Assessment of regulatory needs

Authority: ECHA

Date: 8 June 2020

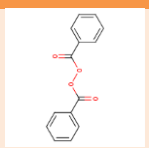
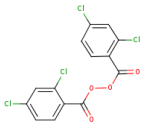
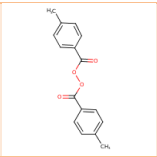
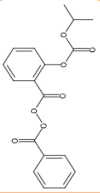
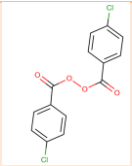
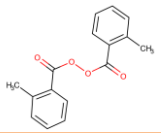
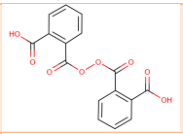
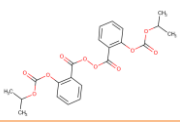
Group Name: dibenzoyl peroxide derivatives

General structure: -

Revision history

Version	*Date*	*Description*
1.0	8 June 2020	

Substances within this group:

EC number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
202-327-6	**94-36-0**	dibenzoyl peroxide		Full, >1000 OSII or TII
205-094-9	**133-14-2**	bis(2,4-dichlorobenzoyl) peroxide		Full, 100-1000
407-950-9	**895-85-2**	bis(4-methylbenzoyl)peroxide		Full, 10-100 NONS, not (publicly) available
814-835-0	**1310672-91-3**	[2-(isopropoxycarbonyloxy)-benzoyl]-benzoylperoxide		Cease manufacture
202-310-3	**94-17-7**	bis(4-chlorobenzoyl) peroxide		C&L notifications
221-231-5	**3034-79-5**	bis(o-toluoyl) peroxide		C&L notification
253-325-7	**37051-42-6**	2,2'-(dioxydicarbonyl)bisbenzoic acid		Not registered
935-239-8		bis(2-isopropoxycarbonyloxy-benzoyl) peroxide		C&L notification

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will 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.

[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

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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 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, 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 the ECHA website[2].

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

Glossary

CCH	Compliance check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
CSS	Chemical strategy for sustainability
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSH	Occupational safety and health
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 eight structurally similar substances based on the presence of the dibenzoyl peroxide moiety. The substances are all organic diacyl peroxides. Four of them are registered (dibenzoyl peroxide, bis(2,4-dichlorobenzoyl) peroxide, bis(4-methylbenzoyl)peroxide, and 2-(isopropoxycarbonyloxy)-benzoyl benzenecarboperoxoate). The substances are unstable (can be explosive in dry form) and therefore additives to stabilise the substances (water or "silicon oil") are part of the substances (up to 50%).

Based on information reported in the REACH registration dossiers, the substances mainly function as reactive ingredients in processes and mixtures with their major use being in the initiation of polymerisation and vulcanisation taking place in industrial settings where the potential for exposure may be limited. Given that in these uses the substances are used in low concentrations and they react upon use by binding to the formed polymer, it is unlikely that these substances are present in the produced polymer articles and therefore the potential for releases and subsequent exposure is considered limited. This holds true especially when the substances are used in formulation and industrial settings.

In contrast, dibenzoyl peroxide is used in mixtures with potentially high potential for exposure for humans and releases to the environment through uses in paints, air care, washing, pharmaceutical and cosmetics/personal care products by professionals and consumers, whereas 2-(isopropoxycarbonyloxy)-benzoyl benzenecarboperoxoate is used in cosmetics by consumers.

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 – restriction combined with authorisation for potential reproductive toxicity hazard due to the potential for release/ exposure of dibenzoyl peroxide (EC 202-327-6) and bis(2,4-dichlorobenzoyl) peroxide (EC 205-094-9).

Dibenzoyl peroxide (EC 202-327-6) has potential reproductive and aquatic toxicity and high potential for exposure resulting from its widespread consumer and professional uses (e.g. in cosmetics, cleaning and air care products). A compliance check (CCH) to obtain reliable data is needed in order to confirm the hazard findings. Restriction combined with authorisation is suggested as the most appropriate regulatory risk management (RRM) tool to address the potential concern.

It is suggested to address bis(2,4-dichlorobenzoyl) peroxide (EC 205-094-9) in the same way, because although it currently has no widespread uses, the similarities among hazard and use information indicate that the substance can be a substitute for dibenzoyl peroxide. In order to avoid regrettable substitution, we consider that both substances should follow the same RRM path if the hazard exists.

