Biosolve Chimie

REACH at BIOSOLVE CHIMIE

As a leading company which produces and distributes selected high purity solvents, reagents and formulations for the research, pharmaceutical and biotechnology industries, Biosolve Chimie has taken all necessary actions to insure supplying our products in Europe under the REACH regulations:

- We are familiar with the regulatory framework of REACH
- We have pre-registered all substances, which are within the scope of REACH
- We ensure successful REACH implementation for all our products.
- We will continue to supply our wide range of products in Europe under the REACH regulations.
- Our MSDS contain the REACH registration number/s where relevant.

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1 June 2007.

REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

Registration applies to substances on their own, substances in mixtures and certain cases of substances in articles. Chemical substances that are already regulated by other legislations such as medicines, or radioactive substances are partially or completely exempted from REACH requirements.

Substances do not need to be registered under REACH if they are manufactured or imported at less than 1 ton per year, per manufacturer/importer. Some substances are exempt from all or certain aspects of REACH ("partial" exemptions). A complete list of exempt or partial exempt substances can be found in annex IV and V of the REACH regulations.

Evaluation under REACH focuses on three different areas:

- Examination of testing proposals submitted by registrants
- Compliance check of the dossiers submitted by registrants
- Substance evaluation

BIOSOLVE CHIMIE 20 rue Roger Husson 57 260 Dieuze
SARL au capital de 10 000€ RCS Metz B522288174- TVA FR60522288174000017- APE : 7211Z
Tel: +33 (0)3 878 675 80 Fax: +33(0)3 878 675 89 Email : info@biosolve-chimie.com Website: www.biosolve-chemicals.com

Once the evaluation is done, registrants may be required to submit further information on the substance.

In line with Article 54 of the REACH Regulation, by 28 February of each year, ECHA has to publish a report on the progress it has made over the previous calendar year on its obligations in relation to evaluation. ECHA is specifically required to include recommendations to potential registrants to foster improvement in the quality of future registrations, in these reports.

The authorization procedure aims to assure that the risks from Substances of Very High Concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the good functioning of the EU internal market.

Substances with the following hazard properties may be identified as SVHCs:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Commission Regulation (EC) No 1272/2008 (CMR substances).
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII).
- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances.

After a two-step regulatory process, SVHCs may be included in the Authorization List and become subject to authorization. These substances cannot be placed on the market or used after a given date, unless an authorization is granted for their specific use, or the use is exempted from authorization. Generally, our chemicals and mixtures do not contain any SVHC above the legal limit of 0.1% w/w unless they are SVHCs themselves as indicated on the Safety Data Sheets (SDS).

Restrictions are a tool to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market or use of a substance.

A restriction applies to any substance on its own, in a mixture or in an article, including those that do not require registration. It can also apply to imports.

Please remember that it is your obligation as a downstream user to verify the information provided within an SDS and to determine if your application of a substance for your specific use is allowed or whether it is subjected to any other use restriction, for example Annex XVII of REACH.

Useful links:

National helpdesks contact details

Registry of SVHC Intentions

Candidate list of SVHCs

Authorization List

List of restrictions table

REACH Regulations