# Assessment of regulatory needs

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

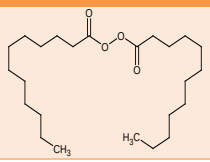
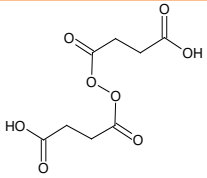
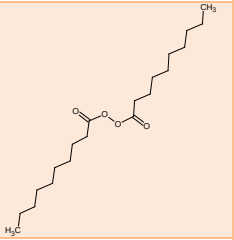
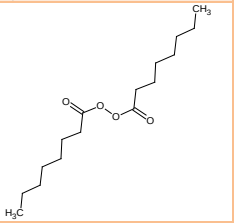
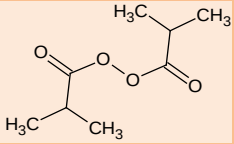
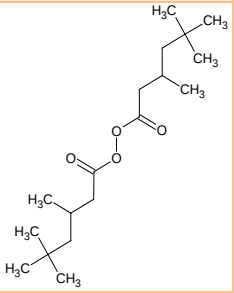
**Group Name: Peroxide anhydrides (non cyclic)**

**General structure: -**

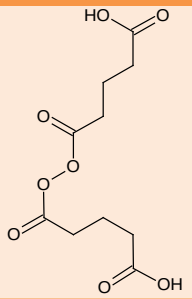
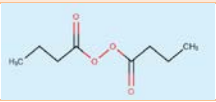
**Revision history**

| *Version* | *Date* | *Description* |
|---|---|---|
| **1.0** | 14 September 2020 | |

**Substances within this group:**

| EC/List number | CAS number | Substance name | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **203-326-3** | 105-74-8 | Dilauroyl peroxide |  | Full, 100-1000 |
| **204-611-5** | 123-23-9 | 4,4'-dioxo-4,4'-dioxydibutyric acid |  | not (publicly) available |
| **212-092-1** | 762-12-9 | Bisdecanoyl peroxide |  | not (publicly) available |
| **212-094-2** | 762-16-3 | Dioctanoyl peroxide |  | not (publicly) available |
| **222-340-0** | 3437-84-1 | Bisisobutyryl peroxide |  | not (publicly) available |
| **223-356-0** | 3851-87-4 | Bis(3,5,5-trimethylhexanoyl) 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 | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **600-254-8** | 10195-54-7 | 5-[(4-carboxybutanoyl)peroxy]-5-oxopentanoic acid |  | not (publicly) available |
| **819-658-2** | 2697-95-2 | Butanoyl butaneperoxoate |  | C&L notification |

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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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 |
| 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 structurally similar substances based on the presence of the peroxide anhydride (non-cyclic) moiety (R-C(O)OOC(O)-R), where R is alkyl group (linear (C7, C9 and C11) or branched with methyl substituted chains (C3 and C8). Each substance contains two (identical) alkyl groups. Two substances have an additional functionality at each R group end: a carboxylic group.

As organic peroxides, the substances are liable to exothermic decomposition at normal or elevated temperatures.

The group consists of eight well-defined mono-constituent substances of which seven have full registrations and one is not registered.

All group members are classified as Org. Perox. B, C or D. One group member (EC 203-326-3) has a harmonised classification under CLP; all the other group members are self-classified. Human health classifications are reported for some group members for skin sensitisation (Cat. 1, 1a or 1b), local hazards (skin/eye irritant; skin corrosive; eye damage), aspiration hazard (Asp. Tox. 1) and acute toxicity (Cat. 4).

Based on information reported in the REACH registration dossiers, the substances are reported to be used in industrial settings only, for formulation of preparations and industrial end-use. The substances are not reported to be used by professional workers or consumers and due to their reactive nature, they are likewise not expected to be present in the final articles.

The peroxides are reported to be used mainly as reactive process regulators, mainly in polymerisation and vulcanization processes. During the reaction process the peroxides moiety is expected to react by binding to the formed polymers.

The potential for release/exposure to the peroxides seems limited to the uses at industrial sites. Releases and exposure might be assumed to be relatively controlled considering the measures that normally apply to uses in industrial settings, as well as the reactive nature of the products and the associated necessary precaution for safe handling.

**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 no need for regulatory risk management action at EU level

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

There is no indication of CMR, ED, PBT/vPvB, aquatic toxicity or ED hazards for any of the substances.

Three group members (EC 212-094-2, EC 222-340-0, EC 223-356-0) are skin sensitisers. All registrants have applied self-classification and the uses of the substances are limited to industrial settings. For EC 223-356-0 a classification as Skin. Sens. Cat. 1 instead of Cat. 1B should be applied.

For industrial and professional uses, sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation. Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances.

