

DOWNSTREAM USERS, ARE YOUR USES COVERED?

This paper has been elaborated and approved by the Directors' Contact Group between Commission, ECHA and Industry Associations (Cefic, Eurométaux, REACH Alliance, Concaawe, FECC and UEAPME) on Meeting the REACH Registration Deadline.

REACH imposes new requirements, related to the communication of uses and conditions of uses, on the registrants and the downstream users.

Under REACH a use of a substance or of a mixture is nearly any utilisation where a potential exposure to the environment or users can take place: e.g filling and re-filling, varnishing, formulating, colouring, etc.

These new requirements are only relevant for certain substances as such or in mixtures. Those are substances meeting the criteria for being classified dangerous according to Directive 67/548/EEC or assessed to be a PBT or vPvB (see Article 14(4) of REACH) or substances of very high concern (SVHC) (REACH Article 31).

The main communication tool, the SDS, will be extended for the relevant substances with detailed exposure scenarios, describing the operational conditions and risk management measures ensuring control of risk for all the identified uses. For mixtures, the uses and conditions of uses have to be communicated through the SDS as well. The several options how to add the uses and conditions of uses to the SDS of mixtures will be explained in a second letter before 1 December 2010.

Are you using such substances classified as hazardous or assessed to be a PBT or vPvB or SVHC? You are then a downstream user under the obligation to secure REACH compliance. The following text and flow chart explain what, when and how to do it.

1. Check the type of the safety data sheet

- In case you receive a substance-related SDS, check whether your use is covered in chapter 1 of the SDS and consider the standard work safety obligation.
- In case you receive an (extended) SDS containing exposure scenarios, you have to check whether it covers your conditions of use.
- In case you further supply the substance downstream in a mixture you need to consider whether the exposure scenarios of your supplier cover the uses and conditions of use inherently connected with the technical purpose of the product you supply.

2. Check whether the extended SDS covers your conditions of use

- Define YOUR conditions of use
 - The definition of uses and conditions has to be considered from an environmental and health perspective. Uses should be defined with the "Use descriptor system" (UDS), which is provided by ECHA as Guidance. It reflects different process and sectors of use, is very flexible and allows over one million combinations of uses.

To define the conditions of use, you have to consider the

- ⇒ physical state of the substance (solid, liquid, gas) and concentration
- ⇒ Frequency and duration
- ⇒ Risk Management Measurement (mask, gloves, ventilation, safety spectacles, double valves, safety zone among storage tanks ...)
- ⇒ Operational conditions (temperature, pressure, ...)

- To your advantage, several associations have already defined the relevant uses and conditions of uses according the UDS system, for their applications e.g. FECC for distribution, FEICA for adhesives etc.). You can find the use library covering the work of several associations on the CEFIC website on <http://cefic.be/en/reach-for-industries-libraries.html>.
- We suggest you to look for the matching definition for your conditions of use via the library first. Only in case you cannot find a matching definition, you have to draw up yourself a definition for your conditions of use in best accordance with UDS-Guidelines.
- Compare YOUR conditions of use with the conditions of use covered by the extended SDS
 - in case they are covered, you are compliant and no further action is required.
 - in case they are not covered, you have to undertake action in order to secure compliance.

3. What to do in case YOUR conditions of use are not covered by the extended SDS

According to REACH you have basically 12 months starting from the reception of a registration number in the SDS of your supplier to make your use compliant (article 37 and 39). 4 options are available to you at that point:

Option 1: Check whether you can change your conditions of use, so that your conditions of use are covered by the existing extended SDS: e.g. change from an open batch to a closed batch, improve the ventilation system etc.

Option 2: You communicate the missing conditions of use via your supplier upstream and request the registrant/supplier to provide exposure scenarios covering your conditions of use.

The registrant than either:

- (1) sends an updated extended SDS containing your condition of use; or
- (2) rejects your condition of use: this takes you back to either option 1, 3 or 4. The registrant/supplier should inform the DU about his reasons for rejection without delay providing detailed information about his decision. This

becomes important especially for Option 3, where a DU has a very short time-line to fulfil his obligations.

Option 3: You report your condition of use to ECHA and carry out an own CSA

In case you use the substance in a quantity $> 1t/a$, you have to inform ECHA within 6 months that you will carry out a CSA (chemical safety assessment) yourself. In case you use the substance in a quantity $< 1t/a$, you should only notify your use to ECHA, a CSA is not necessary.

In case it is stated in the extended SDS that the substance is an intermediate, which should be used only under strictly controlled conditions and you want to use it in another way, a notification is not enough. You should pre-register/register as an importer or choose option 4.

Option 4: Choose another supplier who covers YOUR conditions of use.

