Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

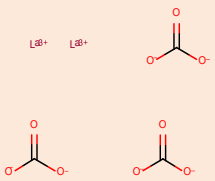
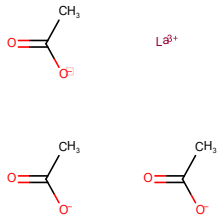
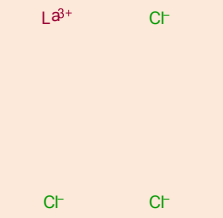
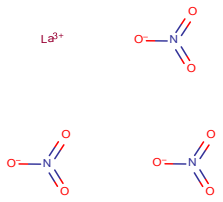
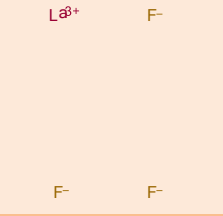
Group Name: Lanthanum and its simple compounds

General structure:

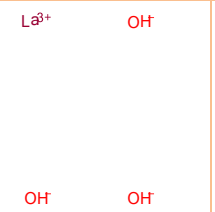
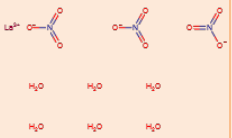
Revision history

Version	*Date*	*Description*
1.0	19 December 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]
209-599-5	587-26-8	dilanthanum tricarbonate		Full, > 1000
213-034-8	917-70-4	lanthanum(3+) acetate		Full, 100 to 1000
215-200-5	1312-81-8	lanthanum oxide	La_2O_3	Full, > 1000
231-099-0	7439-91-0	lanthanum	La	Full, 100 to 1000
233-237-5	10099-58-8	lanthanum chloride, anhydrous		Full, > 1000
233-238-0	10099-59-9	lanthanum trinitrate		Full, 10 to 100, OSII or TII
237-252-8	13709-38-1	lanthanum fluoride		Full, 100 to 1000

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

238-510-2	14507-19-8	lanthanum trihydroxide		Full, 100 to 1000
600-351-5	10277-43-7	lanthanum nitrate hexahydrate		Not registered, C&L notified substance covered by the registration with EC 233-238-0

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.

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.

[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).

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 Lanthanum (La) ion.

The group consists of nine substances including lanthanum metal, lanthanum oxide and salts with trivalent lanthanum as the cation and carbonate, acetate, chloride, fluoride, nitrate, and hydroxide as anions. The release of the trivalent lanthanum ions is expected to be the driver for the toxicity of these substances.

All nine substances in the group are mono-constituent substances with clear substance identity. Eight of the substances have full registrations under REACH while one substance has a C&L notification only. All registrations of the lanthanum salts in the group, excluding fluoride and hydroxide salt, cover also hydrated forms of the substances within the scope of the registrations.

Some of the substances (e.g. lanthanum metal, lanthanum oxide and lanthanum fluoride) are known to exist as nanoparticles but the nanoforms are not reported in any of the registrations. The main impurities are cerium, praseodymium and/or neodymium metal, oxide or salt corresponding with the lanthanum compound in question. In case of lanthanum oxide and lanthanum hydroxide the concentration of the individual impurities is up to 10 %. In other cases, the individual impurities are at the level of 2 % or below.

Based on information reported in the REACH registration dossiers, the substances are mainly used in industrial settings, e.g. as alloying element, conductive agent or binding agent in alloys, welding, catalysts, batteries, or semiconductors. Only for lanthanum fluoride (EC 237-252-8) and lanthanum oxide (EC 215-200-5) there is a high potential for exposure from widespread uses by professional workers such as from polishing powders or metal surface treatment. The latter substance is also used in consumer paints. Most substances can be present in metal articles, ceramics, catalysts as well as batteries or fuel cells, from which potential release is considered to be low.

