# Assessment of regulatory needs

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

**Group Name: Tin and its simple inorganic compounds**

**General structure:** -

**Revision history**

| *Version* | *Date* | *Description* |
|---|---|---|
| **1.0** | 27 October 2023 | |
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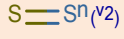
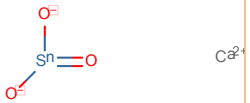
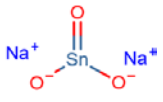
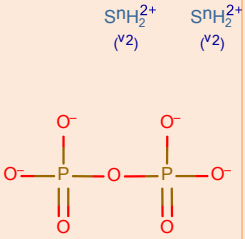
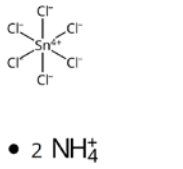
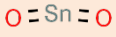
| | | |
| | | |

**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] |
|---|---|---|---|---|
| **215-248-7** | 1314-95-0 | Tin sulphide |  | Full, >1000 |
| **215-252-9** | 1315-01-1 | Tin disulphide | S=Sn=S | Full, 100-1000 |
| **215-689-5** | 1344-13-4 | Tin chloride | | C&L notification |
| **231-141-8** | 7440-31-5 | Tin | Sn | Full, >1000 |
| **231-302-2** | 7488-55-3 | Tin sulphate | $SnSO_4$ | Full, >1000 |
| **231-588-9** | 7646-78-8 | Tin tetrachloride | $SnCl_4$ | Full, not (publicly) available |
| **231-868-0** | 7772-99-8 | Tin dichloride | $SnCl_2$ | Full, 100-1000 |
| **231-999-3** | 7783-47-3 | Tin difluoride | $SnF_2$ | Full, 100-1000 |
| **232-016-0** | 7783-62-2 | Tetrafluorostannane | $SnF_4$ | C&L notification |
| **232-184-5** | 7789-67-5 | Tin tetrabromide | $SnBr_4$ | C&L notification |
| **232-208-4** | 7790-47-8 | Tin tetraiodide | $SnI_4$ | C&L notification |
| **233-087-0** | 10031-24-0 | Tin dibromide | $SnBr_2$ | C&L notification |
| **233-667-3** | 10294-70-9 | Tin diiodide | $SnI_2$ | C&L notification |
| **234-585-0** | 12013-46-6 | Calcium tin trioxide |  | Full, not (publicly) available |
| **234-721-9** | 12027-61-1 | Dipotassium tin hexahydroxide | $K_2[Sn(OH)_6]$ | Full, 10-100 |
| **234-724-5** | 12027-70-2 | Disodium tin hexahydroxide | $Na_2[Sn(OH)_6]$ | Full, 10-100 |
| **234-824-9** | 12035-38-0 | Nickel tin trioxide | NiSnO3 | C&L notification |

[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] |
|---|---|---|---|---|
| **235-030-5** | 12058-66-1 | Disodium tin trioxide |  | Full, not (publicly) available |
| **239-635-5** | 15578-26-4 | Ditin pyrophosphate |  | Full,1-10 |
| **241-033-2** | 16960-53-5 | Diammonium hexachlorostannate |  | C&L notification |
| **242-159-0** | 18282-10-5 | Tin dioxide |  | Full, 100-1000 |
| **244-499-5** | 21651-19-4 | Tin monoxide |  | Full,100-1000 |
| **404-410-4** | 12027-96-2 | Stannate (Sn(OH)62-), zinc (1:1), (OC-6-11)- | | Full, not (publicly) available |
| **405-290-6** | 12036-37-2 | Tin zinc oxide (SnZnO3) | $SnZnO_3$ | Full, not (publicly) available |
| **422-750-1** | Not (publicly) available | [No public or meaningful name is available] | | NONS |
| **485-180-2** | - | [No public or meaningful name is available] | | NONS |
| **600-045-1** | 10025-69-1 | Tin(II) chloride dihydrate | $SnCl_2\ 2*H_2O$ | C&L notification |
| **601-692-2** | 12027-96- | Zinc hydroxy stannate | $ZnSn(OH)6$ | C&L notification |

| 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] |
|---|---|---|---|---|
| **700-126-2** | 12185-56-7 | Dicadmium tin tetraoxide | $Cd_2SnO_4$ | Full, not (publicly) available |
| **810-388-0** | 12067-23-1 | Tin sulfide (Sn2S3) | Sn2S3 | Cease manufacture |
| **944-119-4** | - | Reaction products of tin, citric acid and nitric acid | | Full, not (publicly) available |

This table contains also group members that are only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

# 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. Assessments 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 assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)[2]. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level[3]. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

[2] Working with Groups - ECHA (europa.eu)

[3] Regarding hazard properties the focus is for instance 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 report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website[4].

