## Questions and Answers

# GHS and REACh changes to be implemented from the 1st of December 2010

### Why have the hazard labels on the products I buy changed?

**New regulations have been implemented for hazardous labelling across the European Union.** On December 16th 2008 the Directive (EC) No. 1272/2008 (CLP) came in place, which replaces the old Directives 67/548/EWG and 1999/45/EG. **CLP** (Classification, Labelling and Packaging) is the implementation of **GHS** (Globally Harmonized System of Classification and Labeling of Chemicals) within Europe with a target of a harmonized classification and labelling system around the whole world. This Directive has to be fully implemented for the packing and labelling of all **substances** by all hazardous chemical manufactures in the European Union by the 1st of December 2010. Preparations (mixtures) however can still be manufactured and labelled in accordance with Directive 1999/45/EG until the 31st of May 2015. The most conspicuous part of the change are the new GHS pictographs, a red- framed rhomb with black symbol on white background, which will replace the well-known hazard pictographs, black sign on orange background. A pdf brochure is available from VWR International showing the new symbols and listing all the new Signal words and Hazard and Precautionary statements.

### Will all the products I buy from 1st December 2010 have the new labels?

**No. Hazardous products with old style labels will be delivered by all suppliers for some period, but VWR is working with its manufacturers to try to minimise this period.** Based on article 61.1 (CLP) only substances, which have been related to Directive 67/548/EWG must be labelled with the new classification, when produced after the 31st of November 2010. However, mixtures belonging to Directive 1999/45/EG can be labelled by manufacturers until 01.06.2015 with old style labels. Additionally there is in both cases a 2-year transition period, from these dates where products, produced, classified, labelled and put on the market do not need to be relabelled and these can therefore be supplied with old style labels (article 61.4, CLP), for some period to come.

### Do I have to re-label product in my lab?

**No, responsibility for classification and labelling lies with the manufacturer or importer.** Nevertheless, for workers safety we recommend that workers are aware of both sets of regulations and this data will be available in the **SDS** (Safety Data Sheets) and future catalogues available from VWR.

### Why has the hazard classification of some products changed? What does this mean for me and my company?

**Hazardous chemicals are continually being assessed by the regulatory authorities and the requirements of what defines a hazardous chemical and the level of hazard are periodically updated to ensure all users of these chemicals are made aware of the latest judgements of the authorities.** Within the agreement for global harmonization of the labelling of hazardous chemicals, the types of hazard and the limits for classification which defined these hazards also changed in some cases – especially for toxicology. This reclassification is for example based on information gained from the **REACh** (Registration, Evaluation, Authorisation, of Chemicals) registration process as well as on technical progress. The first Adaptations to Technical Progress (ATP's) for hazardous products identified in (EC) No. 1272/2008 (CLP) is given in Directive (EC) No. 790/2009. Such adaptations will periodically take place.

## I understand the hazard labelling on mixtures and preparations don't have to change till 2015. How is a mixture defined?

**Substances and Mixtures (preparations) have been defined in the Dangerous Preparation Directive (DPD) 1999/45/EG.**

- **Substances**: Means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products 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.
- **Preparations** (mixtures): means mixtures or solutions composed of two or more substances.

## Where can I get more information on the CLP (GHS) changes?

**More information on the GHS changes can be obtained from the official journal of the European Union.**
Official Journal of the European Union

## How will the CLP Regulation affect SDS?

**As the provisions of the CLP regulation are phased in together with the implementation of REACh Annex II, they will affect the information requirements of certain parts of the SDS.** This will include an email contact address which should be included in section 1, for competent person(s) to respond with appropriate advice.

In addition, SDSs for substances or mixtures containing substances that have been fully registered under REACh will require:

- Inclusion of registration numbers where appropriate.
- Inclusion of the identified use(s) and uses advised against in section 1.
- Inclusion of exposure scenarios including any risk management measures required, in an Annex to the SDS. The information in the SDS should be consistent with the information in the **CSR** (Chemical Safety Report) for that substance, or a mixture if a **CSA** (Chemical Safety Assessment) for the mixture is available.
- Inclusion of the relevant **DNEL**s (Derived No Effect Level) and **PNEC**s (Predicted No Effect Concentration) for that substance in section 8.

The guidance on how to compile a SDS (REACh Annex II) will be updated on 1 December 2010 and 1 June 2015 to reflect these changes. To ease the changes there are a number of transitional arrangements, these are described below:

- Transition 1 - 1 December 2010: The SDS for substances must use the first revision to REACH Annex II after this date. The SDS for **new** mixtures must use the first revision to REACh Annex II after this date.
- Transition 2 - 1 December 2012: The SDS for all mixtures must use the first revision to REACH Annex II. Until this time the SDS for a mixture provided to any recipient at least once before 1st December 2010 can continue to be used (unless an update in accordance with Article 31(9) of REACh is required). The SDS for substances that are 'on the shelf' (i.e., that have already been placed on the market and are with, for example, distributors) must be re-issued with one in accordance with the first revision of Annex II (unless an update in accordance with Article 31(9) of REACh had previously been required).
- Transition 3 - 1 June 2015: The SDS for all substances **& mixtures** must use the second revision to REACH Annex II
- Transition 4 - 1 June 2017: The SDS for mixtures 'on the shelf' must be re-issued with one in accordance with the second revision of Annex II (unless an update in accordance with Article 31(9) of REACH had previously been required).

Where suppliers choose to re-classify and label in accordance with CLP rules before the compulsory dates, they need to include information according to both systems on the SDS. Between 1 December 2010 and 1 June 2015, the SDS for all substances should include information according to both systems on the SDS

## I want to register the intended use I have for the BDH Prolabo products I buy. How do I do this?

- **Send information on the product and the use to VWR's REACh-mailbox**. This is **reach@eu.vwr.com**

## I want to register the intended use I have for the Merck products I buy. How do I do this?

Merck has a web-based system for registering the intended uses on its website at http://www.merck.de/en/index.html

## How will REACh affect the availability of BDH Prolabo and Merck products?

**It should have very little impact on these 2 brands.** However, based on the cost of registration, it could be that some products will not be continued. As VWR International is a Distributor, we will search for other sources to continue availability of substances for customers and are confident most substances and purities will continue to be available but the brands may change.

## I have heard of the phrase SVHC. What does this mean? How will it affect me?

**A SVHC ( Substance of Very High Concern) is a chemical substance (or part of a group of chemical substances) for which it has been proposed that the use within the European Union be subject to authorisation under the REACh regulations.** The, listing of a substance as an SVHC by the **ECHA** ( European Chemicals Agency) is the first step in the procedure for authorisation and restriction of use of a chemical. The first list of SVHCs was published on 28 October 2008 and updated on 13 January 2010. The list of SVHCs is primarily a public list of substances for which the European Chemicals Agency is considering imposing a requirement for authorisation for some or all uses. This may lead to these substances or products containing them becoming difficult to obtain or more expensive. Manufacturers must provide their customers with Safety data sheets for any product containing more than 0.1%by weight of any SVHC.

## Where can I get more information on the REACh changes?

Each country has an official REACh-helpdesk for more information but more information can also be obtained from:

ECHA (ECHA – European Chemicals Agency)
European Chemicals Bureau (ECB) concerning REACh
Information portal of the EU