Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

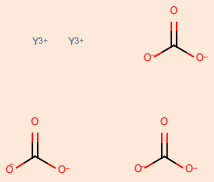
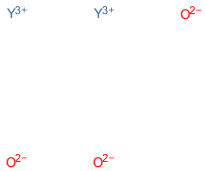
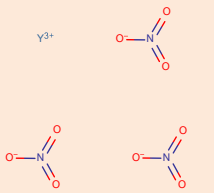
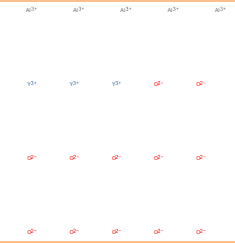
Group Name: Yttrium and its simple compounds

General structure: -

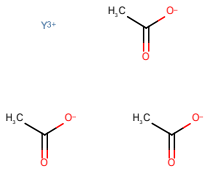
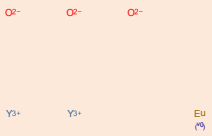
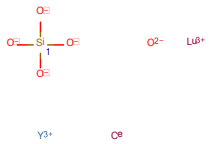
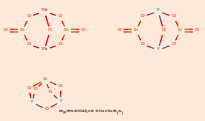
Revision history

Version	*Date*	*Description*
1.0	31 March 2023	

Substances within this group:

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
209-119-4	556-28-5	Diyttrium tricarbonate		OSII or TII
215-233-5	1314-36-9	Yttrium oxide		Full, 100-1000
231-174-8	7440-65-5	Yttrium		Full, 10-100
233-801-0	10361-92-9	Yttrium chloride hexahydrate		Full, not (publicly) available
233-802-6	10361-93-0	Yttrium trinitrate		Full, 10-100
234-465-8	12005-21-9	Pentaaluminium triyttrium dodecaoxide		Full, 1-10

[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 [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
237-257-5	13709-49-4	Yttrium trifluoride		Cease manufacture
245-612-0	23363-14-6	Yttrium(3+) acetate		Full, not (publicly) available
271-591-2	68585-82-0	Yttrium oxide (Y2O3), europium-doped		Full, 10-100
941-731-3	-	Cerium doped lutetium yttrium orthosilicate		Full, not (publicly) available
947-961-0	-	ytterbia stabilised yttrium disilicate		Cease manufacture

This table does not contain group members that are only notified under the CLP Regulation. 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
DNEL	Derived No Effect Level
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
RAC	Committee for Risk Assessment
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STEL	Short-term limit value
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 yttrium.

The group consists of 11 substances including yttrium metal, yttrium oxides and salts with trivalent yttrium as the cation and carbonate, acetate, chloride, fluoride, nitrate, and silicate as anions. Eight substances are registered with full (article 10) registrations, one with an intermediate registration and two substances have ceased manufacturing.

Based on information reported in the REACH registration dossiers, yttrium and its compounds have mainly industrial uses. Industrial use is reported for all eight active registered substances in products such as ph-regulators, neutralizing agents, (non-)metal surface treatment products, coatings and fillers and laboratory chemicals and as intermediate. Three of the eight substances have besides industrial use, also widespread consumer and/or professional use in coatings, thinners, paint removers, fillers, putties, plasters, modelling clay, welding and soldering products, base metals and alloys and semiconductors. Potential exposure via article service life could be foreseen for one substance for the professional use in coatings, and paints, thinners, inks and toners.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – derivation of an EU-wide exposure limit for workers under OSH due to potential for exposure of professional and industrial users.

Currently, according to the review of the Health Council of the Netherlands (2000)[3], yttrium oxide (EC 215-233-5, Annex IX) as a dust, may induce pneumoconiosis and fibrosis in the lungs of workers. Other yttrium compounds are also reported to be retained and to cause lung lesions. According to ECHA's Committee for Risk Assessment (RAC)[4], lung fibrosis is considered as a severe and irreversible effect, relevant for humans and to be classified under CLP (STOT RE). No DNEL (long-term, inhalation) were set by the registrants for inhalation exposure to any yttrium or yttrium compounds. They claim that, according to the process of production and uses at industrial sites, the risk of inhalation exposure is very low. In addition, they consider that the observed effects in experimental species were consistent with lung overload with a limited relevance to the human occupational situation given the levels of exposure (data not reported). However, there is an existing 8-hr OEL of 1 mg/m3 (for yttrium metal and compounds) established in some but not all EU countries[5]. Some Member States have additionally established short-term limit values (STEL).

The first step would be a harmonised classification and labelling for STOT RE (lungs), for all yttrium compounds in this group (potentially a group entry for yttrium and its compounds). Harmonised classification as STOT RE (lungs, inhalation) has been proposed for all these substances.

Although, the exposure potential is expected to be negligible or inexistant for the three yttrium compounds as they are either registered with intermediate use (EC 209-119-4) or have ceased manufacture (EC 237-257-5; EC 947-961-0) these three substances are proposed for CLH as well, due to structural similarities and given that the follow-up step of proposal for OEL is for the entry Yttrium and its compounds.

