# Assessment of regulatory needs

**Authority: ECHA**

**Date: 23 June 2020**

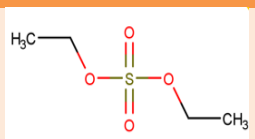
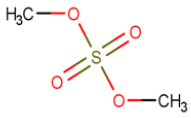
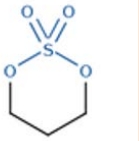
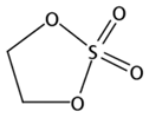
**Group Name: Dialkyl sulfates**

**General structure: -**

**Revision history**

| *Version* | *Date* | *Description* |
|---|---|---|
| **1.0** | 23 June 2020 | |
| | | |

**Substances within this group:**

| EC / List number | CAS number | Substance name | Chemical structures | Registration type (full, OSI or TII, NONS), highest tonnage band among all the registrations (t/y) |
|---|---|---|---|---|
| 200-589-6 | 64-67-5 | diethyl sulphate |  | Full, not (publicly) available |
| 201-058-1 | 77-78-1 | dimethyl sulphate |  | OSII or TII, not (publicly) available |
| 214-022-5 | 1073-05-8 | 1,3,2-dioxathiane 2,2-dioxide |  | Full, not (publicly) available |
| 600-809-4 | 1072-53-3 | 1,3,2-dioxathiolane 2,2-dioxide |  | Full, >1000 |

This table does not contain 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

# DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

# Foreword

The 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[1].

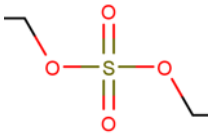
[1] https://echa.europa.eu/understanding-assessment-regulatory-needs

# 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 “O-SO2-O” linked to alkyl/aryl substituents on both oxygen atoms (diesters) moiety shown in the figure below.




The main concern related to this structure is its alkylating properties and the potential for mutagenicity and carcinogenicity. The substance EC 600-809-4 (1,3,2-dioxathiolane 2,2-dioxide), around which the group was built, was flagged for harmonised classification and labelling (CLH) and grouping due to concerns for carcinogenicity on the substance itself and structurally similar substances.

The group includes four substances with three full registrations and three on-site isolated intermediate or transported isolated intermediate (OSII or TII) registrations. Two of the members (EC 200-589-6 and EC 201-058-1) are in the Candidate list due to their CMR properties.

Based on information reported in the REACH registration dossiers, all substances have only industrial uses reported; EC 200-589-6, EC 201-058-1 are used as intermediates in the production of polymers and in the synthesis of other chemicals while EC 214-022-5 is used in functional fluids. Although some level of exposure to workers in the industrial setting is possible, the potential for exposure is expected to be low due to the controlled conditions reported[2]. EC 600-809-4 is used in the production of batteries. The potential for exposure for industrial workers is expected to be low due to the controlled conditions reported[2]. Exposure to professional workers and to the general population during the article service life (batteries) is expected to be low.

[2] PROCs (1 and 3) indicate that these substances are used in closed industrial processes without likelihood of exposure or occasional controlled exposure.

**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 EU regulatory risk management – Harmonised classification and labelling** for carcinogenicity and mutagenicity hazards due to the potential for release/ exposure of all substances in the group.

Two substances in the group (EC 200-589-6 and EC 201-058-1) have harmonised classification as Carc 1B and Muta 1B/Muta 2 and have been included in the Candidate list. The other substances have severe potential carcinogenic and mutagenic hazards based on the alkylating properties (N-methylation) and the strong likelihood that the hazard profile is shared among members, however, generation of data is needed first to clarify those.

The reported uses for the substances with harmonised classification (EC 200-589-6 and EC 201-058-1) are in industrial settings as intermediates in the production of polymers and in the synthesis of other chemicals under controlled conditions. EC 214-022-5 is used in industrial settings in functional fluids and EC 600-809-4 as a film former in the production of batteries (electrolyte). Exposure in industrial settings is possible but assumed to be low due to the controlled conditions reported[2]. Release from batteries during article service life and exposure of professionals and consumers are assumed to be low.

The first step of the regulatory risk management action proposed, should the hazard exist for EC 214-022-5 and EC 600-809-4, is the confirmation of hazard via harmonised classification (CLH) as Carc 1B and/or Muta 1B/Muta 2.

CLH i) will require company level risk management measures (RMM) under the OSH legislation 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 28, 29, and 30.