[4] 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 |
| PMT/vPvM | Persistent, mobile, and toxic / very persistent and very mobile |
| RDT | Repeated dose toxicity |
| 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 |
| TPE | Testing proposal evaluation |

# 1 Overview of the group

*Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report.*

ECHA has grouped together structurally similar substances based on the presence of tin in inorganic compounds.

There are 31 substances in the group of which 18 with full registrations, 1 is a cease of manufacture, and the remaining substances are C&L notified substances. The group includes tin in oxidation state zero, two and four. The compounds, all purely inorganic chemicals, are present as metal (tin), as tin oxides (e.g. tin dioxide), as hydroxides (stannates, e.g. $K_2$ $Sn(OH)_6$), salts ( e.g. tin sulphate), halides showing a nature as ionic salt as SnCl2, as a reactive covalent compound as $SnCl_4$ (Lewis acid) and as coordination compounds as the complex $[SnCl6]^{2-}$ in the substance diammonium hexachlorostannate.

Based on information reported in the REACH registration dossiers, two thirds of the substances in the group have widespread uses e.g. metal surface treatment, polymer preparations, non-metal surface treatment, cosmetics, fillers putties plasters and modelling clay. The substances in the group are used as alloying element, catalyst, pigment, filler, intermediate, opacifier, flame retardant and etching agent and particularly the substance EC 242-159-0 (tin dioxide) has wide variety of uses. Certain uses, such as intermediate and laboratory chemicals, have low potential for exposure and release to the environment whilst wide-dispersive professional, consumer, and article uses e.g., cosmetics, fillers putties plasters and modelling clay have high potential for exposure for workers and consumers and release to the environment.

Finally, ECHA considers there are uncertainties in the uses due to potential over-reporting, unclear use descriptions and lacking article service life reporting.

Two substances in the group have harmonised classifications: tin tetrachloride (EC 231-588-9) with CLH as Skin Corr. 1B and Aquatic Chronic 3 (and STOT SE H335 if concentration ≥ 5%), and the notified substance nickel tin trioxide (EC 234-824-9) with CLH as Carc. 1A, Skin Sens. 1, STOT RE 1 linked to the presence of Nickel. Dicadmium tin tetraoxide (List 700-126-2) should normally fall under the harmonised classifications of cadmium even if those were not applied in the dossier ie. Cadmium metal (EC 231-152-8) and oxocadmium (EC 215-146-2), both have a harmonised classification as Carc. 1B (CLH entries 048-011-00-X and 048-002-00-0, respectively). Therefore, substance List 700-126-2 is also considered as carcinogenic.

Tin sulphate (EC 231-302-2), under Substance Evaluation for initial mutagenicity and carcinogenicity concern, with an additional concern of risk for the environment, acute toxicity and irritation included. Further *in vivo* repeated dose toxicity and mutagenicity studies were requested under Substance Evaluation with the analogue substance, tin dichloride (EC 231-868-0), also part of this group, and the read-across between the two substances was considered acceptable. The results of these studies clarify the initial mutagenicity and carcinogenicity concern, no effects were identified in requested studies. Upon finalisation of the Substance Evaluation conclusion document, the eMSCA, FR CA outlined the conclusion as follows:

- There is a need for follow up regulatory action at EU level. A Harmonised classification and labelling to be considered.

- There is a need for follow up regulatory action at EU level: As data generation on reproductive toxicity is proposed, a re-evaluation of the safe use of the substance is necessary. Depending on the risks identified and the population exposed, the eMSCA, FR CA will decide on the necessity of performing a risk management option analysis (RMOA).

- Regarding the Harmonised classification and labelling: The opportunity to propose a CLH proposal will be evaluated in a further RMOA where such information will be considered.

## 2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). 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 may be updated, and conclusions and actions revisited.