The first step of the RRM action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repr. 1B. CLH i) will trigger company level risk management measures under the occupational safety and health (OSH) legislation for workers, ii) is needed or highly recommended for further regulatory processes and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30 of REACH Annex XVII. CLH will also support regulatory action under the Cosmetic products regulation (EC) No 1223/2009 for uses as fragrance, since CMR cat. 1 are restricted by this regulation. Currently, the use of dibenzoyl peroxide is restricted in cosmetics with the exception of professional use in artificial nail systems.

Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by the OSH legislation. Consumers may be co-exposed to the substances used by professionals. **Therefore, a restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH.

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[3] which aims to extend to professional users under REACH the level of protection granted to consumers.

For the remaining industrial uses, it is proposed to consider what would be the most appropriate way to regulate those at a later stage once the hazards are clarified and the scope of the restriction better defined as actions on professional uses may also impact industrial 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

Following harmonised classification, identification as a substance of very high concern (SVHC) and inclusion in Annex XIV (Authorisation List) is suggested as the most appropriate option to prevent the exposure of workers in industrial settings. Although SVHC identification alone would likely send a message to industry to seek alternatives, inclusion in Annex XIV would ensure that suitable substitutes are sought and that health risks in industrial settings are minimised. SVHC identification could also consider PBT properties of the substance bis(2,4-dichlorobenzoyl) peroxide (EC 205-094-9).

An EU-wide exposure limit for workers under the OSH legislation or REACH as an alternative RRM option to authorisation for industrial uses was also considered especially for the high tonnage substance dibenzoyl peroxide (EC 202-327-6) widely used by workers. For the time being, even though a clear decision between the two regulatory options for uses at industrial sites is not possible, authorisation is suggested as the next RRM option. This proposal will be revisited once the hazard will be clarified after data generation, preferably when developing further the restriction on mixtures used by professionals, which should also support clarifying what are those industrial uses in need for EU RRM action.

Based on currently available information, there is a need for (further) EU regulatory risk management – Harmonised Classification for reproductive toxicity due to the potential for release/ exposure of bis(4-methylbenzoyl) peroxide (EC 407-950-9).

Bis(4-methylbenzoyl) peroxide (EC 407-950-9) has potential reproductive toxicity (fertility) and skin sensitisation and is a confirmed aquatic toxicant (harmonised classification as hazardous for the aquatic environment Acute 1 and Chronic 1). The substance has only industrial uses (reactive ingredients in processes and mixtures with the major use being in the initiation of polymerisation and vulcanisation).
For human health hazard findings, we propose compliance check in order to obtain further data to conclude on the need for classification. There is currently a CLH intention from Germany to harmonise the physical hazard Org. Perox. B. The harmonised classification for environmental hazard should provide sufficient protection of the environment in an industrial setting. In both cases, if any hazards are confirmed, the registrants should update their self-classifications in order to ensure sufficient protection of workers. As neither of the substances is currently used by professionals or consumers, we do not expect widespread exposure or potential releases to the environment.

Based on currently available information, there is no need for (further) EU regulatory risk management for the remaining substances in the group.

The use of 2-(isopropoxycarbonyloxy)-benzoyl benzenecarboperoxoate (EC 814-835-0) has been limited to cosmetics for the treatment of acne by consumers. Its human health hazards are therefore regulated under the Cosmetics Regulation. Currently it has no restrictions. We suspect, however, that the substance can be a developmental toxicant due to its breaking down into salicylic acid (EC 200-712-3), which has a harmonised classification for developmental toxicity (Repr. 2; H361d). Should the substance be confirmed as a developmental toxicant, its use in cosmetics would be prohibited in accordance with the Cosmetics Regulation, unless the substance has been evaluated by the Scientific Committee on Consumer Safety and found safe for use in (specific) cosmetic products. After compliance check, it would require a harmonised classification in order to be addressed under the Cosmetics Regulation.

For the time being there is no need for RRM action for reproductive toxicity and aquatic toxicity hazards due to the potential for release/ exposure of 2-(isopropoxycarbonyloxy)-benzoyl benzenecarboperoxoate (EC 814-835-0) due to cease of manufacture. However, in case the registration of the substance would be reactivated, harmonised classification and labelling would need to be reconsidered.

The remaining substances have no or unlikely health and environmental hazard. The substances are used in industrial settings (reactive ingredients in processes and mixtures with their major use being in the initiation of polymerisation and vulcanisation) with low potential for exposure.

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.

