

# Guidance *Fact Sheet*

## GUIDANCE FACT SHEET

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# Guidance for identification and naming of substances under REACH

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A Guidance Fact Sheet provides a short summary of the key aspects of the respective REACH Guidance Document including bibliographic information and other references.

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## Guidance Fact Sheet

Guidance for identification and naming of substances under REACH

### WHO SHOULD READ THE GUIDANCE DOCUMENT?

The Substance Identification Guidance Document is intended for companies who manufacture in, or import chemical substances into, the European Union. The document is also a relevant source of information for those companies outside the European Union whose products are exported to the EU.

Readers should have an appropriate knowledge of chemistry and regulations in order to fully benefit from the guidance document.

### WHAT IS THIS GUIDANCE ABOUT?

The Guidance Document aims to give clear guidance on how to name and record the identity of a substance within the context of REACH.

A correct and consistent identification substance is a cornerstone of the REACH Regulation. The name and substance identity are the bases for formation of SIEFs (Substance Information Exchange Forum) data sharing and joint submission of data by multiple registrants. Proper understanding of the identity of a substance is also vital when the Agency receives inquiries relating to a substance.

In addition, within other REACH processes such as substance evaluation, classification and labelling harmonisation, authorisation and restriction, discussions on the identity of a substance may occur.

The Guidance Document provides technical guidance on:

- how to give a chemical name to a substance
- when substances may be regarded as the same for the purpose of REACH

It also provides advice on when a substance is a mono- or multi-constituent substance or whether it needs to be

described by additional identifiers such as composition, structure, source or process.

### WHAT IS THE STRUCTURE OF THE GUIDANCE DOCUMENT?

The two first chapters cover the objectives, scope and terminology used in the guidance document. The framework for substance identification and naming and how to do it in practice are given in Chapters 3 and 4.

The subsequent three chapters provide specific guidance for various substance types, as a set of rules with explanations and examples. Finally, Chapter 8 explains the description of substances in IUCLID 5.

The first Appendix lists links to relevant tools to support substance characterisation and checking of its chemical identity. The second provides background information on the nomenclature rules, EC numbers, CAS numbers, notations of molecular and structural formula, and analytical methods.

### KEY TERMS USED IN THE GUIDANCE DOCUMENT

#### Substance

In REACH, a substance is defined as “a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.”

The substance definition in REACH is identical to the definition of a substance that is currently used under the 7th Amendment of the Dangerous Substances Directive (Directive 92/32/EEC amending Directive 67/548/EEC). In both cases, the definition goes beyond a pure chemical compound defined by a single molecule.

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#### Substance Identification

A substance is completely identified by its qualitative and quantitative chemical composition, the chemical identity and the content of each constituent in the substance. When performing the substance identification parameters listed in Annex VI, section 2 of REACH must be used for a proper description of a substance.

a substance. They are further explained in this guidance document and illustrated with examples.

#### Naming of a substance

The approach to identifying a substance depends on the substance type. Substances can be divided into two main groups as described in Chapter 4:

1. **“Well defined substances”**: Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex VI, section 2. Rules for identification and naming for “well defined substances” differ according to whether there is one main constituent or more than one main constituent: the so-called “mono-constituent” versus “multi-constituent” substances.
2. **“UVCB substances”**: Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently identified based on the composition as is the case for well-defined substances. For the various substance types under the umbrella of “UVCB”, different identification and naming rules are described in this guidance document.

#### Criteria for checking if substances are the same

When different manufacturers/importers need to check whether or not their substances can be regarded as the same, they should respect the given rules. These rules, which were applied for establishing EINECS, should be regarded as a common basis for identifying and naming

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### LINKS TO RELATED MATERIAL

[REACH Regulation](#) EC No 1907/2006

[REACH Guidance](#) website is a single point of access to general and detailed technical guidance on REACH.

[REACH Guidance Fact Sheets](#) can be found in the publications section of the ECHA website.

### BIBLIOGRAPHIC INFORMATION OF THE GUIDANCE DOCUMENT

**Guidance for identification and naming of substances under REACH** can be downloaded from the ECHA website. The document is available in English.

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