

A Safety Data Sheet (SDS) must be supplied with hazardous substances and mixtures and made available for the supply of mixtures containing hazardous substances above thresholds of concern. Between now and 2018, as REACH phase-in substances are registered, there will be a transition to the extended SDS (eSDS) that incorporates descriptions of uses and the Risk Management Measures (RMM) considered necessary as a result of the Chemical Safety Assessment / Report (CSA / CSR). These descriptions of use and RMM are known as the Exposure Scenario (ES).

## **Introduction to SDS / MSDS (e-SDS)**

Globally, the production, transport, storage and supply of chemicals are covered by a number of national and international regulations with the objective of protecting man and the environment from potentially hazardous chemicals that are essential to our standard of living. It is not just the chemical industry that is affected by these regulations - any organisation using chemicals, including printing, electronics, textiles, motor trade, health care etc. needs to be aware of chemical safety issues.

For those working with chemicals, it is important to know how to recognise those that are hazardous, how to reduce exposure and ultimately to reduce any risk to ourselves, our colleagues and to the environment. The term RMM is used to describe the recommendations for handling and use to keep exposure levels below thresholds considered to be hazardous.

In Europe, there is a requirement to identify chemical substances and to understand their hazards so that products can be classified, labelled with suitable risk and safety phrases and packaged in an appropriate manner. To communicate hazards and to help identify potential risks, a SDS needs to be provided to commercial users so that they in turn can ensure suitable protection to their own staff.

## **EU Regulatory framework**

The REACH and CLP Regulations have created a new regulatory framework in Europe and there is greater international consistency with adoption of the Global Harmonisation System (GHS) for classification and labelling throughout most of the World. Note that GHS refers to the 'Safety Data Sheet' or SDS and the word 'Material' is not required - therefore, in theory, even US 'Material Safety Data Sheets' will be SDS without the 'M' in future.

Annex II of REACH, as amended by Regulation (EC) no. 453/2010, describes the requirements for SDS preparation and dictates when an SDS is needed, the language, formatting etc. The CLP Regulation (EC) No 1272/2008 covers the details on how to classify a substance or mixture and also covers labelling requirements.

## **Background to European chemical supply regulations**

Along with most of the world, legislation has been enacted in Europe to control the supply of dangerous chemicals. In Europe, the system is based on hazard identification (classification based on hazards) and the control of particular chemicals is set according to the hazard with the objective of reducing risk.

The process of chemical control was first set out in Directive 67/548/EEC (the Dangerous Substances Directive) and almost all pieces of EU legislation relating to the chemical industry since then referred back to the principles laid out in this Directive including REACH. Being Directives, these were all subject to implementation through national legislation. There were new Directives over the years changing the SDS and classification requirements, but from June 2007, the directly acting REACH Regulation (EC) No 1907/2006 has been the EU legal basis.

Confusingly, the final transition to CLP will not be seen until 2015 (for mixtures) and the phase-in period for REACH registration ends May 2018. Until then, there will be dual standards.

The information provided in the SDS is used, for example, to fulfil part of the requirements of Directive 98/24/EC covering chemical safety in the workplace (eg. UK COSHH) and the changes to the SDS introduced by the new Annex II under REACH does not replace existing workplace or consumer safety legislation.

## **The Science**

Despite new regulations and hazard classification systems, the concepts and science have not changed.

The first stage in the reduction of risk is to ensure that the potential hazards of the chemical product (either a single substance or a mixture) are suitably identified and then communicated to those in contact with the product. In Europe, the identification of hazards under Directive 67/548/EEC was formalised into symbols and numbered Risk and Safety phrases. Anyone in Europe can therefore look at a pictogram symbol and associated Risk and Safety phrase numbers and know the potential hazard of the chemical and be advised on the basics of safe handling or disposal.

GHS, and in the EU, CLP, is not changing this principle, but uses a slightly different set of symbols and phrases for communicating hazard. Over time with adoption of GHS globally, the symbols (pictograms) and phrases (statements) will be used universally.

## **National legislation**

Pre-REACH SDS legislation was based on Directives and these needed enacting through national legislation in Member States. REACH is based on an EU Regulation and should (in theory) result in a more unified approach to chemical legislation in Europe (including Norway, Iceland and Liechtenstein). Switzerland will follow GHS, but is not signing up to REACH.

National inspection units are responsible for local interpretation of the Regulation and this is still varying around Europe, with some agencies taking a pragmatic view that hazard and risk communication is the most important objective and other agencies being more concerned with format and procedure.

## **Supply of the SDS**

A Safety Data Sheet (SDS) must be prepared for chemical products considered dangerous to health or the environment. 'Dangerous' is defined in Directive 67/548/EEC and subsequent amendments – REACH does not change this requirement, but does expand the meaning of 'dangerous' to include Persistent, Bioaccumulative, Toxic (PBT) and very Persistent, very Bioaccumulative (vPvB) materials and substances of 'equivalent concern' added to the Candidate List (under CLP, the term 'dangerous' is replaced by the term 'hazardous' with very similar scope).

