Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

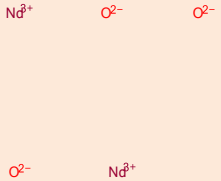
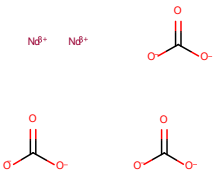
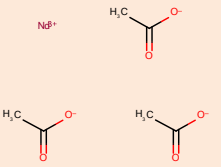
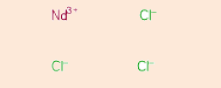
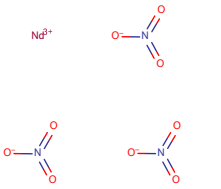
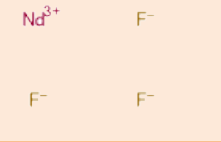
Group Name: Neodymium compounds

General structure: -

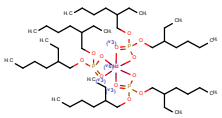
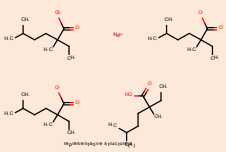
Revision history

Version	*Date*	*Description*
1.0	4 May 2023	

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]
215-214-1	1313-97-9	Neodymium oxide		Full, 100-1000
227-579-4	5895-46-5	Dineodymium tricarbonate		Full, >1000
228-244-5	6192-13-8	Neodymium(3+) acetate		Full, not (publicly) available
231-109-3	7440-00-8	Neodymium		Full, 100-1000
233-031-5	10024-93-8	Neodymium trichloride		Full, not (publicly) available
233-153-9	10045-95-1	Neodymium trinitrate		Full, not (publicly) available
237-253-3	13709-42-7	Neodymium trifluoride		Full, not (publicly) available

[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]
237-610-3	13864-04-5	Neodymium trihydride		OSII or TII
240-514-4	16469-17-3	Neodymium trihydroxide		OSII or TII
482-670-8	-	Neodymium di(2-ethylhexyl) phosphate		NONS
600-768-2	106726-11-8	Neodecanoic acid, neodymium salt		OSII or TII
813-175-0	1809272-92-1	Neodymium fluoride oxide, magnesium-doped		Full, not (publicly) available

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.

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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
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the Neodymium element. There are 13 substances in the group (of which 7 with full registration) including neodymium metal, neodymium oxide and salts with trivalent neodymium as the cation and carbonate, acetate, chloride, fluoride, nitrate and hydroxide as the anions. Two of the substances can be considered organometallic. Most of the substances in the group are mono-constituent substances with clear substance identity, one UVCB substance is included.

Some of the substances (e.g. neodymium oxide and neodymium fluoride) are known to exist as nanoparticles but the nanoforms are not reported in any of the registrations. Via the EU Observatory for nanomaterials, we note that some group members are listed in the FR and/or BE Nano inventories (EC 201-353-5, EC 204-155-7 and EC 204-909-5). This information is not reflected in the registration dossiers of these substances[1]. Consequently, there is uncertainty whether those substances are manufactured or imported in the European Union as nanoforms. The REACH Regulation (as amended by Regulation Commission Regulation (EU) 2018/1881) sets out explicit information requirements for nanoforms of substances. Manufacturers and importers of nanoforms should meet these specific information requirements as of 1 January 2020. However, as the registration dossiers currently submitted on the substances do not cover any nanoforms, the present assessment relates only to non-nanoforms.

Other rare earth elements (Lanthanum, Praseodymium and Cerium oxides/salts) are present as impurities in some of the substances, in low concentrations.

Based on information reported in the REACH registration dossiers, the substances in the group are used predominantly in an industrial setting, as an intermediate or raw material, precursor (for the manufacture of other substances), as alloy for the production of permanent magnets or as an alloying element. Other uses include uses as catalysts, pigments, polishing agents, as a binding agent, or luminescent agents. Only four of the substances in the group (neodymium oxide, neodymium, neodymium trinitrate and neodymium trifluoride) have any professional, or service life uses that could give rise to the potential for release and exposure. Out of these only one substance (neodymium oxide) has consumer uses in coatings, paints and thinners and paint removers. Furthermore, although neodymium has article service life uses (from use in permanent magnets), there is no particular evidence that neodymium would be release from such articles. As such, the potential for exposure for most members of the group is limited.

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 no need for regulatory risk management action at EU level

Based on currently available information, there is no need for (further) EU regulatory risk management for all substances in the group.

