard assessment perspective, all substances in the organic hydroperoxides subgroup are unlikely to be PBT/vPvB based on information reported in the registration dossiers. All the members of this sub-group are not readily biodegradable; however, they have their log Kow below 3 indicating low potential for bioaccumulation. All members have also potential aquatic toxicity.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Carc 1, Muta 2, STOT RE 2 and Repr. 1B (only di-tert-butyl peroxide, EC 203-733-6). When preparing the proposals for the organic hydroperoxides, 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. It should also be considered whether to add skin sensitisation in the proposal together with the other human health endpoints.

CLH i) will require company level risk management measures (RMM) for workers, to be in place, and ii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 28 and 30.

After the confirmation of the hazard via CLH, an EU wide binding occupational exposure limit (BOEL) is proposed to be set to manage the potential exposure of workers on industrial sites which is considered to be the main concern for these substances. From the information available, inhalation is the main route of exposure.

Some Member States have already set national exposure limits for EC 200-915-7 (Italy, Latvia and Lithuania), EC 201-254-7 (Latvia and Lithuania), EC 203-733-6 (Lithuania) and EC 222-321-7 (Latvia and Lithuania). In addition, the volume of the substances is quite high, with most of them having aggregated tonnage bands between 100-10,000 t/y and EC 200-915-7 between 100,000-1,000,000 t/y. All substances are used in similar applications (i.e. polymer production), however their function within the use varies considerably (i.e. processing aid, cross-linker, intermediate) impacting their potential for exposure. Other regulatory risk management options might not cover the whole use profile (e.g. authorisation does not cover intermediate uses) and/or might be less proportionate (e.g. restriction) to address the concern from inhalation.

Due to the high reactivity of organic hydroperoxides, processes are already controlled to some extent though not necessarily sufficiently to protect human health. From the information available in the registrations, it seems that these substances provide specific properties to the polymers that might not be easily

substituted. Given the different technical functions of the organic hydroperoxides in the production of those polymers (e.g. intermediate, processing aid, cross-linker), identifying specific concentration limits within a restriction, would also be difficult. Therefore, setting a BOEL that provides sufficient protection for human health seems to be most appropriate measure.

For the substance EC 201-254-7 also professional end uses are reported. The uses are as intermediate in non-polymeric applications. In such use the substance can be expected to react and thus exposure is expected to be also low. Therefore, no EU regulatory risk management action beyond CLH and OEL is proposed for the substance.

Where substitution is possible, it is suggested to also consider substances that only have intermediates uses for harmonised classification and setting of OEL in order to address the possible risks to workers and to avoid regrettable substitution. Furthermore, there is some substitution potential for organic peroxides with organic hydroperoxides. Therefore, development of volumes and uses of the hydroperoxides should be carefully followed to ensure that the regulatory risk management for this subgroup is still adequate.

Based on currently available information, there is a need for (further) EU regulatory risk management – Restriction for potential reproductive toxicity, ED and PBT/vPvB hazards due to the potential for release/exposure of all organic peroxides (except di-tert-butyl peroxide, EC 203-733-6, already addressed with organic hydroperoxides).

All substances of the organic peroxides subgroup have known or potential hazard for reproductive toxicity. Substance (EC 201-279-3) has CLH for Repr. 1B H360 and substance EC 246-678-3 has been identified to have potential adverse effects on fertility and development as well as potential ED effects via thyroid. In addition, the available studies on EC 203-733-6, EC 222-389-8 and EC 218-664-7 raise concern (reduced foetal weight, litter loss). There are no conclusive studies available within the group. Additional data via compliance check are needed across the subgroup to clarify the potential hazard for toxicity to reproduction.

All the substances in the organic peroxides subgroup are potentially PBT/vPvB based on the reported log Kow values (range 3.2 – 7.3) and lack of ready biodegradability.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repro 1B, ED, and PBT/vPvB. 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 full group of organic peroxide substances, to submit them individually or jointly.

CLH i) will require company level risk management measures (RMM) for workers, to be in place, 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.

Confirmation of the hazard properties via CLH is not considered sufficient to minimise potential releases of the substances in the environment. Potential for release and exposure is expected in particular from consumer uses in adhesives and sealants, air care products, biocidal products, coatings and paints, fillers, putties and plasters as well as in finger paints where releases to the environment cannot be avoided.

The professional uses as reactive processing aid in vulcanisation or polymerisation processes are expected to be widespread (at many sites and by many users) and typically non-contained and non-automated leading to releases to the environment and with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration leading to potential workers' exposure. In addition, professional users may be self-employed and therefore not covered by OSH legislation.

