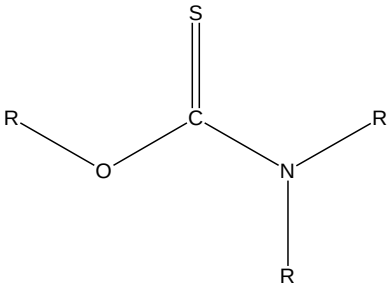
Assessment of regulatory needs

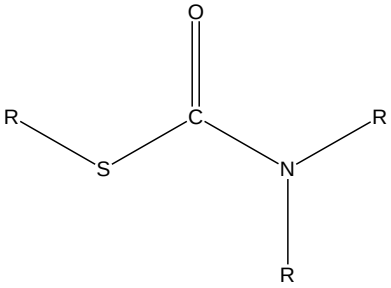
Authority: European Chemicals Agency (ECHA)

Group Name: Thiocarbamates

General structure:



O-thiocarbamate

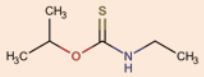
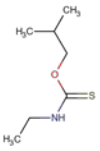
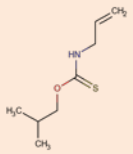
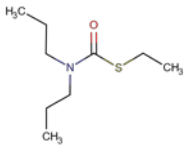
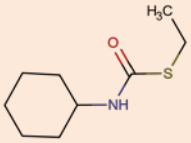
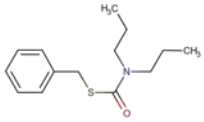


S-thiocarbamate

Revision history

Version	*Date*	*Description*
1.0	4 October 2023	

Substances within this group:

	EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
O-thiocarbamates	**205-517-7**	141-98-0	O-isopropylethyl thiocarbamate		Full, 100-1000
	259-869-1	55860-53-2	O-isobutylethyl thiocarbamate		Full, not (publicly) available
	434-440-3	-	AERO 5100 PROMOTER		Full, not (publicly) available
S-thiocarbamates	**212-073-8**	759-94-4	EPTC		Full, not (publicly) available
	214-482-7	1134-23-2	S-ethyl N-cyclohexyl thiocarbamate		Full, not (publicly) available
	401-730-6	52888-80-9	S-benzyl N,N-dipropylthio carbamate		C&L notified

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

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

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. 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

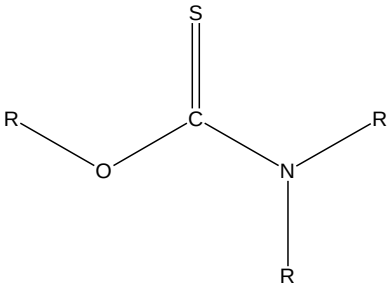
Glossary

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

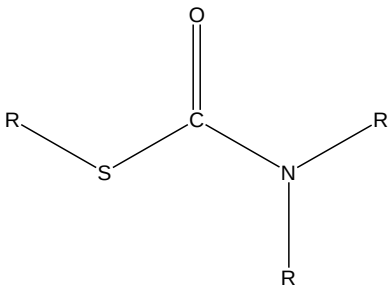
1 Overview of the group

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 the thiocarbamate moiety shown in the figure below.



O-thiocarbamate



S-thiocarbamate

The group consists of six substances out which five have full registration and one is C&L notified. Three of the substances are o-thiocarbamates and three are *S*-thiocarbamates.

Based on information reported in the REACH registration dossiers, the substances in the group are primarily used in industrial processes, with formulation and possible professional use indicated. No consumer uses are expected, based on the information from registrations. Exposure of workers and the environment could potentially occur due to the uses described.

For three of the substances use as active substance in plant protection products is indicated: EC 401-730-6 is approved as for use in the EU (and is thus not subject to registration under REACH (Article 15(1)); and EC 212-073-8 and EC 214-482-7 are, according to the registrant, manufactured for that use only for export.

Further main uses for the substances in the group are as extraction agent in mining industry, intermediate in organic synthesis and metal surface treatment products. The applications in mining industry as extraction agent are described to be closed systems, with little worker exposure, however, some releases to water and air take place. Treatment of metal surfaces is indicated to lead to article service life. It is not evident whether the substance(s) will actually be present in the treated metal articles.

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
***O*-thiocarbamates** 205-517-7 O-isopropylethylthiocarbamate 259-869-1 O-isobutylethylthiocarbamate 434-440-3 AERO 5100 PROMOTER	Known or potential hazard for reproductive toxicity for mutagenicity (only EC 434-440-3)	No hazard or unlikely hazard	Industrial uses in mining and treatment of metal articles and as intermediate. Limited exposure and release to the environment can be expected.	CCH Justification: Self-classification requires company level risk management measures (RMM) for workers to be in place
***S*-thiocarbamates** 212-073-8 EPTC 214-482-7 S-ethyl N-cyclohexylthiocarbamate	Known or potential hazard for skin sensitisation	No hazard or unlikely hazard	Manufacture and export of substances used as plant protection products. No exposure is expected.	CCH Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses.