Anyone being supplied a chemical can demand an SDS even if it is not hazardous if the mixture contains hazardous components above certain thresholds. This requirement applies to all chemical products, unless being supplied for non-professional use, such as retail sales.

The threshold of concern is typically 1% w/w (solids or liquids) or 0.2% v/v (gas) for hazardous substances or where the substance has a defined Community exposure level, or 0.1% for substances of higher concern including Cat. 1 sensitisers, CMR, vPvP, PBT and others meeting the definition in Article 59 of REACH.

## Language

The Regulation states that the supplier placing a hazardous substance or mixture on the market in a specific Member State must provide the SDS (including Exposure Scenario) in the official language(s) of that Member State. Placing on the market is considered pro-active selling in that market; therefore, if a French company goes to a UK sales office and asks to buy the product, it is not being placed on the French market and English language and UK contact details are OK, but if they advertise in French in French journals, that is considered placing on the market and the SDS must be made available in French language with French contact details, whether that person is in the UK or France. A sales agent in France counts as placing on that market and that agents contact details needs to be given.

Effectively, none of this has changed from the old pre-REACH and pre-CLP process, except that SDS requirements were part of national laws and under that system, a UK exporter could not be prosecuted by the French inspectors for failing to provide local contact details; only the French importer or sales office could be prosecuted for failing to provide a suitable SDS. It is no different now in that the French inspectors need someone in France to complain to if it is placed on the French market.

Internet selling has made this very difficult to pin down, but ultimately, it is good practice to help customers.

## Competence and training

The legislation uses the word 'competent' to describe the person preparing the SDS. This is not clearly defined, but the text goes on to suggest training and refresher training work. From this, it can be inferred that unless there is evidence of training or suitable alternatives, competence will be difficult to demonstrate if the quality of the SDS is ever questioned by a regulator.

The lack of definition of 'competence' will give the authorities flexibility in using inadequate competence as a reason for failure to comply with the Regulation.

## Safety Data Sheet – SDS format

The European SDS was formalised in the '16-point' format in Directive 91/151/EEC and amended significantly by Directive 2001/58/EC and was based on the UN International Labour Organisation (ILO) format, also used in other parts of the World. GHS changed this slightly, with sections 2 and 3 changing position.

The content of an SDS must reflect all information available to the supplier, relating to the hazardous chemical, that is considered necessary to provide adequate warning and advice on safe handling to the users.

Although suppliers are not expected to conduct extensive testing on their products to generate data for safety data sheets, there should be sufficient data on the product (or derived from similar materials) to enable a suitable classification to be made and R phrases (or H Statements) assigned. Suppliers must be able to justify their safety data sheets and retain records of how decisions were made to classify (or not classify). Ultimately, the function of the SDS is to communicate potential hazards and it is unacceptable to supply a material if those hazards are not known.

## Format

Headings to be used in European SDS are as follows:

- Section 1: Identification of the substance/mixture and the company/ undertaking;
- Section 2: Hazards identification (assessment);
- Section 3: Composition/information on ingredients;
- Section 4: First aid measures;

Section 5: Fire-fighting measures;  
Section 6: Accidental release measures;  
Section 7: Handling and storage;  
Section 8: Exposure controls / personal protection;  
Section 9: Physical and chemical properties;  
Section 10: Stability and reactivity;  
Section 11: Toxicological information;  
Section 12: Ecological information;  
Section 13: Disposal considerations;  
Section 14: Transport information;  
Section 15: Regulatory information;  
Section 16: Other information.

This '16-point' format, based on GHS recommendations, will be acceptable throughout the world. Note that the word 'Section' must now form part of each heading.

### **Changes in the revised Annex II of REACH & the extended SDS (e-SDS)**

The key changes introduced through Regulation (EC) no. 453/2010 are a more prescribed set of sub-headings aimed to make the SDS more consistent and to prompt the writers with more headings. All sub-sections must be filled in, and no blank sub-sections are allowed. REACH itself will make more data available to the writers, but inputs such as the Derived No Effect Level (DNEL) need to be added.

The biggest problem is the addition of the Exposure Scenarios; these are short guides describing the envisaged routes of exposure and how the use may lead to exposure to workers, public users and the environment. It is essential that the contents of the SDS reflect real use patterns and that readers of the SDS can look at what the authors had in mind when writing risk management measures and precautions.

The Exposure Scenarios (ES) are effectively 'justification' documents that justify that certain uses of the substances and their mixtures have been considered and that potential exposure has been assessed in terms of risk. However, the ES added to the SDS need to be concise and readable to the intended user; avoid complicated text and mathematics, and instead provide easy to follow text. Note that the ES is part of the SDS and will need translation – many organisations will be using standard phrases in the ES so that they can be translated automatically.

### **The REACH Only Representative**

Only Representatives have specific obligations under the REACH Regulation, including keeping records of the supply of the latest SDS. Only Representatives may also be identified as the Supplier in section 1 of the SDS, with the option to also include details of the non-EU company who has appointed them.

Where Downstream Users wish to forward on the SDS they have received from an OR to their own customers, then they will need to make suitable arrangements with the OR in the same way that they would need to do so with any other EU based supplier.

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