**Table 1: Conclusions and proposed actions**

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| 231-302-2<br>231-999-3<br>231-588-9<br>231-868-0<br>234-721-9<br>234-724-5<br>235-030-5<br>242-159-0<br>244-499-5<br>404-410-4<br>405-290-6<br>944-119-4 | Known or potential hazard<br>for STOT RE<br>for skin sensitisation<br>Inconclusive hazard<br>for reproductive toxicity | Known or potential hazard<br>for aquatic toxicity | Industrial, professional and consumer in e.g., washing, cosmetics, polishes, pharmaceuticals, surface treatment, lubricants, polymer preparations, adhesives, fillers, and putties etc, coatings, ink and toners, paper and board treatment, textile dyes, metal surface treatment, metal working fluids welding and soldering, base metals, semiconductors. | **CCH**<br><br>**Potential last action:**<br>**Currently not possible to assess the regulatory needs** |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| | | | High potential for worker, professional and consumer exposure. | |
| 700-126-2 | Known or potential hazard for carcinogenicity, for mutagenicity, and for reproductive toxicity | Known or potential hazard for aquatic toxicity | Industrial uses in non-metallic surface treatment product. Potential article uses in solar panels. Potential exposure for workers, consumers, and releases to the environment. | **No action**<br><br>**Potential last action:**<br>**Currently no need for EU RRM**<br><br>Justification:<br>Potential high hazard but low exposure for industrial workers, consumers, and low releases to environment in addition to low tonnage. |
| 234-585-0<br>239-635-5 | Known or potential hazard for 234-585-0 for carcinogenicity<br><br>Known or potential hazard for 239-635-5 for skin sensitisation | Known or potential hazard for for aquatic toxicity | 234-585-0: Industrial intermediate uses with potential exposure for workers and releases to the environment.<br>239-635-5: Industrial, professional and consumer uses in cosmetics. Industrial uses in coatings and metal surface treatment products. Article service life in | **No action**<br><br>**Potential last action:**<br>**Currently no need for EU RRM**<br><br>Justification:<br>234-585-0: Only industrial uses with potential exposure for industrial workers and releases to the environment. Classification is sufficient.<br><br>239-635-5: Wide-dispersive uses with potential exposure to industrial workers, professionals, and consumers. |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| | | | coatings, textiles, leather treatment and metal surface treatment. High potential for worker, professional and consumer exposure and releases to the environment. | The concern related to the presence of skin sensitisers in consumer mixtures and textile articles is under investigation. |
| 215-248-7<br>215-252-9<br>231-141-8 | Known or potential hazard<br>for skin irritation for 231-141-8 | No hazard or unlikely hazard | Industrial, professional and consumer uses in e.g. lubricants, metal surface treatment and welding<br>High potential for exposure for workers, consumers, and environmental releases. | No action<br><br>**Potential last action:**<br>**Currently no need for EU RRM**<br><br>Justification:<br>Overall, no, or unlikely hazard that would lead to concern for the reported uses. Classification is sufficient. |
| 215-689-5<br>232-016-0<br>232-184-5<br>232-208-4<br>233-087-0<br>233-667-3<br>234-824-9<br>241-033-2<br>422-750-1<br>485-180-2 | Known or potential hazard for 234-824-9<br>for carcinogenicity, and<br>for skin sensitisation | No hazard or unlikely hazard | Not registered: NONS, C&L notification, Inquiry notification | No action<br><br>**Potential last action:**<br>**Currently no need for EU RRM**<br><br>Justification:<br>Negligible exposure. |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| 600-045-1<br>601-692-2<br>810-388-0 | | | | |

# 3 Justification for the no need for regulatory risk management action at EU level

**Currently not possible to suggest regulatory risk management actions** as information on hazard is not sufficient to conclude on reproductive toxicity hazards of the substances ECs: 231-302-2, 231-999-3; 231-588-9; 231-868-0; 234-721-9; 234-724-5; 235-030-5; 242-159-0; 244-499-5; 404-410-4; 405-290-6; 944-119-4 in the group.

Currently, EC 231-302-2 is self classified as:

Acute Tox. 4 H332; Skin Irrit. 2 H315; Eye Damage 1 H318; Skin Sens. 1 H317; STOT Rep. Exp. 1 H372, affected system: respiratory system: upper respiratory tract, affected organs: lungs; Aquatic Chronic 3 H412.

EC 231-588-9 has a harmonised classification as Aquatic Chronic 3 but absent from the REACH registration dossier.

