

Understanding the Safety Data Sheet Changes

Introduction

Safety data sheets (SDS) have been around for a long time and they serve as a key communication tool for supply chains. Suppliers provide SDS to industrial and professional users to ensure they have accurate information on hazards, risks and their management; recipients of the SDS use the information to ensure safe use on site, and to prepare their own SDS for any onward supply of chemicals.

The arrival of REACH in 2006 provided an opportunity for the regulators to make some changes to the SDS. Many of these changes were introduced to align EU SDS with the emerging global standard developed as part of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Annex II to REACH sets out the requirements for safety data sheets (SDS) issued to comply with Article 31 of REACH. Due to the progressive introduction of CLP for substances and mixtures, amending regulations have successively replaced the original version of Annex II. We have prepared this short piece of guidance to help you understand and manage the changes.

SDS – old and new

From **1 June 2008**, a safety data sheet needed to include contact details of the supplier of the SDS (with an email address) and the second and third sections were reversed in their ordering. These requirements were set out in Article 31 and in Annex II of REACH.

The arrival of CLP and further agreement on the GHS meant that, in May 2010, a new Annex II format was agreed with its introduction set for 1 December 2010. The new format was published in the form of two Annexes to Commission Regulation (EC) No 453/2010, successively amending REACH Annex II in 2010 and 2015: Annex I to Regulation 453/2010 applied from **1 December 2010**, and Annex II to 453/2010 from **1 June 2015**, aligning the SDS requirements with the application of CLP to substances and mixtures respectively. This amending regulation also included transitional arrangements for substances and mixtures already in the supply chain on the respective dates, linked to derogations on re-labelling to CLP of goods already placed on the market. The measures set out in Regulation EU 2015/830 applied from **1 June 2015**; however, recipients who received a SDS before 1 June may have continued to use it until **31 May 2017**. Any SDS received after 1 June 2017 must include CLP classifications.

In 2020, the European Commission introduced further changes to Annex II (Regulation 2020/878). The changes further aligned the annex with the revisions of the United Nations' Globally Harmonised System. Most of the physicochemical properties section has been rewritten and the requirements to provide information on the presence of nanoforms, endocrine-disrupting properties as well as the

unique formula identifier used for poison centres notifications have been included. Requirements regarding specific concentration limits, multiplication factors, and acute toxicity estimates are also specified in Annex II. The amendment came into force on **1 January 2021**. A transition period until **31 December 2022** was introduced to give time to adapt existing SDS.

When to provide SDS and when to change them?

Safety data sheets must be provided to business recipients, but not to the general public if the packaging provides sufficient risk management information.

REACH requires the provision of a safety data sheet under specific circumstances:

- ✓ The substance or mixture meets the classification as hazardous under CLP,
- ✓ The substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB),
- ✓ The substance is on the Candidate List of SVHCs.

In addition, in the following situations a SDS must be provided on request:

- ✓ Mixtures not classified as hazardous but contain at least one substance that is hazardous to health or the environment in concentrations of $\geq 1\%$ w/w for non-gaseous mixtures and $\geq 0.2\%$ v/v for gaseous mixtures,
- ✓ Non-gaseous mixtures containing PBT or vPvB substances at concentrations $\geq 0.1\%$ w/w,
- ✓ Mixtures containing substances with Community Exposure Limits.

The SDS need only be provided at the time of first supply and when specific new information requires an update as laid down in Article 31(9):

- ✓ New information on hazard becomes available,
- ✓ New information on risk management becomes available,
- ✓ Once an authorisation has been granted or refused,
- ✓ Once a restriction has been imposed.

Unlike some jurisdictions, the EU has no mandated review period for SDS.

Information in the SDS

EU SDS required under REACH are very prescriptive. There are specific headings and sub-headings all of which must be in the SDS. Under all the headings detailed and specific information is needed, usually with no generic short-cuts such as “not applicable”. In addition, the information required can be very technical and demand specialist knowledge of occupational health and safety and environmental management.



Incorporating information from REACH registration

If a substance is fully registered in your supply chain, or if a mixture contains a substance registered by an upstream supplier, the SDS should include the registration numbers (but see the comments on confidentiality below).

Information about the identified uses (or uses advised against) must be shown in Section 1 of the SDS. In addition, for substances, an annex setting out the exposure scenarios prepared as part of the CSR must be included; however, for mixtures, any relevant exposure scenarios for the components may be incorporated into the main body of the SDS, or appended to it.

The relevant DNELs and PNECs must also be included in the SDS.

Additional technical information

For substances and mixtures alike, comprehensive information requirements are set out in Annex II for each of the SDS headings and sub-headings.

Our advice is not to attempt to compile a SDS unless you are confident you are capable to do so. You will need a range of skills and knowledge, and to be familiar with REACH and CLP as well as the amending regulation on SDS. Those preparing safety data sheets must be competent, which means receiving appropriate training and/or having appropriate experience. REACHReady can help! Please see our ongoing programme of workshops at www.reachready.co.uk/events, or get in touch with the Helpdesk at enquiries@reachready.co.uk for other ways we can help.

Confidentiality

The SDS for a substance must give the identity as set out in Article 18 of CLP, which gives a hierarchy of naming arrangements with no confidentiality provisions. As a general rule, a systematic name and identifying number is required.

For mixtures, the ingredients must be declared in Section 3.2 if present above certain limits. However, for substances with some defined low hazards an alternative name is possible if a justification can be made. There are also some special provisions for distributors, downstream users and suppliers of mixtures to omit part of the registration number referring to the individual registrant of a joint submission (the last four digits).

Languages

The safety data sheet is a key tool in communicating risk and its control through the supply chain – the recipient needs to be able to understand it! The SDS must be in an official language of the recipient's country, unless that country specifies an alternative is acceptable. In practice, this means that for countries with several official languages (e.g. Belgium) one of the languages should suffice



for legal purposes, although customer pressure may well require more than one language – and sometimes in the predominant language of the workforce on-site!

Transmission of the SDS

The distribution of the SDS is a controversial area based on differing interpretations by Competent Authorities of Article 31(8) of REACH. Our advice has always been take a prudent approach and to send the SDS to the recipients of your chemical goods. You may wish to post, fax, or email the SDS as attachment, or to send it using a secure document delivery system. A hyperlink or cross reference to a company website cannot be guaranteed to be acceptable, since REACH requires suppliers to *provide* rather than simply *make available* the SDS. Also, if you choose to provide SDS by email, fax or post do remember that in most case (proof of) sending does not guarantee delivery, or that the SDS has been read!

Further information

ECHA's [Guidance on the compilation of safety data sheets](#) is a detailed source of information; many Competent Authorities offer guidance via their website. REACHReady Gold subscribers may also seek advice from our helpdesk – please contact us on +44 (0) 207 901 1444.

If you are looking for a consultant or a software system to compile your SDS, or if you need a delivery system to provide your customers with SDS, that's where our Matchmaker service comes in! Simply email us at enquiries@reachready.co.uk or call us on +44 (0) 207 901 1444 with details of your requirements and we will put you in touch with suitable Approved Service Providers who can help.

We also hold regular SDS training days and workshops to help you understand the implications of the changes on your business, which can also be delivered on-site. Please see <http://www.reachready.co.uk/events> or call +44 (0) 207 901 1443 for more information.