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Solvents Generic Exposure Scenarios (GES) under REACH. By Cornelia Tietz and Alison Margary, ESIG.

GUIDANCE TO COMPLY WITH REACH

ESIG, the European Solvents Industry Group, a Sector Group within Cefic, provides guidance to solvent manufacturers and importers on ways to comply with REACH requirements.

Since 2007, chemical substances including solvents have been regulated at the European level under the Registration, Evaluation, Authorisation and Restriction of Chemicals regulation, known as REACH ((EC) 1907/2006). REACH requires all manufacturers within and importers to Europe (M/I) to register detailed technical dossiers addressing the health, safety and environmental risks of each chemical substance. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. ESIG provides guidance to solvent manufacturers and importers on ways to comply with these requirements. Our Generic Exposure Scenarios (GES) are THE solvents industry standard in Europe today to ensure REACH compliance through the supply chain and form the basis for supporting the Downstream User (DU) sectors activities on Use Mapping that is recommended by the European Chemicals Agency (ECHA).

A key component of the registration of a substance under REACH is identifying all its uses and associated conditions of use throughout the supply chain. Already during the pre-registration phase of REACH (prior to 2010), DUs were encouraged to interact with their suppliers and trade groups to ensure that the M/I of their substances were aware of their uses and would include them in their Chemical Safety Assessments (CSA). Once a (classified) substance is registered, the M/I is expected to communicate any safe handling measures resulting

from the CSA to the DU in the Annex of the REACH extended Safety Data Sheet (SDS). DUs then have a legal obligation (REACH Article 37) to follow this advice, or demonstrate they have implemented equivalent measures. If their use or associated conditions of use are not covered, they have a number of options, including asking their supplier to update the registration, looking for an alternative supplier covering their use, substituting the substance for another with the relevant details, preparing own DU CSA.

AWARENESS OF SUBSTANCE USE

A chemical manufacturer first needs to be aware of the uses of their substances in order to evaluate the associated risks and this preferably with a high degree of consistency between substances with similar properties across different supply chains. It is then equally important that the outcome of this process, i.e. the SDS and its associated Exposure Scenario, is developed in a manner that is understandable and relevant for any DU of a given substance.

With more than 1,000 different solvents used in hundreds of different applications, industry needed a smart and simplified approach to develop the many exposure scenarios required.

The process was led by the manufacturing trade group, ESIG. As part of the GES approach, ESIG has always worked with its downstream users' sectors via the European Solvents Downstream User Cooperation Group (ESVOC) to align on use details and exposure conditions. About 30 DU associations or their partners were involved as early as 2008, including CEPE (the European Council of the Paint, Printing Ink and



GES UPDATES

All 2018 GES updates, be it xml transfer files, use maps or Excel files, have been revised to take account of:

- Adjustments to meet the updated ECHA guidance R12 on Use Descriptors
- Changes in Contributing Scenario (CS) titles and CS additions resulting from the mapping of the GES to the now also available Downstream User Sectors Use Maps
- Baseline Operational Conditions and Risk Management Measures for the demonstration of safe use for the different DNEL and Vapour Pressure bands

Artists' Colours Industry), AISE (International Association for Soaps, Detergents and Maintenance Products), FEICA (the European Adhesive and Sealant Industry) and FEA (European Aerosol Federation) as direct members of the GES Working Group.

The solution was to develop a generic approach to consolidate the many different solvent applications into Generic Exposure Scenario (GES) Use Titles covering Workers (Industrial and Professional), Consumers and the Environment. The 22 GES Use Titles developed cover around 90 % of solvent uses today.

This cluster approach helped to substantially reduce complexity and harmonise compliance across the value chain – and the resulting scenarios are also applicable to other solvent-like materials. This is recognised as a major added value for registrants.

As stated, developing the GES was a collaborative effort with downstream users via ESVOC and this collaboration was vital to establish effective use mapping and a comprehensive phrase library to support compilation of associated Exposure Scenarios within a company's SDS system.

FORMATS AND UPDATES

The GES files for assessing Worker health risks were initially created using Microsoft Excel to meet the first Registration deadline in 2010. These files were then updated in 2014 using the Cefic CSA Excel tool and took account of feedback from solvent users who registered in 2010 and 2013. A second update took place in 2018.

Recent 2018 efforts have also focused on making it more efficient to conduct and report solvents Chemical Safety Assessments using the European Chemical Agency's (ECHA) preferred tool, 'Chesar'. After conducting a substance exposure assessment, Chesar enables users to directly populate the outputs into a Chemical Safety Report (CSR) and the REACH Registration tool, IUCLID.

For each Use Title in the ESIG Worker GES library, a supporting xml transfer file allowing the auto-population of the details into Chesar is available. For Consumer GES, health exposure assessments are

“Solvents’ GES are the industry standard in Europe today.”

still carried out using the Solvents EGRETv2 tool, which is outside of Chesar. However, the assessment output from EGRET can also be converted into an xml file that imports directly into Chesar. For Environmental assessments specific environmental release values (so-called SpERCs) have been compiled for each Use Title which are also available as Chesar import files.

In addition, there are also Chesar Use Maps available for the Worker GES which consolidate many Use Titles into the one file to allow their direct import into Chesar in one go.

There are occasions when a company may wish to carry out a stand-alone assessment for a substance for which the use of Chesar is not needed, for example for a confidential use or to demonstrate safe handling for a particular use with alternative Operational Conditions (OCs) or Risk Management Measures (RMMs) to those given in the Exposure Scenario provided with the substance SDS. In any such cases, it may be more convenient to complete the assessment using the GES Worker files in the stand-alone Excel-tool format which, as mentioned, have also been updated in 2018.

OUTLOOK

ESIG continues to work to keep the Generic Exposure Scenario (GES) package of tools up-to-date and relevant to meet the latest REACH guidance, and use updates communicated by the Downstream Users. Solvents' GES are the industry standard in Europe today to ensure REACH compliance through the supply chain and form the basis for the supporting Downstream User (DU) sectors activities on Use Mapping as recommended by the European Chemicals Agency (ECHA). They represent the vast majority of impacts of solvents' uses on workers, consumers and the environment to help registrants carry out their Chemical Safety Assessments (CSAs). 



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