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

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
209-599-5 213-034-8 215-200-5 231-099-0 233-237-5 233-238-0 237-252-8 238-510-2 600-351-5	Known or potential hazard for reproductive toxicity for all Known or potential hazard for skin sensitisation for EC 233-237-5 Inconclusive hazard for ED for all	Known or potential hazard for aquatic toxicity for all	Mainly industrial uses with limited potential for exposure and release. Two substances EC 215-200-5 and 237-252-8 with high exposure potential from widespread professional uses as polishing powders, non metal and metal (EC 215-200-5 only) surface treatment are reported, EC 215-200-5 also professional and consumer uses in coatings and paints.	**First step:** **CCH** for EC 237-252-8, 233-238-0, 209-599-5, 215-200-5, 238-510-2, 233-237-5 **Potential next steps (if hazard confirmed after data generation):** CLH **Potential last action:** **Restriction for professional uses, OEL for industrial uses (under REACH or OSH)** Justification: Harmonised classification as Repr 1B would lead to generic restriction of the substance(s) in consumer mixtures by means of restriction entry 30 .

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. There is also a need to set an EU wide exposure limit for professional workers under OSH or REACH (restriction). At the same time the need for an exposure limit also for industrial workers to be assessed. Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses.

3 Justification for the need for regulatory risk management action at EU level (if hazards confirmed)

Suggested regulatory risk management action for all substances if reproductive toxicity hazard is confirmed.

Based on currently available information, there is a potential hazard for reproductive toxicity. Data available (especially from external assessments[5]) for a number of substances in the group show effects that indicate toxicity for reproduction (developmental neurotoxicity) and may warrant a classification as Repr. 1B. Since the toxicity is driven by the trivalent lanthanum ion this hazard is likely also for substances currently lacking adequate data. Nevertheless, for many substances these hazard findings need to be confirmed by data generation, via compliance checks (CCHs), as there is no data for several substances. The CCHs and any data generated will also allow to assess the read-across approaches used in the registration dossiers between the substances of the group. If toxicity for reproduction is clarified and the generated data indicate Repro. 1B the substances would warrant harmonised classification, as discussed further below.

The main uses of the substances are in catalysts, battery electrodes, semiconductors, ceramics, base metals and alloys as well as uses as intermediate, which take place mainly in industrial settings. For two substances lanthanum fluoride (EC 237-252-8) and lanthanum oxide (EC 215-200-5) also widespread professional use as polishing powders and in metal surface treatment are reported, for the latter also consumer uses in paints.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of the potential reproductive toxicity via harmonised classification (CLH). The toxicity is expected to be caused by the lanthanum ion. When preparing the proposals, it may be considered what would be the best way to develop them, for instance whether to make a proposal for the group of substances, to submit them individually or jointly.

If the CLH process confirms the substances as being Repro 1B then the CLH

i) will require company level risk management measures (RMM) for workers to be in place; ii) is needed or highly recommended in support of further regulatory processes under REACH; and iii) would lead to generic restriction of the substance(s) in consumer mixtures by means of restriction entry 30.

The professional uses of lanthanum fluoride (EC 237-252-8) and lanthanum oxide (EC 215-200-5) as polishing powders and in non-metal surface treatment for the oxide also metal surface treatment and uses in paints and coatings, are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation. Consumers may be co-exposed to the

[5] US EPA report EPA/690/R-18/004 - Provisional Peer-Reviewed Toxicity Values for Lanthanum | Science Inventory | US EPA.

substances used by professionals as lanthanum oxide (EC 215-200-5) is also used in consumer paints.

Therefore, a **restriction of the substances as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH.

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[6] which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, potential exposure from articles needs further investigation. Although the release of a number of substances from articles (like metal or ceramic articles, batteries or semiconductors) is considered to be low, there is uncertainty whether dust from processing of metal, ceramic or coated or painted articles could cause a concern. In particular, the need for restricting substances in articles used by professionals or consumers (reported for substances lanthanum fluoride (EC 237-252-8) and lanthanum oxide (EC 215-200-5)*)* should be considered in the context of the restriction of professional uses.