Based on the draft Substance Evaluation Conclusion document on tin sulphate (EC 231-302-2), the initial mutagenicity and carcinogenicity concerns coming from the tin moiety are clarified by the results of the *in vivo* repeated dose toxicity and mutagenicity studies requested. However, the available data confirm repeated dose toxicity after inhalation and an aquatic chronic hazard and the need for a more severe classification for the corresponding hazard classes as STOT RE 1 and Aquatic chronic 2. Moreover, due to missing higher-tier data, the eMSCA FR CA proposes data generation for EC 231-302-2 under compliance check to clarify its reproductive and developmental toxicity potential.

Due to structural similarity with EC 231-302-2 and the low data density for higher-tier reproductive and developmental toxicity studies in this subgroup, the toxicity potential of the other substances in this subgroup for this endpoint will also be confirmed after data generation.

The substance EC 231-302-2 has a high aggregated tonnage as well as wide and dispersive professional and consumer uses in fillers, putties and metal working fluids.

In the group, particularly the substance EC 242-159-0 has various registered industrial, professional and consumer uses with some of its uses potentially leading into its incorporation into articles. This substance is also registered as a nanoform for the same uses as its bulk form. Its professional uses include activities such as roller application or brushing, spraying, and hand-mixing with intimate contact where the potential exposure to ultra fine dust cannot be excluded.

The substances ECs/Lists 231-999-3, 231-588-9, 231-868-0, 234-721-9, 234-724-5, 235-030-5, 244-499-5, 404-410-4, 405-290-6 and 944-119-4 have mainly industrial uses but also professional and consumer uses with exposure potential for professionals and consumers.

Currently, it is not possible to assess the needs for regulatory risk management for ECs/Lists 231-302-2, 231-999-3, 231-588-9, 231-868-0, 231-999-3, 234-721-9, 234-724-5, 235-030-5, 242-159-0, 244-499-5, 404-410-4, 405-290-6 and 944-119-4 as information on hazard is not sufficient to conclude on reproductive toxicity. The needs for regulatory risk management actions will be re-assessed once generation of data is completed (CCH) for reproductive toxicity.

**Currently no need to suggest (further) regulatory risk management actions for all the other substances**

Based on ECHA's assessment of currently available hazard information, there is potential for:

- carcinogenicity, mutagenicity, reproductive and developmental toxicity, repeated dose toxicity and aquatic toxicity for List 700-126-2 (covered by other cadmium substances entries in Annex VI to CLP (covering the CMR Classifications: 048-011-00-X and 048-002-00-0).

- carcinogenicity and skin sensitisation for the substances EC 234-585-0 and EC 234-824-9.

- skin sensitisation for the substances EC 234-824-9, 239-635-5 and 244-499-5.

- repeated dose toxicity for substances EC 234-824-9, 239-635-5 and 244-499-5.

However, with the exception of skin sensitisation and skin and lung irritation, the above hazards are substance-specific and mainly linked to the non-tin part of the substances.

Based on ECHA's assessment of the hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety, low potential hazards for human health (except for skin sensitisation and skin and lung irritation) but known or potential aquatic hazards for the environment were identified for most of the other substances in the group, due to the tin presence.

Tin compounds are generally of low solubility so there are often no effects observed up to the limit of solubility in test systems. For environmental hazards, tin compounds that exhibit aquatic toxicity are of chronic toxicity ranging from Aquatic Chronic 2 to Aquatic Chronic 3; EC 231-999-3 and EC 239-635-5 are self classified as Aquatic Chronic 2. ECs 231-302-2, 231-868-0, 234-585-0234-721-9, 234-724-5, 235-050-5 are self–classified as Chronic 3. EC 231-588-9 has a harmonised classification as Chronic 3 but not indicated in the dossier. The only substance with a higher hazard for the aquatic environment is List 700-126-2 due to the presence of cadmium, meaning that this substance is covered by the other cadmium substances entries in Annex VI to CLP (048-011-00-X and 048-002-00-0). Aquatic Acute 1 and Aquatic Chronic 1. M-factors are to be applied by importers, manufacturers, users, etc. following CLP Art. 10(2). As all substances in the group are inorganic metal compounds, PBT or PMT is not applicable for inorganic metal compounds.