Subgroup name, EC / List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
401-730-6 S-benzyl N,N-dipropylthiocarbamate				

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

Currently no need to suggest (further) regulatory risk management actions for *O*-thiocarbamates

Based on currently available information, there is a potential hazard for reproductive toxicity and mutagenicity (only EC 434-440-3). The screening studies available for EC 205-517-7 and 434-440-3 show significant developmental effects. EC 434-440-3 is also self-classified as Repro 2 (H361d). The observed effects appear to be sufficient warrant classification as Repr. 1B (H360D). Specifically, the available data for EC 205-517-7 warrant a classification for Repr. 1B for developmental effects based on the effects observed in the screening study OECD TG 422 and OECD TG 414 study. Due to the structural similarity, there is also potential for the developmental toxicity of EC 259-869-1.

Based on the observations of developmental toxicity, there may be a concern for endocrine disrupting or genotoxic modes of action as the underlying cause for *O*-thiocarbamates. The causative mode of action could not yet be determined as being ED or genotoxic.

EC 205-517-7 has indications of toxicity to reproduction/fertility, based on effects in the available studies. This should be clarified through compliance check.

A potential concern for mutagenicity for EC 434-440-3 from positive results in *in vitro* studies has not been clarified through an *in vivo* follow-up test. This should be confirmed via CCH.

The *O*-thiocarbamates are registered only by few registrants and, in some cases, at high tonnage level. Their use appears to be mainly industrial (mining and intermediate in organic synthesis), but for EC 259-869-1 the registrant has indicated use in treating metal articles. Professional or industrial uses as metal surface treating agent have not been reported but they cannot be fully excluded. At the same time, the possible presence of the substances in articles and whether professional or consumer uses really exist are highly uncertain.

For industrial and professional uses, it is expected that following data generation registrants would adequately self-classify the substances. The self-classification will require company level risk management (RMM) to be in place. In addition, a harmonised classification would not impact any known legislations based on the uses of the substances. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

Currently no need to suggest (further) regulatory risk management actions for *S*-thiocarbamates

Based on currently available information, there is a potential hazard for skin sensitisation for substances EC 212-073-8 and EC 214-482-7. Studies on CMR hazards of all substances in the subgroup are unreliable. Data generation via CCH is proposed to confirm suspected low hazard. The environmental hazards appear

to be low and there is no PBT concern due to the substances not being bioaccumulative.

EC 212-073-8 and EC 214-482-7 are both manufactured for use in plant protection products but are not approved for that use in the EU (there is no decision on non-approval, the approvals have only expired without request to renew). Based on the information on uses for EC 212-073-8, the substance is fully exported outside the EU. Therefore, the uses of these substances in the EU are only industrial (where also formulation may take place).

EC 401-730-6 is an approved active substance under the Plant Protection Products Regulation (PPP) and thus not subject to REACH registration obligations (Article 15(1)). The substance already has a CLH for Acute Tox. 4, Skin Sens. 1 and Aquatic Chronic 2.

Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances due to overall, no or unlikely hazard that would lead to concern for the reported uses. Furthermore, the substances are used only in plant protection products for which regulation (EC) No 1107/2009 applies in EU. 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 these substances.

Annex 1: Overview of classifications

Data extracted on 25 November 2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
205-517-7	141-98-0	O-isopropylethylthiocarbamate	-	Aquatic Chronic 2 H411 Eye Irrit. 2 H319 Flam. Gas 2 H221 Acute Tox. 4 H302 Skin Irrit. 2 H315 Aquatic Chronic 3 H412
212-073-8	759-94-4	EPTC	Index number: 006-030-00-0 Acute Tox. 4 Hazard Statement: H302 (Minimum classification)	Acute Tox. 4 H302 Acute Tox. 3 H311 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 2 H411
214-482-7	1134-23-2	S-ethyl N-cyclohexylthiocarbamate	-	Acute Tox. 4 H332 Skin Sens. 1 H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
259-869-1	55860-53-2	O-isobutyl ethylthiocarbamate	-	Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Chronic 3 H412
401-730-6	52888-80-9	S-benzyl N,N-dipropylthiocarbamate	-	-
434-440-3	-	AERO 5100 PROMOTER	-	Repr. 2 H361 Acute Tox. 4 H302

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				Skin Sens. 1B H317 STOT Rep. Exp. 2 H373, affected organs: liver Aquatic Acute 1 H400, M-factor: 100.00 Aquatic Chronic 1 H410, M-factor: 100.00

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

Data extracted on 27 June 2023

Main types of applications structured by product or article types	EC/ List	205-517-7	259-869-1	434-440-3	212-073-8	214-482-7
PC 27: Plant protection products					P	F
PC 14: Metal surface treatment products			(I, P)**, A			
PC 19: Intermediate		I	I, (P, C)*			
PC 40: Extraction agents		F, I	F, I, (P, C)*	I, (P)*		

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.
* Professional and consumer uses are highly uncertain
** Industrial and professional uses cannot be fully excluded

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

Data extracted on 4 September 2020

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