The next step would be the setting of an OEL. Although it is expected that manufacturers apply the national OELs and that workers are protected from respiratory exposure in industrial settings, no exposure or monitoring data are presented by the registrants. There may be some release of particles to local air during the handling process. For example, the air release factor has been set at 0.03% for the manufacture scenario of yttrium trinitrate (EC 233-802-6). The reference to an existing OEL is not systematically mentioned by the registrants. Further, registrants do not self-classify for any respiratory hazard, contrary to many notifiers (STOT SE, H335). The substances, yttrium and its compounds have mainly industrial uses/applications, where occupational exposure via inhalation could occur. Industrial use is reported for all eight active registered substances in products such as ph-regulators, neutralizing agents, (non-)metal surface treatment products, coatings and fillers, laboratory chemicals and intermediates. Therefore, a EU-wide exposure limit for workers for yttrium and its compounds under OSH is proposed.

Based on currently available information, there is potential hazard for reproductive toxicity (developmental toxicity) of yttrium trinitrate (EC 233-802-6). The available OECD TG 422 study with yttrium trinitrate revealed effects on pups (decreased growth and increased mortality). This effect might be specific to this substance and is not extrapolated to other group members at this stage as it is the only group member containing in addition nitrate moieties. Further assessment under CCH is needed. Based on the information reported in the REACH registration dossier, the

[3] https://www.healthcouncil.nl/documents/advisory-reports/2000/12/14/yttrium-and-yttrium-compounds

[4] https://echa.europa.eu/documents/10162/19cef803-4ba7-dc99-469c-c6f3a75e7b47

[5] https://limitvalue.ifa.dguv.de/WebForm_ueliste2.aspx

substance EC 233-802-6 has widespread and wide dispersive use in industrial- and professional uses in coatings and paints, thinners, paint removes, ink and toners. If the hazards of reproductive and repeated dose toxicity (Repr.2 and STOT RE) are confirmed, and this then followed by a harmonised exposure limit value, it would cover the risk management of the industrial and professional uses. Most probably the OEL would not address the self-employed professional users and therefore the need for registrants to assess the risk and set up DNELs. As an uncertainty would need to be flagged the potential exposure of EC 233-802-6 in articles, as it is used, besides industrial use, by professionals in coatings, and paints, thinners, inks and toners.

Yttrium trichloride hexahydrate (EC 233-801-0) is self-classified as Skin Sens. 1B based on experimental data with the substance. The substance has industrial and professional uses. Self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace.

There is unlikely skin sensitisation potential for the remaining group members: other yttrium compounds (e.g., yttrium oxide and yttrium oxide, europium-doped, lutetium yttrium oxyorthosilicate, cerium-doped) were tested negative.

There is unlikely hazard for mutagenicity, reproductive toxicity (except for yttrium trinitrate (EC 233-802-6, see above)), ED, STOT RE (oral, dermal), carcinogenicity (oral, dermal) hazards for the remaining group members based on experimental data. No hazard is identified for yttrium oxide (EC 215-233-5) in the available OECD TG 422 study. Yttrium oxide did not show any target organ toxicity up to 1000 mg/kg bw/day in a combined repeated dose and reproduction / developmental screening assay after oral gavage (OECD TG 422). Lack of toxicity was also observed in an independent 28-day repeat dose study with microparticles (MPs) (oral gavage; similar to OECD TG 407).

The Health Council of the Netherlands (2000) reported old negative in vitro mutagenicity studies obtained with yttrium chloride. Yttrium trinitrate and yttrium trichloride hexahydrate were confirmed negative in recent in vitro mutagenicity studies. Based on currently available information, it is unlikely that the substances will show carcinogenicity (inhalation) hazard. According to the report of the Health Council of the Netherlands (2000), no carcinogenicity was observed by the oral route in mice. This review also did not report tumours in the lungs of workers exposed to yttrium oxide or other yttrium compounds so the potential for carcinogenicity seems rather low.

Since all substances are inorganic, the requirement for PBT/vPvB assessment does not apply.
As regards to bioaccumulation, no experimental data for this endpoint is provided. The available review on the “Aquatic Bioaccumulation of Lanthanides, Yttrium and Zirconium” concludes that yttrium is unlikely to bio-magnify in predatory organisms or humans exposed via the environment.
The substances are not expected to be ED for environment.
Yttrium compounds have a wide range of solubility values, ranging from 0.1 mg/L to 1136 g/L, reflecting the chemistry of the group. Strong acids produce soluble salts while weak acids produce sparingly soluble or insoluble salts. As for all metals the adsorption of Yttrium will depend on environmental variables such as pH, ionic strength, temperature, the presence of additional ligands such as carbonate or organic species and surface coverage among others. Yttrium compounds are expected to dissolve in dilute acid.

Three substances of the group are self-classified: two as Aquatic Acute 1 and Aquatic Chronic 1 (EC 233-801-0 and EC 233-802-6) based on the data generated

on short term fish for EC 233-802-6. Substance EC 271-591-2 is self-classified as Aquatic Chronic 4. Two other substances, EC 231-174-8 and (237-257-5) are notified for classification as Aquatic Chronic 4.