When further investigating the uses under the restriction proposed above it is suggested to consider also the need for potential risk management actions on industrial uses. For instance, the setting up of an **EU-wide exposure limit for industrial workers** which can be implemented either by setting a binding occupation exposure limit (OEL) under the Chemical Agents Directive (Directive 98/24/EC) or by including it in the restriction under REACH.

Currently, there are no national or EU wide exposure limit values available for any of the substances in the group. Setting **an EU OEL under the OSH legislation** mainly addresses exposure via inhalation which for these substances is possible via dust (like catalyst powders, polishing powders or from use of steel tools), spray application of coatings and paints, welding fumes or from uses in metal surface treatment or battery production or maintenance. These uses include industrial uses of coatings, paints and polishes as well as in metal surface treatment. The advantage of an OEL is that it also covers the manufacture of the substances, the waste stage, intermediate uses as well as dust or welding fumes generated at the workplace, which cannot (or only partly) be addressed by a restriction.

Furthermore, uses in paints or coatings, polishes or metal surface can also lead to dermal exposure. Thus, adding a skin notation to the OEL may be considered. As a result of the proposed CLH (Repr. 1B) it is expected that exposure via the dermal route will be reduced by measures under the OSH legislation.

Alternatively**, a restriction can** also **define** reference exposure values to be used by registrants and downstream users for performing chemical safety assessments.

[6] European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

Such a restriction proposal may consider the approach taken in the restriction proposal for five cobalt substances[7].

For one substance in the group also intermediate registrations are available. In general, a restriction can cover uses as transported isolated intermediate but not as on-site isolated intermediate, which are exempted from restrictions under REACH. However, for such uses under strictly controlled conditions the proposed harmonised classification as Repr. 1B should trigger sufficient risk management measures under occupational safety and health legislation.

Data on skin sensitisation is available for several substances with only Lanthanum chloride (EC 233-237-5) being identified as a skin sensitiser (category 1). The proposed regulatory risk management activities and the measures under OSH legislation triggered by the CLH also address concerns caused by skin sensitisation for this substance.

Furthermore, all the substances are (likely) toxic to the aquatic environment, with the toxicity being driven by the La ion. Lanthanum(3+) acetate (EC 213-034-8) and Lanthanum trinitrate (EC 233-238-0) are self-classified as Aquatic Acute and Chronic 1 (for acetate M factors 1, for trinitrate none given) based on Ecotoxicity reference values (ERVs) of 0.049 mg La/L, acute, and 0.03 mg La/L, chronic, derived from Daphnia magna studies on Lanthanum chloride anhydrous (EC 233-237-5). Lanthanum chloride anhydrous (EC 233-237-5) is self-classified as Aquatic Chronic 2 even if a stricter classification may be warranted based on the ERVs quoted above and reported in many registration dossiers. Registrants of Lanthanum chloride anhydrous (EC 233-237-5) are invited to consider the information available, and update their registration dossiers and Safety Data Sheets accordingly.

Currently, there is no classification for aquatic toxicity for any of the non-readily soluble substances. Transformation dissolution data to ensure that an appropriate conclusion on classification can be reached is lacking and will be requested in CCHs also proposed to clarify the reprotoxicity hazard. It is expected that following data generation registrants would adequately self-classify the substances and the self-classification will require company level risk management measures (RMM) for environment to be in place. However, the need for a group CLH on aquatic toxicity could be considered to be addressed at the same time as the CLH for reprotoxicity. This would ensure consistent obligations across all actors.

The data available on endocrine disrupting properties are inconclusive. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH). Once the data to be generated are available the need for further EU RRM will be reassessed , if required.