Regarding the human health hazards identified for List 700-126-2, they are also not related to tin but to the presence of cadmium. The substance is registered for low tonnage, has industrial uses as a 'thin film on glass' suggesting controlled conditions thus exposure to industrial workers is likely low. In addition, Cd-compounds have an OEL of 0.004 mg/m$^3$ amended in 2022 for inhalation which decreases to 0.001 mg/m$^3$ in 2027. Nonetheless, if the substance would be

incorporated into an article e.g. solar panel[5], it is likely contained as a thin layer and of low concentration, thus potential direct exposure to consumers and releases to the environment are considered low. Moreover, the harmonised classification concerning Cd-compounds should ensure proper disposal by users thus minimising releases to the environment.

The use of Cd-compounds in electrical and electronic equipment is restricted under Directive 2011/65/EU with exclusions, while Directive 2012/19/EU concerning waste electrical and electronic equipment should cover the substance and minimise releases to the environment at the waste stage. Considering the above, we consider that no further EU wide regulatory actions are necessary for List 700-126-2 at this stage.

Regarding the human health hazards identified for EC 234-585-0, these are not related to tin but to an impurity, calcium arsenate (EC 231-904-5), which EC 234-585-0 has a concentration of above the classification threshold. Nonetheless, regarding exposure, the substance is registered for only industrial uses as intermediate use in manufacture of metals. In this use the substance presumably dissociates and the level of As impurity in the resulting metal is at negligible concentrations. According to the registrant, the worker activities include chemical production and handling operations which could result in worker exposure.

Based on the information in the registration, the potential exposure to consumers and releases to the environment are low. In addition, the registrant has self-classified the substance as Carcinogenic 1A and a harmonised classification (CLH) of As, Aquatic chronic 3 applies to the substance. Inorganic As-compounds have also an 8 hour OEL-limit of 0.01 mg/m$^3$ according to Directive 2004/37/EC. Therefore, it is considered that no further EU wide regulatory action is necessary for EC 234-585-0 at this stage.

Regarding the substance EC 239-635-5, it has various industrial, professional and consumer uses as well as article service life. These uses include cosmetics, coatings, textiles, leather treatment, metal surface treatment and laboratory chemicals. Based on the information in registrations, there is a high potential for worker and consumer exposure and releases to the environment e.g., from the uses in cosmetics, coatings, textiles, and leather treatment. Particularly, uses in textiles and leather treatment may potentially lead to chronic exposure when article service life (i.e., incorporation into clothing) is considered.

Substances EC 231-588-9, and EC 234-824-9 have harmonised classifications (EC 231-588-9: STOT SE 3, Skin Corr. 1B, Aquatic Chronic 3; EC 234-824-9: STOT RE 1, Carc. 1A, Skin Sens. 1) and/or are already restricted under REACH (EC 231-141-8, 231-588-9 entry 75, 234-824-9 entries 28 and 75), or regulated under the Cosmetics regulation or Food Contact Materials legislation for the relevant uses.

Some of the substances have uses in e.g., washing and cleaning products, cosmetics (dental care), lubricants, greases, release products, fillers, putties, plasters, modelling clay, adhesives, sealants, and coatings and paints, thinners, paint removes. These uses have high exposure potential for professionals and consumers, as well as releases to the environment. In addition, uses in e.g., in coatings and leather treatment have the potential to lead into an incorporation into an article with potential exposure from leather clothing etc.

[5] Diliegros-Godines, C.J., Flores-Ruiz, F.J., Castanedo-Pérez, R. et al. Mechanical and tribological properties of CdO + SnO2 thin films prepared by sol–gel. J Sol-Gel Sci Technol 74, 114–120 (2015). https://doi.org/10.1007/s10971-014-3584-1

In contrast, some substances have intermediate, laboratory chemical etc. uses with low potential for exposure or releases to the environment or are unregistered or C&L notified substances without use information.

It should be noted, that based on ECHA's scientific assessment there are uncertainties in the registered uses, technical functions, and article service life due to over-reporting and/or missing data. In addition, from the information available on the substances and/or similar substances within the group, we have assumed that article service life is of relevance to the assessment of the substances within this group. Therefore, the assessment of regulatory needs has considered those (article) uses relevant. Industry should update their registration dossiers and clarify, whether all of the uses reported for these substances are supported or whether these uses should be reported for these substances and if not, bring sufficient justification for not considering those uses. In the next iteration to this assessment of regulatory needs, if no update of the registration dossiers has been submitted or if no additional information is provided, those uses will be considered of relevance and if the potential hazard properties confirmed, then further regulatory risk management will be considered.