Regarding skin sensitisation, mutagenicity and carcinogenicity, reproductive toxicity and ED, and repeated dose toxicity, there is no or unlikely hazard.

Because there are consistently negative skin sensitisation data available for ECs 227-579-4, 215-214-1, 237-253-3, 228-244-5, 233-031-5, 813-175-0, 482-670-8, and 600-768-2, no skin sensitisation potential is expected for any of the substances in the group. EC 231-109-3 is classified as a skin irritant 2, and thus restricted under Annex XVII, entry 75, for use in tattoo inks and permanent make up.

Furthermore, *in vitro* and/or *in vivo* genotoxicity data are available for all substances, except ECs 231-109-3, 228-244-5, 233-031-5, and 237-610-3. All available data were negative, except for one OECD TG 475 study performed with EC 215-214-1 (however, this study shows deficiencies that question the reliability of the observed positive results). Although no information was available on carcinogenicity, it is considered an unlikely hazard based on the negative mutagenicity data.

Overall, there is very limited information available to inform on reproductive toxicity and repeated dose toxicity at the group level. Most substances in the group are not subject to information requirements informing on reproductive/developmental toxicity due to their registration status (i.e., intermediate registrations, low tonnage). On the remaining substances, only one OECD TG 422 study is available

on neodymium oxide (EC 215-214-1) which shows no indications of effects on reproduction/development. The results of the few repeated dose toxicity studies available (OECD TG 422 study on EC 215-214-1 and OECD TG 407 study on EC 482-670-8) do not indicate effects on reproductive organs. With regard repeated dose toxicity, available sub-acute studies indicate limited adverse effects following administration of EC 233-031-5 (OECD TG 401: clinical effects at 5068 mg/kg bw and effects on the stomach with surrounding tissues at 3980 mg/kg bw) and EC 600-768-2 (EG 84/449 and OECD TG 401: clinical and stomach effects at 1000-2000 mg/kg bw). Adverse effects were also observed with EC 215-214-1 (OECD TG 422: clinical observations, neurotoxicity, reduction in bodyweight gain during lactation at 1000 mg/kg bw. Haematology/clinical chemistry changes at ≥300 mg/kg/day) and EC 482-670-8 (OECD TG 407: hypersalivation, reduced white blood cells, increased liver weight (male) and abnormal hind limb spread at 1000 mg/kg bw. At ≥150 mg/kg bw and ≥450 mg/kg bw, respectively stomach and liver anomalies were observed. These effects do not warrant classification as STOR RE.

While the conclusion of unlikely hazard for repeated dose toxicity, reproductive toxicity and ED (whether for human health or environment) is extrapolated to the whole group, this conclusion is subject to high uncertainty due to the limited data available and differences in water solubility between the substances. The conclusion will need to be clarified, when possible, through further data generation under compliance check (CCH). Neodymium (EC 231-109-3), registered at 100-1000 tpa, is a pyrophoric substance and therefore no relevant data can be generated. For neodymium oxide (EC 215-214-1), registered at 100-1000 tpa, a PNDT study in a first species and a 90-day repeated dose toxicity study were requested under CCH (currently under enforcement). Therefore, CCH is not proposed for this substance and CCH is proposed only for the following group members: EC 227-579-4 and EC 237-253-3.

The substances of this group are inorganics or organometallics. For those substances which are considered as “inorganic”, the PBT/vPvB assessment does not apply. The only organometallic substances (i.e. neodymium acetate, EC 228-244-5) is a salt and the counter ion does not raise any concern with regard PBT/vPvB.

Available chronic aquatic toxicity studies show that neodymium trinitrate (EC 233-153-9) fulfils the criteria for classification as Aquatic Chronic 1 (M-factor 1). This is based on the results of an OECD TG 210 study showing a 28d-NOEC of 20 µg/L (based on weight reduction). The registrants of EC 233-153-9 correctly self-classified the substance.

EC 233-153-9 is a well soluble substance (water solubility reported as 1000 g/L) and this value could be regarded as the chronic ecotoxicity reference value (ERV) for neodymium compounds. Considering that the chronic ERV is low compared to the relative solubility of most neodymium compounds, it is considered that all substances from the group should be considered to have a potential for (chronic) aquatic toxicity and should be subject to classification as Aquatic chronic 1. It is also hypothesised that the counter ion would not impact aquatic toxicity to a significant extent in most cases (with the exception of ECs 237-253-3 and 813-175-0). This conclusion is subject to higher uncertainty for sparingly soluble neodymium compounds. Therefore, this conclusion will need to be confirmed, when possible, through further data generation under compliance check (CCH). As a result, CCH is proposed for ECs 227-579-4, 237-253-3 and 813-175-0.