Consumers may be co-exposed to the substances used by professionals (polymer and rubber preparations).

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

In addition, the use of the most harmful substances (e.g. PBT/vPvB, CMR) by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[3].

Moreover, potential exposure from articles needs further investigation. The need for restricting substances in articles used by professionals or consumers (reported for substance EC 201-279-3) should be considered in the context of the restriction of professional uses.

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

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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Organic hydroperoxides 200-915-7 tert-butyl hydroperoxide 201-254-7 α,α-dimethylbenzyl hydroperoxide 221-341-3 1-phenylethyl hydroperoxide 222-321-7 tert-pentyl hydroperoxide 227-369-2 1,1,3,3-tetramethylbutyl hydroperoxide 247-987-6 Menthane, monohydroperoxy derivative	Known or potential hazard for carcinogenicity for STOT RE for mutagenicity for skin sensitisation Inconclusive hazard for reproductive toxicity for respiratory sensitisation	Known or potential hazard for aquatic toxicity No hazard or unlikely hazard for PBT/vPvB	Mainly industrial uses as processing aid and cross-linker in polymers or intermediates in polymer production. EC 201-254-7 Consumer uses in adhesives and sealants, coatings, paints, inks, air care products, biocides with potential for exposure and release to the environment.	**Need for EU RRM: EU-wide exposure limit for workers under OSH** <u>Justification:</u> The harmonised classification as Carc 1 or Repr. 1 – inhalation would trigger the restriction entry 28 and 30, respectively, and by that ensure that the substances are not included in consumer mixtures above	**First step:** CCH **Next steps (if hazard confirmed):** CLH EU-wide exposure limit for workers under OSH

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
247-988-1 Menthane, monohydroperoxy 911-929-4 Reaction mass of (1α,2β,5α)-2,6,6-trimethylbicyclo[3.1.1]heptane and pinanyl hydroperoxide 918-860-9 Reaction mass of 3,7-Dimethyl-1,5-octadien-3-ol-7-hydroperoxid and 3,7-Dimethyl-1,7-octadien-3-ol-6-hydroperoxid 943-996-0 Reaction product of d-Limonene obtained by oxidation, UV-rays and rose bengale 944-113-1 Not (publicly) available 944-211-4 Reaction mass of (E)-7-hydroperoxy-3,7-dimethyl-oct-5-en-1-ol and isomer 1 of 6-hydroperoxy-3,7-dimethyl-oct-7-en-1-ol and isomer 2 of 6-				the limits specified in that entry. Many of the substances are manufactured / imported at high tonnages. National OELs already exist for some of the substances. Main route of exposure is inhalation. OEL is considered as most appropriate measure to cover all industrial use profiles	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
hydroperoxy-3,7-dimethyl-oct-7-en-1-ol 944-285-8 Reaction mass of 1-isopropyl-4-methylenebicyclo[3.1.0] hexan-3-hydroperoxide and 4-hydroperoxy-1-isopropyl-4-methylbicyclo[3.1.0]hex-2-ene and pin-2(3)-ene					
203-733-6 Di-tert-butyl peroxide	Known or potential hazard for reproductive toxicity for mutagenicity	No hazard or unlikely hazard			
Organic peroxides 201-128-1 Di-tert-butyl 1,1,4,4-tetramethyltetramethylene diperoxide 201-279-3 Bis(α,α-dimethylbenzyl) peroxide 213-944-5 Di-tert-butyl 1,1,4,4-	Known or potential hazard for reproductive toxicity for ED	Known or potential hazard for PBT/vPvB	Mainly industrial uses as processing aid and cross-linker in polymers EC 201-279-3 Professional uses as process regulator in vulcanisation or polymeration process. Service life in articles used by professional	**Need for EU RRM: Restriction** <u>Justification:</u> Releases to the environment from consumer uses cannot be avoided. The reported professional uses are widespread (at many sites and many users) with	**First step:** CCH **Next steps (if hazard confirmed):** CLH Restriction

