

Classifications of Chemicals Regulated Under REACH

REACH groups substances based on prior legislation, as follows:

Phase-in substances, which meet at least one of the following three criteria:

- a) Existing chemical, which was on the market between 1 January 1971 and 18 September 1981, and is currently listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). [About 100,106 substances, of which an estimated 30,000 substances of 1 tonne per year or more. Some EINECS substances are only identified by broad descriptions.]
- b) Not placed on the market in the 15 years prior to 1 June 2007, even though manufactured in the EC (or in countries acceding to the EU on 1 January 1995 and 1 May 2004), and the manufacturer has documented evidence.
- c) No-longer polymer (NLP) substances were excluded from reporting to EINECS and notified under Directive 67/548/EEC (per a change in definition of 'polymer' in 7th amendment), and were placed on the market in the EC (or in countries acceding to the EU on 1 January 1995 and 1 May 2004) before 1 June 2007 by a manufacturer or importer, who has documented evidence. Substances that fulfill the NLP criteria but are not on the list are also considered NLPs.
[Note: For phase-in substances imported or manufactured for three consecutive years, quantities per year are based on average volumes for the three preceding calendar years.]

Notified substances, which are "new chemical" substances placed on the market since 18 September 1981, and for which a notification was submitted under pre-REACH chemical Directive 67/548/EEC. Notified substances contained in the European List of New Chemical Substances (ELINCS), are considered registered for REACH by the submitting companies (Article 24), and will be assigned REACH registration numbers by 1 December 2008. [Includes about 3,700 substances.] The Agency will publish a list of these pre-registered substances by 1 January 2009.

[Note: After REACH enters into force, as substances not previously identified are first registered for REACH, the Agency will add them to the inventory of chemicals and assign an EC number.]

REACH applies additional requirements to some substances due to their hazardous properties:

Substance of very high concern (SVHC) [est. 1,500 substances] to be set by REACH, to include:

- ❑ Carcinogenic, mutagenic, or reproductive toxics (CMRs) in category 1 and 2, CMRs are classified in three categories, and only two categories of substances for which there are high levels of evidence of health damage to humans are substance of very high concern under REACH.
- ❑ Persistent bioaccumulative toxics (PBTs) as defined by criteria in REACH Annex XIII, including: persistence as a half-life in marine water >60 days, in fresh water >40 days, in marine sediments >180 days, and in fresh water or estuarine sediments or soil >120 days. Bioconcentration factor of >2,000. Toxicity as having a no-observable effect concentration for marine or freshwater organisms <0.01 mg/l, or CMR 1, 2, or 3 substance, or other evidence of toxicity by classification T, R48 or Xn, or R48 per Directive 67/548/EEC (REACH page 348).
- ❑ Very persistent, very bioaccumulative (vPvB) substances as defined by criteria in Annex XIII.

[Notes: Registration for SVHC must include: exposure assessment, risk characterization, & exposure scenarios. Articles containing SVHC >0.1% require notification (Articles 7, 33) from 1 June 2011, starting 6 months after substance is named a priority substance. Authorisation is to be required for SVHC, in REACH Annex XIV.]

Very Toxic to Aquatic Organisms (R50/53) chemicals may cause long-term adverse effects in the aquatic environment per Directive 67/548/EEC. [Notes: R50/53 substance registrations are due 1 December 2010 for phase-in substances, which were manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer at least once after 1 June 2007 (Article 23(b)).]

Dangerous Substances were originally identified in Annex I of the Classification and Labelling of Dangerous Substances Directive (67/548/EEC), which contains about 7,000 substances (5,000 existing substances and 2,000 new substances).

Additional terms used to describe chemicals under REACH include:

- **Preparation:** A mixture or solution of two or more substances. Both alloys and inorganic catalysts are preparations under REACH, but the individual component metals are substances.
- **Substance:** A chemical element and its compounds in a natural state or produced by a manufacturing process (including additives for stability and any impurities resulting from the originating process) but excluding solvents that can be removed without destabilizing the substance or changing its composition. (Article 3; 7th amendment to Directive 67/548/EEC). The main constituent (e.g., 80% or more by weight) is used to name a substance for REACH, but no differentiation is made for grades (i.e., technical or analytical). Hydrated and anhydrous forms of chemicals having different names and CAS numbers require separate registrations. Impurities at 1% or greater, or affecting the substance classification, must be identified by name, CAS number, EC number, or molecular formula. Additives (i.e., stabilizers, buffers, colourants) must be identified, and typical concentration and concentration ranges reported. [Note: Markedly different impurities from various manufacturing processes may justify separate REACH registrations.]
- **Multi-constituent substances** has several main constituents between 10 and 80 percent by weight as the result of a manufacturing process. However, some multi-constituent substances were registered under their components per Directive 67/548/EEC as “existing substances”, and those will qualify as phase-in substances for REACH. So the existing information on the constituents’ hazards is considered sufficient for REACH. For example, a mix of isomers of difluorobenzenes was covered by individual EINECS entries for 1,2-, 1,3- and 1,4-difluorobenzene, so although the mixture was not listed on EINECS, the mixture of isomers is considered registered for REACH.
- **Substance of unknown or variable composition (UVBCB)** include complex reaction products that are not predictable, and biological materials not sufficiently identified by name, chemical identifiers, molecular structure, or composition. Examples: natural fragrances, dyes, fermentation products, and petroleum distillates. Known constituents in a UVCB at 10% or greater should be identified by English IUPAC name and CAS number, with typical concentration and concentration range. Unknown constituents should be given a generic description of chemical nature. Additives must be fully identified, and typical concentration and concentration range provided.
- **Groups of substances** are substances whose physiochemical, toxicological, and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity (Annex 1(0.4)). Chemical safety assessments carried out by a manufacturer or importer for one substance can be used for other substances in the group, as long as the reuse of the assessment is justified by the manufacturer or importer.
- **Substance which occurs in nature** is a naturally occurring substance, unprocessed or processed only by manual, mechanical or gravitational means, dissolution in water, flotation, extraction with water, steam distillation, or heating solely to remove water, or extracted from air (Article 3(39)).
- **Not chemically modified substance** has a unchanged chemical structure, even after undergoing a chemical process, treatment, or physical transformation, for instance to remove impurities (Article 3(40)). [Note: Minerals are exempt from registration if not chemically modified.]

References for information on REACH chemicals:

Guidance for Identification and Naming of Substances (RIP 3.10) (June 2007)

http://ecb.jrc.it/documents/REACH/RIP_FINAL_REPORTS/RIP_3.10_SUBSTANCE_IDENTITY/substance_id_en.pdf