For industrial and professional uses, harmonised classification along with sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation. Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of the substances. In addition, it is expected that following data generation registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use.

Concerning the potential presence of the substance EC 239-635-5 in textile articles, the use of skin sensitisers in textile and leather articles, intended to come into direct and prolonged contact with the skin is covered in an ongoing restriction proposal from FR/SE as supported by ECHA's committees. The restriction proposal targets substances that have harmonised classification as skin sensitisers, Category 1/1A/1B according to the CLP Regulation. Thus, under the current proposal for restriction, harmonised classification would be needed for the restriction to apply.

In addition, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern. Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

Based on the above, no further EU regulatory risk management action is currently proposed for these substances due to low concern as exposure is limited and/or current regulatory risk management is considered sufficient. 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 more severe hazards are confirmed. This is linked to the wide-dispersive uses of the substances. If the registration status changes for the non-registered substances, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

# Annex 1: Overview of classifications

Data extracted on 20.12.2022

| EC / List No | CAS number | Substance name | Harmonised classification | Classification in registrations[6] |
|---|---|---|---|---|
| 215-248-7 | 1314-95-0 | tin sulfide | - | - |
| 215-252-9 | 1315-01-1 | tin disulphide | - | - |
| 215-689-5 | 1344-13-4 | tin chloride | - | - |
| 231-141-8 | 7440-31-5 | tin | - | - |
| 231-302-2 | 7488-55-3 | stannous sulphate = tin sulphate | - | Acute Tox. 4 H332<br>Skin Irrit. 2 H315<br>Eye Damage 1 H318<br>Skin Sens. 1 H317<br>STOT Rep. Exp. 1 H372, affected system: respiratory system: upper respiratory tract, affected organs: lungs<br>Aquatic Chronic 3 H412 |
| 231-588-9 | 7646-78-8 | stannane, tetrachloro; tin tetrachloride - non intermediate | Category: STOT SE 3<br>Class: Specific Target Organ Toxicity - Single Exposure<br>Statement: H335: C>=5%<br><br>Index number: 050-001-00-5<br>Hazard Category: Skin Corr. 1B<br>Hazard Statement: H314<br>Aquatic Chronic 3<br>Statement: H412 | Skin Corr. 1B H314<br>Eye Damage 1 H318<br>Aquatic Chronic 3 H412 [intermediate (active)]<br>STOT Single Exp. 3 H335, affected organs: respiratory tract, specific concentration: >=5 [intermediate (active)] |
| 231-868-0 | 7772-99-8 | tin dichloride | - | STOT Rep. Exp. 2 H373, affected organs: blood sytem [intermediate (inactive)]<br>STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (inactive)]<br>Eye Irrit. 2 H319 [intermediate (inactive)]<br>Met. Corr. 1 H290<br>Acute Tox. 4 H302<br>Acute Tox. 4 H332<br>Skin Corr. 1B H314<br>Eye Irrit. 2 H318<br>Skin Sens. 1 H317 |

[6] The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

| | | | | |
|---|---|---|---|---|
| | | | | STOT Rep. Exp. 2 H373, affected organs: cardiovascular / hematological: other STOT Single Exp. 3 H335, affected organs: respiration tract Aquatic Chronic 3 H412 |
| 231-999-3 | 7783-47-3 | tin difluoride | - | Met. Corr. 1 H290 Acute Tox. 3 H301 Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Chronic 2 H411 |
| 232-016-0 | 7783-62-2 | tetrafluorostannane | - | - |
| 232-184-5 | 7789-67-5 | tin tetrabromide | - | - |
| 232-208-4 | 7790-47-8 | tin tetraiodide | - | - |
| 233-087-0 | 10031-24-0 | tin dibromide | - | - |
| 233-667-3 | 10294-70-9 | tin diiodide | - | - |
| 234-585-0 | 12013-46-6 | calcium tin trioxide art. 10 | - | Carc. 1A H350 Aquatic Chronic 3 H412 |
| 234-721-9 | 12027-61-1 | dipotassium tin hexahydroxide | - | Skin Corr. 1 H314 Eye Damage 1 H318 Aquatic Chronic 3 H412 |
| 234-724-5 | 12027-70-2 | disodium tin hexahydroxide | - | Skin Corr. 1 H314 Eye Damage 1 H318 Aquatic Chronic 3 H412 |
| 234-824-9 | 12035-38-0 | nickel tin trioxide | Index number: 028-044-00-6 STOT RE 1 Hazard Statement: H372 (No information to prove exclusion of certain routes of exposure) Carc. 1A Hazard Statement: H350i Skin Sens. 1 Statement: H317 | - |
| 235-030-5 | 12058-66-1 | sodium stannate = Disodium tin trioxide | - | Skin Corr. 1 H314 Eye Damage 1 H318 Aquatic Chronic 3 H412 |
| 239-635-5 | 15578-26-4 | stannous pyrophosphate; tin(ii) pyrophosphate | - | Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Damage 1 H318 Eye Irrit. 2 H319 Skin Sens. 1 H317 STOT Rep. Exp. 1 H372, affected organs: respiration tractt, kidney STOT Rep. Exp. 2 H373, affected organs: cardiovascular / hematological: other |