[7] More information on the restriction proposal: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181d575c8

Annex 1: Overview of classifications

Data extracted on 23 February 2021

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
209-599-5	587-26-8	dilanthanum tricarbonate	-	-
213-034-8	917-70-4	lanthanum (3+) acetate	-	*Eye Damage 1 H318* *Aquatic Acute 1 H400* *Aquatic Chronic 1 H410*
215-200-5	1312-81-8	lanthanum oxide	-	-
231-099-0	7439-91-0	lanthanum	-	*Massive: -* *Powder: Flam. Solid 1 H228*
233-237-5	10099-58-8	lanthanum chloride, anhydrous	-	*Met. Corr. 1 H290* *Eye Damage 1 H318* *Skin Sens 1 H317* *Aquatic Chronic 2 H411*
233-238-0	10099-59-9	lanthanum trinitrate	-	*Eye Damage 1 H318* *Aquatic Acute 1 H400*
237-252-8	13709-38-1	lanthanum fluoride	-	-
238-510-2	587-26-8	lanthanum trihydroxide	-	-
209-599-5	587-26-8	dilanthanum tricarbonate	-	-
213-034-8	917-70-4	lanthanum (3+) acetate	-	*Eye Damage 1 H318* *Aquatic Acute 1 H400* *Aquatic Chronic 1 H410*
215-200-5	1312-81-8	lanthanum oxide	-	-
231-099-0	7439-91-0	lanthanum	-	*Massive: -* *Powder: Flam. Solid 1 H228*
233-237-5	10099-58-8	lanthanum chloride, anhydrous	-	*Met. Corr. 1 H290* *Eye Damage 1 H318* *Skin Sens 1 H317* *Aquatic Chronic 2 H411*
233-238-0	10099-59-9	lanthanum trinitrate	-	*Eye Damage 1 H318* *Aquatic Acute 1 H400*
237-252-8	13709-38-1	lanthanum fluoride	-	-
238-510-2	587-26-8	lanthanum trihydroxide	-	-

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

Data extracted on 23 February 2021

Main types of applications structured by product or article types	EC 209-599-5	EC 213-034-8	EC 215-200-5	EC 231-099-0	EC 233-237-5	EC 233-238-0	EC 237-252-8	EC 238-510-2
PC 7: Base metals and alloys	F, I, **A**		F, I, **A**	F, I, **A**				
PC 38: Welding and soldering products, flux products			I	I				I
PC 24: Lubricants, greases, release products*				I				
PC 25: Metal working fluids*				I				
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents (incl. catalyst)	F, I		F, I		F, I	I		
Manufacture and use of catalyst	F, I	F, I	F, I, **A** (incl. automotive catalyst)		I	I		I
Ceramic base for catalyst		I, **A**			F, I	I, **A**		F, I
Ceramics (also glass)		F, I, **A**	F, I, **A**			I, **A**	I, **A**	
PC 33: Semiconductors, electro-ceramics	I, **A**		F, I, **A**					
Batteries (MH electrodes for Ni-MH batteries)				I, **A**				
Production of fuel cells			I, **A**					
PC 37: Water treatment chemicals								I
PC 2: Adsorbents			F, I		F			

Main types of applications structured by product or article types	EC 209-599-5	EC 213-034-8	EC 215-200-5	EC 231-099-0	EC 233-237-5	EC 233-238-0	EC 237-252-8	EC 238-510-2
PC 9a: Coatings and paints, thinners, paint removes			F, I, **P, C**					
PC 9b: Fillers, putties, plasters, modelling clay			F, I					
PC 9c: Finger paint			F, I					
PC 31: Polishes and wax blends			F, I, **P, A**				F, I, **P** (polishing powders)	
PC 15: Non-metal-surface treatment products			F, I, **P**				I, **P**	
PC 14: Metal surface treatment products			F, I, **P**	I, **A**				I
PC 29: Pharmaceuticals and health care products	I		F, I					
PC 21: Laboratory chemicals		I	F, I		I	I		
PC 19: Intermediate	F, I	F, I	F, I		F, 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

* Used in the production of granulate or magnets from alloy powders, i.e. not really uses as lubricants or metal working fluids. Probably refers to metallurgic processes.

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

Data extracted on 10 March 2021

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