Data on algae is not available for most of the registrations in this group. Only dossiers for EC 271-591-2 and EC 941-731-3 contain studies on algae. In addition, read across adaptation is proposed for Yttrium oxide (source test material (CAS number): 1306-38-3). The results of the available studies showed significant adverse effects on algal growth resulting in effect concentrations that could trigger classification for the environment.

Long term data on aquatic species is not provided for any of the members of the group.

Overall, based on the currently assessed information, all the substances are likely to be aquatic toxic. This will be further assessed under compliance check which might lead to changes on the need for (self)-classification for aquatic toxicity. If after data generation correct self-classification is applied there will be no need for further regulatory measures for this hazard class. However, if CLH for STOT RE takes place the hazard class for aquatic toxicity can also be examined under that process.

Compliance check is suggested for the following specific substance(s) for further assessment of aquatic toxicity and human health endpoints:

- 215-233-5 Yttrium oxide
- 233-802-6 Yttrium trinitrate
- 234-465-8 Pentaaluminium triyttrium dodecaoxide
- 271-591-2 Yttrium oxide (Y2O3), europium-doped

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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
EC 215-233-5 EC 231-174-8 EC 233-801-0 EC 233-802-6 EC 234-465-8 EC 245-612-0 EC 271-591-2 EC 941-731-3 EC 209-119-4 EC 237-257-5 EC 947-961-0	Known or potential hazard for STOT RE (inhalation) Known or potential hazard for reproductive toxicity 2 only for EC 233-802-6 Known or potential hazard for skin sens only for EC 233-801-0	Known or potential hazard for aquatic toxicity	Industrial use is reported for all eight active registered substances in products such as ph-regulators, neutralizing agents, (non-)metal surface treatment products, coatings and fillers and laboratory chemicals. Consumer use is only reported for EC 215-233-5 for use in fillers, putters and modelling clay. Professional use for some group members in coatings, thinners, paint removers, fillers, putties, plasters, modelling clay, welding and soldering products,	Need for EU RRM OEL Justification: Due to potential for worker exposure via the inhalation route can be characterised as high Existence of national OELs may provide an argument to consider EU OELs. Usually this will give some indication that the above criteria are met and there may be a merit in harmonising the risk management of the	**First step:** CCH EC 215-233-5 EC 233-802-6 EC 234-465-8 EC 271-591-2 **Next steps:** CLH OEL

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			base metals and alloys and semiconductors. Article service life exposure is reported for EC-233-802-6 for use in coatings, and paints, thinners, inks and toners and for EC 231-174-8) for the use in base metals and alloys. EC 237-257-5, EC 947-961-0: Ceased manufacture EC 209-119-4: registered as intermediate	substance across the EU.	

Annex 1: Overview of classifications

Data extracted on 22/09/2022.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
209-119-4	556-28-5	Diyttrium tricarbonate	-	Not classified
215-233-5	1314-36-9	Yttrium oxide	-	Not classified
231-174-8	7440-65-5	Yttrium	-	Not classified
233-801-0	10361-92-9	Yttrium chloride hexahydrate	-	Skin Sens. 1B Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1
233-802-6	10361-93-0	Yttrium trinitrate	-	Acute Tox. 4 Eye Dam. 1 or 2 Aquatic Acute 1 Aquatic Chronic 1
234-465-8	12005-21-9	Pentaaluminium triyttrium dodecaoxide	-	Not classified
237-257-5	13709-49-4	Yttrium trifluoride	-	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3
245-612-0	23363-14-6	Yttrium(3+) acetate	-	Not classified
271-591-2	68585-82-0	Yttrium oxide (Y2O3), europium-doped	-	Aquatic Chronic 4
941-731-3	-	Cerium doped lutetium yttrium orthosilicate	-	Aquatic Acute 1 Aquatic Chronic 1
947-961-0	-	ytterbia stabilised yttrium disilicate	-	-

(*) 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 22/09/2022.

EC number	209-119-4	215-233-5	231-174-8	233-801-0	233-802-6	234-465-8	237-257-5	245-612-0	271-591-2	941-731-3	947-961-0
Products such as ph-regulators, flocculants, precipitants, neutralisation agents		I		I							
Adsorbents		F									
Non-metal-surface treatment products		F, I									F, I
Fuels		I									
Finger paint		I									
Fillers, putties, plasters, modelling clay		I, **C**									
Coatings and paints, thinners, paint removes		F, I	I		I, **P, A**	I	F		F, I		F, I
Ink and toners		F, I		F	F, I, **A**						
Metal surface treatment products		F, I	I								
Welding and soldering products, flux products		F, I, **P**									
Base metals and alloys		F, I, **P**	F, I, **A**		F						
Semiconductors		F, I, **P**									
Laboratory chemicals		I		**P**	I	**P**					
Intermediate	I	F, I,		I	I	F		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 22/09/2022.

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