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
tetramethylbut-2-yn-1,4-ylene diperoxide 218-664-7 [1,3-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide 220-479-1 Di-tert-butyl α,α,α',α'-tetramethyl-(p-phenylenedimethylene) diperoxide 222-389-8 tert-butyl α,α-dimethylbenzyl peroxide 234-042-8 Di-tert-pentyl peroxide 246-678-3 [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide 410-840-3 A mixture of: 1-methyl-1-(3-(1-methyl ethyl)phenyl)ethyl-1-methyl-1-phenylethylperoxide, 63% by weight; 1-methyl-1-(4-(1-			workers and consumers as flame retardant EC 246-678-3 Professional and consumer uses	relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, these uses are typically non-contained and non-automated leading to releases to the environment. 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.	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
methyl ethyl)phenyl)ethyl-1-methyl-1-phenylethylperoxide, 31% by weight; 412-140-3 A mixture of: 2,2'-bis(tert-pentylperoxy)-p-diisopropylbenzene; 2,2'-bis(tert-pentylperoxy)-m-diisopropylbenzene				Industrial uses to be considered as part of the restriction Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses	

Annex 1: Overview of classifications

Data extracted on 6 July 2023

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
200-915-7	75-91-2	tert-butyl hydroperoxide TBHP	Muta. 2 H341	Flam. Liquid 3 H226 Org. Perox. Type F H242 Acute Tox. 4 H302 Acute Tox. 3 H311 Acute Tox. 2 H330 Skin Corr. 1C H314 Eye Damage 1 H318 Skin Sens. 1 H317 Muta. 2 H341 Carc. 2 H351 STOT SE3 H335 Aquatic Chronic 2 H411
201-128-1	78-63-7	Di-tert-butyl 1,1,4,4-tetramethyltetramethylene diperoxide DMHBP		Org. Perox. Type C H242 Skin Irrit. 2 H315
201-254-7	80-15-9	α,α-dimethylbenzyl hydroperoxide	Org. Perox. E H242 Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B H314 Acute Tox. 3 H331 STOT RE 2 H373 Aquatic Chronic 2 H411	Org. Perox. E H242 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 3 H331 Skin Corr. 1B H314 STOT Rep. Exp. 2 H373 Aquatic Chronic 2 H411
201-279-3	80-43-3	Bis(α,α-dimethylbenzyl) peroxide	Repr. 1B H360D Org. Perox. F H242 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Chronic 2 H411	Repr. 1B H360 Org. Perox. F H242 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Chronic 2 H411
203-733-6	110-05-4	Di-tert-butyl peroxide DTBP	Muta. 2 H341 Flam. Liq. 2 H225	Muta. 2 H341 Flam. Liq. 2 H225

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
			Org. Perox. E H242	Org. Perox. E H242 Aquatic Chronic 3 H412
213-944-5	1068-27-5	Di-tert-butyl 1,1,4,4-tetramethylbut-2-yn-1,4-ylene diperoxide		Org. Perox. C H242 Aquatic Chronic 2 H411
218-664-7	2212-81-9	[1,3-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide		Org. Perox. D H242 Aquatic Chronic 4 H413
220-479-1	2781-00-2	Di-tert-butyl α,α,α',α'-tetramethyl-(p-phenylenedimethylene) diperoxide		Org. Perox. D H242 Aquatic Chronic 4 H413
222-321-7	3425-61-4	tert-pentyl hydroperoxide		Muta. 2 H341 Flam. Liquid 3 H226 Org. Perox. Type E H242 Acute Tox. 4 H302 Acute Tox. 3 H311 Acute Tox. 3 H331 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1 H317 Aquatic Chronic 2 H411
222-389-8	3457-61-2	tert-butyl α,α-dimethylbenzyl peroxide	Org. Perox. Type E H242 Skin Irrit. 2H315 Aquatic Chronic 2 H411	Org. Perox. Type E H242 Skin Irrit. 2H315 Aquatic Chronic 2 H411
227-369-2	5809-08-5	1,1,3,3-tetramethylbutyl hydroperoxide TMBH		Org. Perox. Type D H242 Acute Tox. 4 H302 Acute Tox. 3 H331 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1B H317 Aquatic Chronic 2 H411
234-042-8	10508-09-5	Di-tert-pentyl peroxide		Muta. 2 H341 Flam. Liquid 3 H226 Org. Perox. Type E H242 Skin Irrit. 2 H315 Aquatic chronic 2 H411