The classification criteria for Aquatic Chronic 1 (M-factor 1) are met for well soluble neodymium compounds but no self-classification is reported in the registration dossier(s). Industry is invited to consider updating the registration dossiers with

adequate classification and labelling information of the substance(s) with aquatic toxicity and inform accordingly the users of these substances (via SDS update).

Depending on the outcome of data generation and whether adequate self-classification is applied by registrants, further need for CLH as aquatic Chronic 1 may need to be considered.

The substances within the group are used predominantly in industrial uses, including uses as intermediates or raw materials to produce other chemicals. Consumer uses limited to one substance in coats, paints, and thinners, with some professional uses in lab chemicals, polishes/waxes and article service life in permanent magnets/magnetic elements that may give rise to widespread exposure. Article service life in magnets may give rise to consumer exposure for some of the substances. Therefore, depending on the outcome of the compliance check for reproductive toxicity and repeated dose toxicity endpoints, additional EU RRM may be necessary for (some) members of the group.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
215-214-1 **227-579-4** **228-244-5** **231-109-3** **233-031-5** **233-153-9** **237-253-3** **237-610-3** **240-514-4** **482-670-8** **600-768-2** **813-175-0**	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity	Predominantly industrial uses, including uses as intermediates or raw materials for the production of other chemicals. Consumer uses limited to one substance in coats, paints, and thinners (215-214-1), with some professional uses in lab chemicals, polishes/waxes (215-214-1, 233-031-5, 233-153-9, 237-253-3) and article service life in permanent magnets/magnetic elements (231-109-3) that may give rise to exposure.	**Currently no need for EU RRM** <u>Justification:</u> Currently available toxicological data do not raise concern. However, this conclusion is based on limited data available and will need to be confirmed, when possible, through data generation. There is sufficient information to indicate that all members of the group are, or are	**First step:** CCH for EC 227-579-4, EC 237-253-3 and 813-175-0 Pending Action – CCH ongoing For EC 215-214-1

EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				likely to be, toxic to the aquatic environment leading to classification as Aquatic chronic 1. Data generation, when possible, is needed in order to confirm the hazard for sparingly soluble group members.	

Annex 1: Overview of classifications

Data extracted on 12/09/2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
215-214-1	1313-97-9	neodymium oxide	-	-
227-579-4	5895-46-5	dineodymium tricarbonate	-	-
228-244-5	6192-13-8	neodymium(3+) acetate	-	-
231-109-3	7440-00-8	neodymium	-	Flam. Solid 2 H228
233-031-5	10024-93-8	neodymium trichloride	-	Self Heat. 1 H251
233-153-9	10045-95-1	neodymium trinitrate	-	Skin Irrit. 2 H315
237-253-3	13709-42-7	neodymium trifluoride	-	Eye Irrit. 2 H319
237-610-3	13864-04-5	neodymium trihydride	-	Eye Damage 1 H318
240-514-4	16469-17-3	neodymium trihydroxide	-	Aquatic Chronic 3 H412
482-670-8	-	482-670-8	-	Met. Corr. 1 H290
600-768-2	106726-11-8	600-768-2	-	Eye Damage 1 H318
813-175-0	1809272-92-1	tetraneodymium hexafluoride trioxide, magnesium doped, orthorhombic	-	Aquatic Acute 1 H400

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

Data extracted on 18.11.2022

Main types of applications structured by product or article types	EC/List 215-214-1	EC/List 227-579-4	EC/List 228-244-5	EC/List 231-109-3	EC/List 233-031-5	EC/List 233-153-9	EC/List 237-253-3	EC/List 813-175-0
REACH Annex	IX	X	VII	IX	VII	VII	IX	VII
PC 2: Adsorbents	F							
PC 35: Washing and cleaning products				I				
PC 29: Pharmaceuticals					I			
PC 31: Polishes and wax blends	I						I, P	
PC 32: Polymer preparations and compounds	I							
PC 9a: Coatings and paints, thinners, paint removes	I, C	F		I				I

PC 18: Ink and toners	I							
PC 14: Metal surface treatment products				F, I				
PC 7: Base metals and alloys	F, I	F, I		F, I, **A**			I	
PC 21: Laboratory chemicals				F, I	**P**			
PC 19: Intermediate	F, I, **P**	I	I	F	I	F, 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

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

Data extracted on 19/12/2022

EC / List number	RMOA	Authorisation		Restriction *	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
231-109-3				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 of the group.