

## An overview of the consequences of the REACH implementation for the composites industry.

### Substances, Articles and Preparations

The basis of the REACH regulation is the description of human health and environmental risks of chemical *substances*. Substances do exist on their own, but may also occur in the form of a component in a *preparation* or they may be contained in an *article* from which they may be released during use.

REACH defines these three items as follows:

#### Substance

*Substance* means 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.

#### Preparation

*Preparation* means a mixture or solution composed of two or more substances

#### Article

*Article* means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

Let us go somewhat deeper in the consequences of these definitions.

### Identification of a substance

For a proper registration under REACH it is of paramount importance to identify a substance correctly and unambiguously. This is not always very easy. There are a number of tools however, that makes proper identification of the substance easier.

Many chemical substances are rather straight forward with a well defined chemical formula and structure. Examples are substances like styrene, acetone and ethylene glycol. after the principal constituent in the substance.

Another group of well defined chemical substances are those that occur in the form of mixtures of different chemicals. Examples

are substances like styrene, acetone and ethylene glycol. These substances are called *mono-constituent* substances. As a general rule, the main constituent is present to at least 80% (w/w). The substance is named after the principal constituent in the substance.

Another group of well defined chemical substances are those that occur in the form of mixtures of different chemicals. Examples are mixtures of isomers of xylene. In this case the substances are called *multi-constituent* substances. As a general rule the main constituent is present in a concentration between 10% (w/w) and 80% (w/w).

Although such a straight-forward identification may be possible for most substances, certain substances cannot be sufficiently identified by the above parameters. These substances belong to the very heterogeneous group of so-called *UVCB substances*. UVCB substances are "substances of Unknown or Variable composition, Complex reaction products or Biological materials". Examples are natural fragrances, enzymes, fermentation products, fractions or distillates from crude oil, etc.

A separate Technical Guidance document on substance identification can be found at the website of the European Chemical Agency under the following link:

[http://reach.jrc.it/docs/guidance\\_document/substance\\_id\\_en.pdf](http://reach.jrc.it/docs/guidance_document/substance_id_en.pdf)

### EC inventory of Substances

There are three separate inventories under the previous chemicals regulatory framework. These were the European Inventory of Existing Commercial Chemical Substances (EINECS), the European List of New Chemical Substances (ELINCS) and the No-Longer Polymers (NLP) list. Substances on the European market *between 1<sup>st</sup> January 1971 and 18<sup>th</sup> September 1981* are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

There are roughly 100.000 different substances mentioned in the EINECS inventory.

Substances notified and placed on the market *after 18<sup>th</sup> September 1981* are listed in the European List of New Chemical Substances (ELINCS).

*Polymers were excluded* from reporting to EINECS. However, in 1992 the term “polymer” was further defined in an amendment of Directive 67/548/EEC. As a consequence of the implementation of this definition, some substances which were considered to be polymers under the reporting rules for EINECS are no longer considered to be polymers under the 7th amendment. These substances were placed on the “No-Longer-Polymers” list (NLP-inventory).

These three lists of substances, EINECS, ELINCS and the NLP-list, in combination are called

the *EC Inventory*. Each substance in this inventory has an EC number allocated by the European Commission.

The EC Inventory can be used as a tool for manufacturers and importers to decide whether a substance is a phase-in substance or a non-phase-in substance. Thus, the EC Inventory will help manufacturers and importers to find out *when* the registration of a substance will be required, and if a pre-registration or an inquiry is necessary.

If a substance is listed on *EINECS* or on the *NLP-list* the substance is considered to be a phase-in substance for any manufacturer or importer.

If a substance was previously notified in accordance with Directive 67/548/EEC and is, thus, listed in *ELINCS*, the notification submitted shall be regarded as a registration for the purpose of REACH. These substances are considered to be already registered by the relevant manufacturer or importer and require no initial registration from this manufacturer/importer.

### CAS number

CAS numbers are unique numerical identifiers for chemical compounds, polymers, biological sequences, mixtures and alloys. They have been developed by the *Chemical Abstracts Service* (CAS), a division of the *American Chemical Society*. CAS numbers can also be used to identify a substance.

Other tools to describe substances is by molecular or structural formula.

### Preparations

Preparations are basically physical mixtures of two or more substances. Many commercial products in the composites industry are in fact preparations.

Examples are gel coat formulations, organic peroxides, polyester resins dissolved in styrene etc. In the latter case the UP resin itself is most cases a polymer, so it does not have to be registered by the manufacturer or the importer. Most commercial resin formulations contain several substances, like styrene, cobalt octoate, fumed silica as thixotropic agent, UV stabilizers, etc. Each substance has to be registered separately by its manufacturer or importer provided the quantity involved is more than 1 tone per year.

### Articles

Articles are only relevant in as far substances are intentionally released from the article during its use. If the substances being released from the articles are exceeding the quantity of 1 ton per year per manufacturer/importer, these substances have to be registered.

It is important to define adequately what exactly is the use of an article. There is still quite some debate how to interpret the definition of an article and what exactly is intended use.

The ECHA has issued a draft technical guidance document about substances in articles. It can be found under [http://ecb.jrc.it/documents/REACH/RIP\\_FINAL\\_REPORTS/RIP\\_3.8\\_ARTICLES/RIP\\_3.8\\_Final\\_report\\_Draft\\_TGD\\_May\\_2006.pdf](http://ecb.jrc.it/documents/REACH/RIP_FINAL_REPORTS/RIP_3.8_ARTICLES/RIP_3.8_Final_report_Draft_TGD_May_2006.pdf). The definite report on the requirements for substances in articles is expected in the coming months.