



Environmental Read-across Approach

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The purpose of this document is to describe approaches taken by the Ni REACH Consortia for addressing risks of exposure to Ni from compounds that contain Ni and potentially other metals. The first approach addresses the need for read across of Ni ecotoxicity and environmental fate data that originate from studies on different soluble Ni substances. This approach applies to all substances where the basis of risk assessment is the release of the Ni ion. The second approach addresses the need to utilize relevant ecotoxicological data from other metals in the assessment of risk. This approach applies to substances that release Ni ions as well as ions of other metals.

Nickel Metal and Nickel Compounds

The approach for determining the relevant environmental fate and ecotoxicity effects data for Ni metal and Ni compounds is based on the observation that adverse effects to aquatic, soil- and sediment-dwelling organisms are a consequence of exposure to the bioavailable Ni-ion, as opposed to the parent substances. Hence, Ecotoxicity Reference Values (ERVs) for metals are derived using data from several soluble metal substances, and in most cases, are based on the dissolved metal concentration, not the parent substance. The basis for this approach is that the parent substances (e.g., NiCl₂, NiSO₄, and Ni(NO₃)₂) all release the same toxicologically relevant metal ion (i.e., Ni²⁺). Therefore, the toxicities of the parent substance will be the same when normalized to the concentration of the free metal ion. On this basis, all reliable data from tests performed with soluble nickel substances that report toxicity as a function of dissolved Ni were considered to be relevant. Data on ecotoxicity of dissolved Ni to aquatic organisms, sediment dwelling organisms, and terrestrial organisms are identified in the IUCLID entries and CSR dossiers for every Ni substance. Hence, Predicted No-Effects Concentrations (PNECs) were derived using dissolved Ni concentrations from all available, relevant ecotoxicity tests. This read-across approach is applied to the following endpoints:

- Aquatic toxicity
- Sediment toxicity
- Terrestrial toxicity
- Bioaccumulation
- Adsorption/Desorption

In this assessment, the aquatic toxicity classification of Ni metal and Ni compounds is derived by comparing the reactivity of the substance with the toxicity reference values for soluble nickel. The rate and extent to which the Ni substance reacts with the media to transform to water soluble forms is measured using the OECD Transformation/Dissolution test (Annex 10 to UN GHS). Resulting classifications are based on a comparison with the respective ERVs. In the case of Ni, acute ERVs are



available for pH 6 and pH 8, and a single chronic ERV is available. The acute ERV at pH 6 is based on available ecotoxicity data for an algal species, *Pseudokirchneriella subcapitata*, while the pH 8 and chronic ERVs is based on available ecotoxicity data for the invertebrate *Ceriodaphnia dubia* (<http://ecb.jrc.ec.europa.eu/>). The Ni ERVs are as follows:

Acute	pH 6	<i>P. subcapitata</i>	120	µg/L
Acute	pH 8	<i>C. dubia</i>	68	µg/L
Chronic	pH 8	<i>C. dubia</i>	2.4	µg/L

Substances that are classified in the 1st ATP to the CLP regulation are registered using the harmonized classification. No changes to harmonized classifications are proposed within the registration files; however, in the cases where additional data (e.g., T/D P results) suggest a different classification, text describing the appropriate classification and the supporting tests results are included in the registration files (e.g., IUCLID Section 5).

Isolated Intermediates

Ni substances being registered as a transported isolated intermediates under REACH do not require data on acute and chronic toxicity to fish, toxicity to aquatic plants, toxicity to micro-organisms, sediment toxicity, and terrestrial toxicity.

Where no definitive acute toxicity test data (LC50 or EC50) are available, the classification of the intermediate is based on acute and chronic toxicity for the individual components of the intermediate. According to ECHA Guidance to Regulation (EC) No 1272/2008 on classification, labeling and packaging (CLP) of substances and mixtures, for circumstances where no or inadequate test data are available for a mixture or a complex substance, the classification can be determined based on sufficient data for individual components.

The assessment of aquatic toxicity for intermediates is based on the observation that adverse effects to aquatic organisms are a consequence of exposure to the bioavailable metal ions, as opposed to the parent substances. Hence, ERVs for metals are derived using data from several soluble metal substances, and in most cases, are based on the dissolved metal concentration, not the parent substance. The basis for this approach is that the parent substances (e.g., NiCl₂, NiSO₄, and Ni(NO₃)₂) all release the same toxicologically relevant metal ion (i.e., Ni²⁺). Therefore, the toxicities of the parent substance will be the same when normalized to the concentration of the free metal ion. On this basis, data from tests performed with soluble nickel substances that report toxicity as a function of dissolved Ni were considered to be relevant. Data on acute toxicity of dissolved Ni to invertebrates and aquatic algae, as well as chronic toxicity data of dissolved Ni to invertebrates, are identified in the IUCLID entries. Relevant toxicity data for copper, cobalt, and iron are based on published or readily available ERVs.



In this assessment, the aquatic toxicity classification of intermediates is derived by comparing the Transformation/Dissolution data for the intermediate with the acute and chronic toxicity reference values for the appropriate soluble metal compounds. This approach is outlined in the classification schemes for metals and metal compounds described in European Union (EU) and United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (United Nations, 2009). The rate and extent to which the intermediate reacts with the media to transform to water soluble forms can be measured using the OECD Transformation/Dissolution test (Annex 10 to UN GHS). Resulting classifications are based on a comparison with the respective ERVs, as well as the summation of the net toxic effect using the Toxic Unit (TU) approach. The TU approach assumes that toxicity following exposure to multiple metals is additive.

Substances that are classified in the 1st ATP to the CLP regulation are registered using the harmonized classification. No changes to harmonized classifications are proposed within the registration files; however, in the cases where additional data (e.g., T/D P results) suggest a different classification, text describing the appropriate classification and the supporting tests results are included in the registration files (e.g., IUCLID Section 5).

Data Package

The studies used for the Environmental Fate Pathways and Ecotoxicological Assessments are provided in I5z format. In addition to all relevant high quality vertebrate studies, the Environmental I5z file contains relevant, high quality key studies used in the environmental assessment. Key studies are defined as any study used for classification or in the development of PNECs. Note that PNEC values are derived from the Species Sensitivity Distributions (SSD) for each environmental compartment. As described above, relevant ecotoxicity data for all soluble metal substance in which toxicity is based on the dissolved metal ion were combined to develop SSDs for each compartment. More information on the derivation of PNEC values is provided in the PNEC Derivation document.