

Safety Data Sheets without Exposure Scenarios

Introduction:

The REACH regulation (Regulation (EC) N° 1907/2006) includes the requirement for Manufacturers and Importers (M/I) to perform a Chemical Safety Assessment (CSA) and to document this CSA into a Chemical Safety Report (CSR). The CSA shall cover the “Exposure Assessment” of the different “Identified Uses” of the registered substances for their risks to the users and to the environment. The Exposure Assessment shall describe the safe Conditions of Use (CoU) of the Identified Uses with the relevant Risk Management Methods (RMM) in corresponding “Exposure Scenarios (ESs)”. The CoU are acceptable when the Risk Characterisation Ratio (RCR) for the relevant exposure scenario is less than 1.

These ESs are further transmitted down to the supply chain to the “Downstream Users (DUs) as attachments to the Safety Data Sheets (SDSs) that are therefore called “extended Safety Sheets”.

The purpose of this Technical Bulletin is to explain why the SDSs of some substances do not have ESs attached to them.

Note: there is no requirement to attach ESs to SDSs for mixtures. It is sufficient to describe the safe CoUs in the main body of the SDS.

Cases where no ES is attached to the SDS:

1. The substance is exempted from registration under REACH

This is the case for the gases listed in Annex IV and Annex V of REACH: **Nitrogen, Argon, Carbon Dioxide, Helium, Krypton, Xenon, Oxygen, Hydrogen** and the gases gained from natural sources without undergoing any chemical modification such as **Methane, Propane, Butane, Ethane, Isobutane**, etc.

It is also the case for the gases that are manufactured or imported below the threshold tonnage for registration of 1T/year which may apply to some gases used in the electronics industry.

The exemption will be mentioned in section 1.1 of the SDS with a sentence such as “*Listed in Annex IV/V REACH, exempted from registration.*” or “*Registration not required. Substance manufactured or imported < 1T/y.*”

2. The substance is registered but is exempted for submitting a CSR

This is the case for substances that have been registered but have a total tonnage of less than 10 tons/year. In this case, the registrant does not need to complete a CSA and to submit a CSR. The SDS for these gases should mention in section 15.2 a sentence such as “*A CSA does not need to be carried out for this product*”.

3. The substance is registered but exempted for submitting an Exposure Assessment in the CSA/CSR.

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This is the case for substances that are only classified for hazards that do not require an Exposure Assessment according to art 14.4 of REACH. This exemption applies to gases that are only classified as “gases under pressure” (e.g. SF6 and some refrigerants) or as “STOTSE H336 for narcotic effects”.

The SDS for those gases should mention in section 15.2 a sentence such as “*An Exposure Assessment does not need to be carried out for this product*”.

Note: Several CSA/CSR for gases with only physchem hazards did not include at the time of registration exposure assessments with the argument there was no health hazard to evaluate the exposure. The revised ECHA Guide Part E published in May 2016 has clarified the requirements for the ESs. Some CSR have been revised in the meantime and the relevant ESs issued by EIGA, e.g. for **acetylene**.

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