| | | | | |
|---|---|---|---|---|
| | | | | STOT Single Exp. 3 H335, affected organs: Respiratoy system Aquatic Chronic 2 H411 |
| 241-033-2 | 16960-53-5 | diammonium hexachlorostannate | - | - |
| 242-159-0 | 18282-10-5 | tin dioxide | - | - |
| 244-499-5 | 21651-19-4 | 21651-19-4_tin monoxide; tin monoxide | - | Acute Tox. 4 H302 Eye Irrit. 2 H319 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: cardiovascular / hematological: other STOT Rep. Exp. 1 H372, affected organs: respiration tractt, kidney |
| 244-499-5 | 21651-19-4 | 21651-19-4_tin monoxide; tin monoxide intermediate TII | | |
| 404-410-4 | | flamtard h Zinc stannate | - | - |
| 404-410-4 | | flamtard h Zinc stannate NONS | | |
| 405-290-6 | | flamtard s Zinc oxide | - | - |
| 422-750-1 | Not publicaly available | [No public or meaningful name is available] | - | - |
| 485-180-2 | | | - | - |
| 600-045-1 | 10025-69-1 | 600-045-1 | - | - |
| 601-692-2 | 12027-96-2 | zinc hexahydroxystannate(2-) | - | - |
| 700-126-2 | 12185-56-7 | dicadmium tin tetraoxide | Cadmium metal (EC 231-152-8) and oxocadmium (EC 215-146-2), both have a harmonised classification as Carc. 1B (CLH entries 048-011-00-X and 048-002-00-0, respectively)<br><br>Pyr. Sol. 1<br>Carc. 1B<br>Muta. 2<br>Repr. 2<br>Acute Tox. 2 * | - |

| | | | | |
|---|---|---|---|---|
| | | | STOT RE 1<br>Aquatic Acute 1<br>Aquatic Chronic 1 | |
| 810-388-0 | 12067-23-1 | ditin trisulfide | - | - |
| 944-119-4 | | 944-119-4_master_reaction product of tin, citric acid and nitric acid | - | Met. Corr. 1 H290<br>Acute Tox. 1 H330<br>Skin Corr. 1A H314<br>Eye Damage 1 H318 |

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

Data extracted on 05/08/2022

| Main types of applications structured by product or article types | 215-248-7 | 215-252-9 | 231-141-8 | 231-302-2 | 231-588-9 | 231-868-0 | 231-999-3 | 234-585-0 | 234-721-9 | 234-724-5 | 235-030-5 | 239-635-5 | 242-159-0 | 244-499-5 | 404-410-4 | 405-290-6 | 700-126-2 | 944-119-4 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents** | | | | F | | F, I, **P** | | | | | | | F, I, **P, C** | | | | | |
| **PC 2: Adsorbents** | | | | | | | | | | | | | F, I, **P** | | | | | |
| **PC 35: Washing and cleaning products** | | | | | | | | | | | | | F, I, **P, C** | | | | | |
| **PC 39: Cosmetics, personal care products** | | | | | | | F, **P, C** | | F, I | F, I | F, I | F, I, **P, C** | F, I, **P, C** | | | | | |
| **PC 29: Pharmaceuticals** | | | | | | F, I | | | | | | | | F, I | | | | |
| **PC 31: Polishes and wax blends** | | | | | | | | | | | | | F, I, **P, C** | | | | | |
| **PC 15: Non-metal-surface treatment products** | | | F, I, **A*** | F, I | F, I | F, I | | | | | | | F, I, **P, C, A*** | | | | I*, **A*** | |
| **PC 24: Lubricants, greases, release products** | F, I, **P, C** | F, I, **P, C** | | | | | | | | | | | | | | | | |
| **PC 25: Metal working fluids** | F, I, **P** | F, I, **P** | | F, I | | | | | | | | | | | | | | |

