

SOLUTIONS

Winter 2018



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Editorial



Dear reader,

It is my pleasure as ESIG Chairman to introduce our Solutions Winter Newsletter 2018 to you.

It has been again a very busy year for our association and I am proud of the progress made with our projects. This newsletter will give you an insight into our recent activities, including our latest exposure assessment work and improvements to the website.

We are also looking forward to the launch, in February 2019, of the ESIG Solvents Award. Our communications team has worked very hard to prepare for this and I would like to thank them. It goes without saying that these thanks also extend to all the ESIG teams and the secretariat in Brussels for their work in 2018.

The ESIG Solvents Award is our way of highlighting the safe and sustainable use of solvents, taking account of health and safety, environmental protection, product performance or a combination of these.

We invite our downstream users involved in the distribution, formulation, storage or use of a solvent to apply for the Award. It is an excellent opportunity to tell your story about how you have boosted product performance, improved environmental protection or looked after the health and safety of your employees. So, do not hesitate to apply!

Last but not least, the ESIG calendar 2019 will focus on the contribution that solvents make to the UN sustainable developments goals (SDGs) in the fields of innovation, health, environment, climate etc.

I wish all our readers a Merry Christmas and a happy and peaceful New Year.

Dr Robert Oades, ESIG Chairman



UPDATE ON GENERIC EXPOSURE SCENARIO TOOLS PACKAGE

ESIG continues to work on its generic exposure scenario (GES) package of tools to keep them up-to-date and relevant as well as to meet the latest REACH guidance. 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).

In previous editions of Solutions, we have reported updates like the introduction of the GES Worker package as Chesar Files, which allows users to perform solvent CSAs in ECHA's Chesar Tool. This makes the most of the efficiencies of this assessment tool in preparing a Chemical Safety Report under REACH.

However, there may be cases when companies do not want to carry out a substance exposure assessment in Chesar. For example, a company may prefer to carry out its own assessment for a substance as a DU for a confidential use. It may also decide to demonstrate safe handling for a particular use with alternative Operational Conditions (OCs) or Risk Management Measures (RMMs) rather than those given in the Exposure Scenario provided with the substance SDS. In such cases, it may be more convenient to complete the assessment using the GES Worker files in Excel, which is a standalone tool.

History of the GES Worker Excel files

The GES Worker files were initially created using Microsoft Excel: ESIG published them to help registrants meet the first REACH deadline of 2010. These files were updated in 2014 using the Cefic CSA Excel tool, and took account of feedback from solvent users who registered in 2010. The latest update still uses the Cefic CSA Excel tool, but the content has been reviewed to take account of revisions to the GES Worker Chesar files so that the two GES tools are aligned.

They include:

- 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 DU Sectors Use Maps
- baseline OCs and RMMs for the demonstration of safe use for the different DNEL and vapour pressure bands

New files on the ESIG website

The following files have been uploaded to the ESIG website (and the replaced files have been archived):

1. GES Worker xls files for industrial and professional use
2. GES Worker xls Master (Cefic CSA Excel tool with some revisions, including 'Life Cycle Stage' replacing 'Sector of Use', PROC28 and new/amended CS phrases in picklists)
3. ESIG/ESVOC Overview Use Map Template with adjustments to streamline CS numbering and some corrections to content.

www.esig.org/reach-ges/workers

EXPERIMENTAL ASSESSMENT OF INHALATION AND DERMAL EXPOSURE DURING SPRAYING ACTIVITIES

The Fraunhofer Institute for Systems and Innovation Research recently conducted an experiment to study the contribution of aerosol and vapour to personal exposure in solvent spraying activities.

The study responded to external research suggesting a conflict between the modelled exposure estimates for inhalation from the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)'s Targeted Risk Assessment (TRA) tool, and the field data for industrial and professional spraying activities (PROC7 and PROC11).

The ECETOC TRA does not take aerosol exposure into account in its estimation of inhalation exposure of workers during spraying activities, and this may explain the mismatch between model and field data estimates, especially for substances with a lower vapour pressure.