Due to the similarities with the substances already on the Candidate list and potential for substitution it could have been considered to propose for EC 214-022-5 and EC 600-809-4 also SVHC identification, however, based on the registered uses of all substances (the ones under this group and the ones on the Candidate list) it was concluded that authorisation would not be the most appropriate route to regulate the uses of the substances so no further regulatory steps are proposed at this point. Moreover, the recent batteries regulation proposal that aims to ensure that batteries placed in the EU market are sustainable and safe throughout their entire life cycle[3] would likely cover the risks related to EC 600-809-4 in batteries and therefore no further regulatory action is proposed here for the substance.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0798

# 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 |
|---|---|---|---|---|---|
| **EC 600-809-4** | Known or potential hazard for carcinogenicity, mutagenicity and skin sensitisation | No hazard or unlikely hazard | Industrial use in the production of batteries (electrolyte). Potential for exposure for industrial workers low due to the controlled conditions reported. | **Need for EU RRM: CLH**<br><br><u>Justification:</u><br>CLH will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place | **First step:**<br>CCH<br><br>**Next steps (if hazard confirmed):**<br>CLH |
| **EC 214-022-5** | | | Industrial use in functional fluids. Potential for exposure for industrial workers low due to the controlled conditions reported. | | |
| **EC 200-589-6** | Known or potential hazard for carcinogenicity, mutagenicity and skin sensitisation | | Industrial use as an intermediate in the production of polymers and synthesis of other chemicals. Potential for exposure for industrial workers low due to the controlled conditions reported | | No action |
| **EC 201-058-1** | | | | | |

# Annex 1: Overview of classifications

Data extracted on 18 February 2020.

| EC/List No | Substance name | Harmonised classification | Classification in registrations | Classification in C&L notifications |
|---|---|---|---|---|
| 200-589-6 | Diethyl sulphate | Acute tox 4 (H302); Acute Tox 4 (H312); Acute Tox 4 (H332) Skin Corr 1B (H314); Eye Damage 1 (H318); Muta 1B (H 340); Carc 1B (H350) | Acute tox 4 (H302); Acute Tox 4 (H312); Acute Tox 4 (H332) Skin Corr 1B (H314); Eye Damage 1 (H318); Muta 1B (H 340); Carc 1B (H350) | *Acute Tox 3 (H311)* *Eye Damage 1 (H318)* |
| 201-058-1 | Dimethyl sulphate | Acute tox 3 (H301)<br>Acute Tox 2 (H330)<br>Skin corr 1B (H314)<br>Skin Sens 1 (H317)<br>Muta 2 (H341)<br>Carc 1B (H350) | Acute tox 3 (H301); Acute Tox 2 (H330)<br>Skin corr 1B (H314)<br>Skin Sens 1 (H317) Muta 2 (H341);<br>Carc 1B (H350) | *Eye Damage 1 (H318)* *STOT SE 3 (H335)* |
| *214-022-5* | 1,3,2-dioxathiane 2,2-dioxide | *Not included in Annex VI* | Acute tox 4 (H302); Eye damage 1 (H318); Skin Sens 1B (H317); Muta 2 (H341); | *Acute Tox 3 (H301)*<br>*Skin Irrit 2 (H315)*<br>*Carc 2 (H351)* |
| 600-809-4 | 1,3,2-dioxathiolane 2,2-dioxide | *Not included Annex VI* | Acute tox 4 (H302); Skin corr 1 (H314); Eye damage 1 (H318); skin sens 1B (H317); Carc 2 (H351) | *Acute Tox 1 (H330)* *Acute Tox 3 (H301)* *Skin Irrit 2 (H315)* *Eye Irrit 2 (H319)* *STOT SE 3 (H335)*<br>Aquatic Chronic 3 (H412) |

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

Data extracted on 18 February 2020.

| Main types of applications structured by product or article types | 200-589-6 | 201-058-1 | 214-022-5 | 600-809-4 |
|---|---|---|---|---|
| Use in production of polymers | I | I | | |
| Use in synthesis of other chemicals (e.g. pharmaceutical products) | I | I | | |
| Use in functional fluid | | | I | |
| Use in production of batteries | | | | F, I, P, C, A |

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life

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

Data extracted on 18 February 2020.

| EC / List number | RMOA | Authorisation | | Restriction* | CLH | Actions not under REACH / CLP |
|---|---|---|---|---|---|---|
| | | Candidate list | Annex XIV | Annex XVII | Annex VI (CLP) | |
| 200-589-6 | Yes | Yes | | | | |
| 201-058-1 | Yes | 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.