Moreover, potential skin sensitisation hazard was identified for the substances EC 203-326-3, EC 204-611-5, EC 212-092-1 and EC 600-254-8. No self-classification has been applied by registrants for these substances. EC 204-611-5 was not tested because of the corrosive nature of the substance. For the others, OECD TG 406 (GPMT) studies are available showing negative results. However, there is doubt about the negative results because of the dose level selection.

Further investigation of the skin sensitising properties of the substances is however not proposed because they are only handled in industrial settings (mainly polymerisation and vulcanisation processes, assumed to involve limited direct

manual intervention), and careful handling for these reactive substances may be assumed (all classified as Org. Perox. B, C or D). For 204-611-5 it is assumed that the risk management measures required due to the corrosive nature of the substance would also address a potential skin sensitisation concern, therefore not justifying additional data generation.

As a summary, for industrial uses of the four substances, there is low exposure potential. For the hazards Org. Perox. B, C or D and Skin Sens. sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation.

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

For EC 819-658-2 a skin sensitisation self-classification has been notified. There are no registrations so it is not possible to clarify the potential hazards for the substance. Therefore, it is proposed that there is currently no need for EU RRM action on the substance.

It is worth noting however that the strategy may need to be revisited and need for further regulatory action reconsidered if there is a change in the registration status or reported uses for any of the substances in this group.

# 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/List number | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|---|---|---|---|---|
| **EC 212-094-2**<br>**EC 222-340-0**<br>**EC 223-356-0** | Known or potential hazard<br>for skin sensitisation | No hazard or unlikely hazard | Industrial use as reactive process regulators. Potential for exposure for industrial workers. | **Currently no need for EU RRM**<br><br><u>Justification:</u><br>Harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace. | No action |

| EC/List number | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|---|---|---|---|---|
| **EC 204-611-5**<br>**EC 203-326-3**<br>**EC 600-254-8**<br>**EC 212-092-1** | | | Industrial use mainly in polymerisation and vulcanisation processes, assumed to involve limited direct manual intervention, low potential for exposure. | **Currently no need for EU RRM**<br><br>Justification:<br>According to the reported uses, low potential for exposure to both human health and environment is expected.<br>Moreover, harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace | No action |
| **EC 819-658-2** | | | Not registered | **Currently no need for EU RRM**<br><br>Justification:<br>Substance is not registered, no data generation is possible to clarify the hazards currently. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change. | No action |

# Annex 1: Overview of classifications

Data extracted on 21 January 2020.

| EC/ List No | Substance name | Harmonised classification | Classification in registrations |
|---|---|---|---|
| **203-326-3** | Dilauroyl peroxide | Org. Perox. Type D, H242 | |
| **204-611-5** | 4,4'-dioxo-4,4'-dioxydibutyric acid | | Org. Perox. Type D, H242<br>Eye Dam. Cat. 1, H318<br>Skin Corr. 1, H314 |
| **212-092-1** | Bisdecanoyl peroxide | | Org. Perox. Type C, H242 |
| **212-094-2** | Dioctanoyl peroxide | | Org. Perox. Type C, H242<br>Skin Irrit. 2, H315<br>Skin Sens. 1A, H317 |
| **222-340-0** | Bisisobutyryl peroxide | | Org. Perox. Type B, H241<br>Skin Corr. 1B, H314<br>Eye Irrit. 2, H319<br>Skin Sens. 1, H317<br>Asp Tox 1, H304 |
| **223-356-0** | Bis(3,5,5-trimethylhexa-noyl) peroxide | | Org. Perox. Type C, H242<br>Skin Irrit. 2, H315<br>Skin Sens. 1B, H317<br>Asp Tox 1, H304 |
| **600-254-8** | Diglutaroyl-peroxid | | Org. Perox. Type D, H242<br>Acute Tox. 4, H302<br>Eye Dam. 1, H318 |
| **819-658-2** | Butanoyl butane-peroxoate | | *Not registered* |

(*) 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 notifiers.

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

Data extracted on 21 January 2020.

| Main types of applications structured by product or article types | EC 203-326-3 | EC 204-611-5 | EC 212-092-1 | EC 212-094-2 | EC 222-340-0 | EC 223-356-0 | EC 600-254-8 |
|---|---|---|---|---|---|---|---|
| Formulation/repacking /distribution to the chemical distribution sector | F | F | F | F | F | F | F |
| Use as polymerization initiators, crosslinking agents, curing agents (polymerisation and vulcanisation process) | I | I | I | I | I | I | |
| Use as reactive processing aid (organic products fabrication) | I | | | | | | |
| Other use as reactive processing aid (unspecified) | I | I | | | | I | |

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

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

Data extracted on 30 October 2019.

| EC / List number | RMOA | Authorisation | | Restriction* | CLH | Actions not under REACH / CLP |
|---|---|---|---|---|---|---|
| | | Candidate list | Annex XIV | Annex XVII | Annex VI (CLP) | |
| **203-326-3** | | | | | 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.