

## Guidance in metals and inorganic substances

### Introduction

Most of the guidance on testing and evaluation for REACH, and indeed the test methods themselves, is aimed at organic chemicals. If registering metals and other inorganic substances, testing and evaluation will be 'different'; in many cases, endpoints will not be possible to assess. Even substance identity is not without issue – crystal form, impurities, mixtures, for example, must be considered.

ECHA's [Endpoint Specific Guidance](#) does, however, provide some good information regarding the hazard and risk assessment for metals. Even if you need to register inorganic non-metals, the concepts and principles in this guidance should prove useful in the evaluation of hazard and exposure data.

This concise REACHReady guidance document has been prepared to address some of the issues our subscribers have asked the Helpdesk regarding metals and inorganic substances and REACH.

### Inorganic Substances: Substance Definition

Many inorganic substances, such as single-element metals and anhydrous salts, may be easier to define than organic substances. However, in the same way that organic molecules may have different isomers or molecular weight variation, inorganic substances can have different crystal forms or even isotopes that define materials as different substances. Likewise, there can be mixed-element crystals, surface treated materials and other 'special cases' to consider.

### What to register: mono- or multi-constituent substances?

Many inorganic chemicals can be considered either as a pure substance, a mixture, or a multi-constituent substance. Deciding on the correct definition is not easy and there may be many commercial, as well as technical, considerations.

The decision to register a multi-constituent substance or a number of individual component substances will depend on various factors. If justifiable, a single registration for a multi-constituent substance could be easier than submitting one for each of the components. However, if there is a large SIEF for each individual component, there may be more registrants to contribute to the registration work and lead to lower individual data costs. Even the additional ECHA registration fees for multiple substance registrations may be cheaper and easier than registering a multi-constituent substance in a smaller SIEF.

Alloys are regarded as mixtures of metals: only the individual chemical elements in the alloys are subject to registration. However, it needs to be understood whether any trace materials present are a functional part of the alloy and may require registration, or whether they are impurities.

Note that to register a multi-constituent substance with several distinct components, the product needs to form during a reaction process and is not mixed or blended from the component materials after production. Examples will include inorganic materials that form a complex crystal lattice that is effectively a single substance when formed.

## Evaluate the substance or its ions?

For metal salts, read-across is often relatively easy as it is usually the toxicity or environmental effects of specific ions that are significant: it is often possible to read across data from different salts or from blends. Justification for use of surrogate data is required, but caution must be taken before performing new testing.

Bulk metals, such as iron, cannot be directly tested for toxicity, but solutions of iron chloride would provide a surrogate for testing. Likewise, there is perhaps limited need to test sulphuric acid for systemic long-term toxic effects if there are data on calcium sulphate (gypsum). The only way to test for sub-acute toxicity on sulphuric acid, for example, is to buffer the pH effects or dose at very low concentrations; at low concentrations, natural minerals in the body such as sodium, potassium and calcium will form sulphate salts anyway.

## Surface treated – substance or mixture?

Specific guidance has been given to confirm that clays, silica and other amorphous materials that are reacted with active chemicals to provide surface treated materials can neither be regarded as preparations nor be defined by the criteria of the [Guidance for identification and naming of substances](#) under REACH.

Chemically surface treated substances should not be registered as such under REACH, but the following requirements should be fulfilled:

1. Registration of the basis substance (macroscopic particle)
2. Registration of the surface treating substance
3. Description of the use “surface treatment” in the registration dossier of the surface treating substance and in the registration dossier of the basis substance
4. Any specific hazards or risks of the surface treated substance should be appropriately covered by the classification and labelling and by the chemicals safety assessment and resulting exposure scenarios.

This decision was made under the old Notification system (Directive 67/548/EEC) and is described in the ECHA Q&A [No. 0038](#) but is not in the REACH legal text.

Therefore, if manufacturing or importing a reacted clay, the starting bulk material (clay) needs to be considered as a substance (itself a combination of various minerals) and the substances stuck to the surface also need their own registration.



The good news for some is that some of these clays may be exempt under Annex V if natural and non-hazardous. Either way, classification and labelling of the supplied material will rely on the estimates for mixtures in the Classification, Labelling and Packaging (CLP) Regulation (EC) 1272/2008.

## Preparing a risk assessment and correct classification for supply

The registration process for substances is a regulatory activity and does not always follow intuition, but when determining the risk of the inorganic material in terms of actual hazard and exposure, the real properties of the material must be considered. This consideration needs to consider the solubility and bioavailability, particle size, dissociation properties and so on. This scientific evaluation may in turn impact on the classification – the calculations described in CLP.

## So what to do?

The simple answer is to proceed through registration using good scientific practice. In the case of metals, the elemental substances should be registered: remember that REACH does not require registration of mixtures such as alloys.

Although the physical properties of mixtures may appear to have little in common with the constituents (e.g. the property of steel is not the same as iron, carbon, molybdenum and other starting materials), biological properties are generally possible to determine from considering the atoms (ions) present. Therefore, the physical and biological properties may need to be assessed on completely different sources of material.

Therefore, decide on substance identity based on the dissociated and separated constituents and evaluate the data on each of these. Like polymers, where the monomers and other starting reagents must be registered and assessed, the hazards and risk associated with the constituents of any mixture (e.g. the constituent metals of an alloy) will be greater than those of the mixture or alloy itself. Therefore, testing and evaluation of the components will provide a reasonable margin of safety in terms of direct hazards and exposure risks. In addition, any later assessment of the mixture, and development of controls for it, can consider the special way the constituent substances behave when in the form of a mixture or alloy.

It is worth attempting to obtain as much data as possible from the first Registrant as possible; even if this costs more to purchase access, sharing data will in the long term save time and money. Agreement on the value of data is, of course, a commercial process.



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## Need further help?

If you need help understanding the impact of REACH on your business, you can get advice by emailing our Helpdesk at [enquiries@reachready.co.uk](mailto:enquiries@reachready.co.uk) or calling +44 (0) 207 901 1444.

If your customers or suppliers need help, get them to sign up to REACHReady's Gold service at <http://www.reachready.co.uk/> and let us help them too!

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