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
202-327-6	Known or potential hazard for skin sensitisation, reproductive toxicity, mutagenicity	Known or potential hazard for aquatic toxicity	Widespread use e.g. in cosmetics, cleaning and air care products, high potential for exposure for professionals and consumers.	**Need for EU RRM: Restriction combined with authorisation** <u>Justification</u>: The harmonised classification as Repr. 1B would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient	**First step:** CCH **Next steps (if hazard confirmed):** CLH Restriction for professional uses. SVHC identification followed by authorisation of industrial uses.
205-094-9	Known or potential hazard for skin sensitisation, reproductive toxicity, mutagenicity and repeated-dose toxicity	Known or potential hazard for aquatic toxicity and PBT	No widespread uses, however, the similarities among hazard and use information indicate that the substance can be a substitute for dibenzoyl peroxide.		

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				and effective to introduce controls at the level of placing on the market rather than at the level of uses. For industrial uses, authorisation is suggested as the most appropriate option.	
407-950-9	Known or potential hazard for reproductive toxicity and skin sensitisation	Known or potential hazard for aquatic toxicity	Industrial use as reactive ingredients in processes and mixtures with their major use being in the initiation of polymerisation and vulcanisation, low potential for exposure.	**Need for EU RRM: CLH** <u>Justification:</u> No professional or consumer uses. Sufficient risk management in place for environmental hazard. Self-classifications as skin sensitiser should ensure sufficient protection of workers.	**First step:** CCH **Next steps (if hazard confirmed):** CLH[4]
814-835-0	Known or potential hazard for reproductive toxicity and skin sensitisation	Known or potential hazard for aquatic toxicity	Used in cosmetics, potential for exposure for consumers.	**Currently no need for EU RRM** <u>Justification:</u> No active registrations.	No action

[4] Note that there is a CLH intention from DE to harmonise the physical hazard Org. Perox. B.

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
202-310-3 **253-325-7** **221-231-5** **935-239-8**	No hazard or unlikely hazard	No hazard or unlikely hazard	Industrial use as reactive ingredients in processes and mixtures with their major use being in the initiation of polymerisation and vulcanisation, low potential for exposure.	**Currently no need for EU RRM** Justification: No or unlikely human health and environmental hazard. Release and exposure are expected to be low.	No action

Annex 1: Harmonised classifications and self-classifications reported by registrants

Data extracted on 13 January 2020.

EC No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
202-327-6	94-36-0	Dibenzoyl peroxide	Eye Irrit. 2 H319 Skin Sens. 1 H317 Org. Perox. B H241	Aquatic Acute 1 H400 Aquatic Chronic 1 H410	-
205-094-9	133-14-2	Bis(2,4-dichlorobenzoyl) peroxide	*Not included in Annex VI*	Org. Perox. D H242 Skin Sens. 1 H317 Repr. 1B H360	Self-react. C H242 Org. Perox. B H241 Skin Irrit. 2 H315
407-950-9	895-85-2	Bis(4-methylbenzoyl)peroxide	Org. Perox. B H241 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	-	Org. Perox. D H242
814-835-0	1310672-91-3	[2-(Isopropoxycarbonyloxy)-benzoyl]-benzoylperoxide	Not included in Annex VI	Org. Perox. C H242	-
202-310-3	94-17-7	Bis(4-chlorobenzoyl) peroxide	-	-	Org. Perox. B H241 Org. Perox. D H242 Skin Irrit. 2 H315 Eye Irrit. 2 H319
253-325-7	37051-42-6	2,2'-(dioxydicarbonyl) bisbenzoic acid	-	-	-
221-231-5	3034-79-5	Bis(o-toluoyl) peroxide	-	-	-
935-239-8	-	bis(2-isopropoxycarbonyloxy-benzoyl) peroxide	-	-	Org. Perox. C H242 Skin Irrit. 2 H315 Eye Irrit. 2 H319

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

Data extracted on 13 January 2020.

Main types of applications structured by product or article types	EC 202-327-6	EC 205-094-9	EC 407-950-9	EC 814-835-0
Use in polymerisation initiation crosslinking agents or curing agents for resins, rubbers, polymers	F, I, **P, C**	F, I	F, I	-
Use in cosmetics/PCPs	F, I, **P, C**	-	I	F, **C**
Use in adhesives, sealants	F, I, **P, C**	F, I	F, I	-
Use in air care products	F, I, **P, C**	-	-	-
Use in coatings, paints, ink and toners	F, I, **P, C**	F, I	F, I	-
Use in washing and cleaning products	F, I, **P, C**	F, I	F, I	-
Use in fillers, putties, plasters, modelling clay	F, I, **P, C**	F, I	F, I	-

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

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

Data extracted on 13 January 2020.

EC number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
202-327-6					X	
407-950-9					x (one completed and an ongoing intention)	

*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.