| Main types of applications structured by product or article types | 215-248-7 | 215-252-9 | 231-141-8 | 231-302-2 | 231-588-9 | 231-868-0 | 231-999-3 | 234-585-0 | 234-721-9 | 234-724-5 | 235-030-5 | 239-635-5 | 242-159-0 | 244-499-5 | 404-410-4 | 405-290-6 | 700-126-2 | 944-119-4 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **PC 17: Hydraulic fluids** | F, I, **P, A*** | F, I, **P, A*** | | | | | | | | | | | | | | | | |
| **PC 32: Polymer preparations and compounds** | | | F, I, **A*** | I | | F, I, **A** | | | | | | | F, I, **P, C, A*** | | F, I, **A** | F, I, **A** | | |
| **PC 1: Adhesives, sealants** | | | | | | | | | | | | | F, I, **P, C, A*** | | | | | |
| **PC 9b: Fillers, putties, plasters, modelling clay** | | | F, I | F, I, **P, C, A** | | F*, I, **A*** | | | | | | | F, I, **P, C** | F*, I | | | | |
| **PC 9a: Coatings and paints, thinners, paint removes** | | | | | | | | | | | | F, I, **A*** | F, I, **P, C, A*** | | I, **A*** | | | |
| **PC 18: Ink and toners** | | | | | | F, I | | | | | | | F, I, **P, C** | | | | | |
| **PC 26: Paper and board treatment products** | | | | | | | | | | | | | F, I, **P, C, A*** | | | | | |
| **PC 34: Textile dyes, and impregnating products** | | | | | | F, I | | | | | | F*, **A** | F, I, **P, C, A*** | | | | | |
| **PC 23: Leather treatment products** | | | | | | | | | | | | F*, **A** | | | | | | |
| **PC 14: Metal surface treatment products** | | | F, I, **P, C, A*** | F, I, **P, A** | | F, I | | | F, I | F, I | F, I | F, I | F, I, **P, C** | F*, I, **A*** | | | | |

| Main types of applications structured by product or article types | 215-248-7 | 215-252-9 | 231-141-8 | 231-302-2 | 231-588-9 | 231-868-0 | 231-999-3 | 234-585-0 | 234-721-9 | 234-724-5 | 235-030-5 | 239-635-5 | 242-159-0 | 244-499-5 | 404-410-4 | 405-290-6 | 700-126-2 | 944-119-4 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **PC 38: Welding and soldering products, flux products** | | | F, I, **P**, **C**, **A** | | | | | | | | | | F, I, **P**, **C, A*** | | | | | |
| **PC 7: Base metals and alloys** | | | F, I, **P**, **C**, **A** | | | | | | | | | | F, I, **P**, **C, A*** | | | | | |
| **PC 33: Semiconductors** | | | F, I, **A*** | F*, I | | | | | | | | | F, I, **P**, **C, A*** | | | | | |
| **PC 21: Laboratory chemicals** | F, I | F, I | I, **P** | F, I | F | F, I, **P** | I, **P** | | F, I | F, I | F, I | F | F, I, **P** | F, I | | | | |
| **PC 19: Intermediate** | F, I | F, I | F, I | F, I | F, I | F, I | I | F, I | | | | | F, I | F, I | | | | I |
| **PC x1: Food and feed additives** | | | | | | 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. *=potential uses identified based on ECHA's assessment.

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

Data extracted on 29/08/2022

| EC / List number | RMOA | Authorisation | | Restriction* | CLH | Actions not under REACH / CLP |
|---|---|---|---|---|---|---|
| | | Candidate list | Annex XIV | Annex XVII | Annex VI (CLP) | |
| 231-141-8 | | | | YES | | Food contact material |
| 231-588-9 | | | | YES | YES | |
| 231-999-3 | | | | | | Cosmetics |
| 234-824-9 | | | | YES | YES | Cosmetics |

*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.