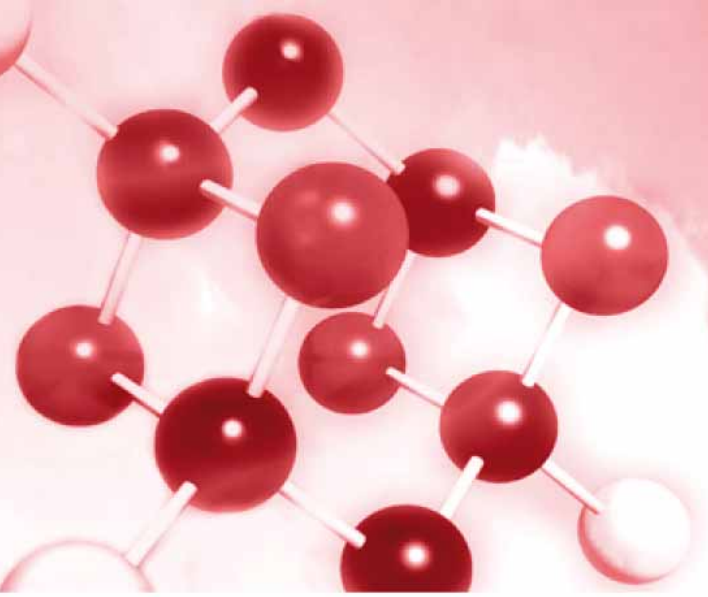

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# Guidance for identification and naming of substances under REACH and CLP

**The European Chemicals Agency (ECHA) has issued a series of Fact Sheets which provide a structured overview of each REACH guidance document published by the Agency. These documents are available in the following 22 languages:**

*Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish*

**A Guidance Fact Sheet provides a short summary of the key aspects of the respective REACH (CLP) guidance document including bibliographic information and other references.**

**If you have questions or comments in relation to this Fact Sheet please send them by e-mail to info@echa.europa.eu quoting the Fact Sheet reference, issue date and language version, shown above.**

## WHO SHOULD READ THE GUIDANCE DOCUMENT?

The guidance document for identification and naming of substances under REACH and CLP 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 and CLP.

A correct and consistent identification of a substance is a cornerstone of the REACH and CLP Regulations. The name and substance identity are the basis 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, authorisation and restriction) and CLP processes (such as notification to the Classification and Labelling inventory and harmonisation of Classification and Labelling) 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 and CLP

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

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. The third Appendix shows the main changes made in each new version of the guidance.

## KEY TERMS USED IN THE GUIDANCE DOCUMENT

### Substance

In REACH and CLP, 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.*"

### 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, the parameters listed in Annex VI, section 2 of REACH must be used for a proper description of a substance.

### 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. Four main sub-types of UVCB are identified in the 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 a substance. They are further explained in this guidance document and illustrated with examples.

## INQUIRY

For non phase-in substances, or phase-in substances that have not been pre-registered, the potential registrants have the duty to inquire from the Agency whether a registration has already been submitted for the same substance as they intend to register. This inquiry must contain information on the identity of the potential registrant, the identity of the substance and on which new studies would be required by the potential registrant to comply with the information requirements.

## LINKS TO RELATED MATERIAL

REACH Regulation EC No 1907/2006.

CLP Regulation EC No 1272/2008.

REACH Guidance website is a single point of access to general and detailed technical guidance on REACH.

Guidance in a nutshell documents are aimed at managers and decision-makers and explain the main elements of the full Guidance documents in simple terms.

ECHA database of Frequently Asked Questions contains questions and answers on specific aspects of REACH.

## BIBLIOGRAPHIC INFORMATION OF THE GUIDANCE DOCUMENT

The **Guidance for identification and naming of substances under REACH and CLP** can be downloaded from the ECHA website.

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