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				Aquatic Chronic 4 H413
246-678-3	25155-25-3	[1,3(or 1,4)-phenylenebis(1-methylethylidene)] bis[tert-butyl] peroxide		Org. Perox. D H242
247-987-6	26762-92-5	Menthane, monohydroperoxy derivative		Org. Perox. F H242 Skin Corr. 1A H314 STOT RE 2 H373
247-988-1	26762-93-6	Diisopropylbenzene hydroperoxide		Org. Perox. F H242 Acute Tox. 4 H332 Skin Corr. 1B H314 Eye Damage 1 H318 Skin Sens. 1 H317 Asp. Tox. 1 H304 Aquatic Chronic 2 H411
410-840-3	71566-50-2	A mixture of: 1-methyl-1-(3-(1-methylethyl)phenyl)ethyl-1-methyl-1-phenylethylperoxide, 63% by weight; 1-methyl-1-(4-(1-methyl ethyl)phenyl)ethyl-1-methyl-1-phenylethylperoxide, 31% by weight		Symbol: O Risk phrases: R7 Symbol: N Risk phrases: R51-53
412-140-3	32144-25-5	A mixture of: 2,2'-bis(tert-pentylperoxy)-p-diisopropylbenzene; 2,2'-bis(tert-pentylperoxy)-m-diisopropylbenzene		Symbol: E Risk phrases: R2 Symbol: O Risk phrases: R7 Risk phrases: R53
911-929-4		Reaction mass of (1α,2β,5α)-2,6,6-trimethylbicyclo[3.1.1]heptane and pinanyl hydroperoxide		Muta. 2 H341 Flam. Liquid 3 H226 Org. Perox. Type F H242 Skin Corr. 1B H314 Asp. Tox. 1 H304
918-860-9		Reaction mass of 3,7-Dimethyl-1,5-octadien-3-ol-7-hydroperoxid and 3,7-Dimethyl-1,7-octadien-3-ol-6-hydroperoxid		Flam. Liquid 2 H225 Org. Perox. Type B H241 Eye Irrit. 2 H319
943-996-0		Reaction product of d-Limonene obtained by oxidation, UV-rays and rose bengale		Flam. Liquid 2 H225 Org. Perox. Type B H241 Eye Irrit. 2 H319 Skin Sens. 1 H317

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				Aquatic Chronic 2 H411
944-113-1		Not (publicly) available		Flam. Liquid 2 H225 Org. Perox. Type B H241 Eye Irrit. 2 H319
944-211-4		Reaction mass of (E)-7-hydroperoxy-3,7-dimethyl-oct-5-en-1-ol and isomer 1 of 6-hydroperoxy-3,7-dimethyl-oct-7-en-1-ol and isomer 2 of 6-hydroperoxy-3,7-dimethyl-oct-7-en-1-ol		Flam. Liquid 2 H225 Org. Perox. Type B H241 Eye Irrit. 2 H319
944-285-8		Reaction mass of 1-isopropyl-4-methylenebicyclo[3.1.0]hexan-3-hydroperoxide and 4-hydroperoxy-1-isopropyl-4-methylbicyclo[3.1.0]hex-2-ene and pin-2(3)-ene		Flam. Liquid 2 H225 Org. Perox. Type B H241 Eye Irrit. 2 H319 Skin Sens. 1 H317

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

Data extracted on 20 July 2020

Organic hydroperoxides

EC / List number	Main types of applications structured by product or article types		
	Intermediate in polymer	Process aid, process regulator	Cross-linker in polymer
200-915-7	I	F, I, **(A)**	F, I
201-254-7	F, I	F, I, **P, C, (A)**	F, I
221-341-3	I		
222-321-7	I	F, I, **(A)**	F, I
227-369-2	I	F, I, **(A)**	F, I
247-987-6		F, I, **(A)**	
247-988-1		F, I, **(A)**	
911-929-4	I		
918-860-9	I		
943-996-0	I		
944-113-1	I		
944-211-4	I		
944-285-8	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. (A): article service life is not reported in the registrations but assumed by using expert judgement.

Organic peroxides

EC / List number	Main types of applications structured by product or article types			
	Intermediate in polymer	Process aid, process regulator	Cross-linker in polymers	Flame retardant in polymer or other product
201-128-1		F, I, **(A)**	F, I	
201-279-3		F, I, **P, (A)**	F, I	F, I, **A**
203-733-6		F, I, **(A)**	F, I	
213-944-5		F, I, **(A)**	F, I	
218-664-7		F, I, **(A)**	F, I	
220-479-1		F, I, **(A)**	F, I	
222-389-8		F, I, **(A)**	F, I	
234-042-8	I	F, I, **(A)**	F, I	
246-678-3		F, I, **P, C, (A)**	F, I	
410-840-3	I			
412-140-3	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. (A): article service life is not reported in the registrations but assumed by using expert judgement.

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

Data extracted on 9 June 2020

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
200-915-7					YES	
201-279-3					YES	
203-733-6					YES	
246-678-3	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).

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