As well as generating experimental data on the contribution of both aerosols and vapours, the study also investigates the link to different parameters, like vapour pressure and spraying method.

Three substances with differing vapour pressures were selected for the study. A spray task involving vertical spraying of a wall was repeated for each substance using a spray gun selected based on a worst-case generation of aerosol.



Results and conclusions

Aerosol-dominated exposure is to be expected for vapour pressures below 10 Pascal (Pa). Above this value there is a transition regime (10–100 Pa) characterised by simultaneous exposure to aerosols and vapours. For substances above 100 Pa, the saturation concentration of the vapour is the parameter controlling exposure. The measurements have shown a direct proportionality of estimated exposure concentration to the saturation concentration of the substance. For aerosol-dominated exposure scenarios, the experiments demonstrated the impact of the spraying method caused by the difference in the droplet size distribution on the exposure concentration – the smaller the droplet size, the higher the aerosol concentration.

The findings indicate that ECETOC TRA underestimates the inhalation baseline concentration for high vapour pressure substances (>300 Pa). However, it could not make a direct comparison between the findings of the study and ECETOC TRA estimates because of the limits of the experimental set up to mimic representative exposure scenarios. ECETOC TRA estimates a shift exposure that includes a much more complex exposure profile than what is reflected by the experiments.

For dermal exposure, the assessment should be seen as preliminary and may be considered as a conservative starting point. Indeed, neither the conceivable evaporation of the substances from the skin surface nor the wearing of clothes, ordinary or protective, are considered in the calculations.

This short study provides useful insights into the parameters impacting the generation of vapour versus aerosol during spraying activities, including vapour pressure and the design of spray generating equipment. Other task related parameters will impact the actual exposure profile for an individual over a working shift, e.g. maintenance of equipment and type of spraying activity, which may have varying directions and intensity of spray. The limited nature of the study meant it was not possible to characterise exposures to cover this level of detail.

Next steps

The results were shared with the ECETOC TRA task force to see how the data fits with the parameters applied in the TRA model exposure estimates – and with other studies looking into TRA performance. In turn, these may inform the design of additional experiments to verify or support adjustments to the TRA inhalation and/or dermal estimates for PROC7 and PROC11. A larger study sponsored by Cefic Long Range Research (LRI) initiative is currently under development.

If ECETOC TRA exposure estimates are eventually revised for PROC7 and PROC11 spraying activities, it may mean reviewing the existing REACH chemical safety assessments for the associated tasks/contributing scenarios.

When planning spraying activities, consideration of substance vapour pressure and spray nozzle design are two parameters that may be applied to reduce airborne concentration levels.

The [study report](#) is available on the ESIG website.

LIFE CYCLE ASSESSMENT DATA TO DEFINE PRODUCT ENVIRONMENTAL FOOTPRINTS

The Oxygenated Solvents Producers Association (OSPA) and the Hydrocarbon Solvents Producers Association (HSPA) began collecting Life Cycle Assessment (LCA) data for secondary data sets for Product Environmental Footprint (PEF) or related activities. This follows their in-depth analysis of EU sustainability policies and activities.

Both OSPA and HSPA will focus on three solvents with consumer end uses. Thinkstep, a sustainability software and consulting company, will support this important exercise, which should be finalised in 2019.

The outcome will be up-to-date information that companies and organisations can access free of charge to establish their PEFs.

ESIG SOLVENTS AWARD



We will launch the ESIG Solvents Award in the first quarter of 2019. This award highlights the safe and sustainable use of solvents. It covers health and safety, environmental protection, product performance or any combination of those.

Applications are open to downstream users of solvents, including anyone involved in the distribution, formulation, storage or use of a solvent including their respective trade associations.

HOW DO YOU ENTER?

It is easy! The online application tool will be launched on 1st February 2019 at www.esig.org/solventsaward2019. You just need to complete and submit your application by 30th April 2019.

SPECIFIC ENVIRONMENTAL RELEASE CATEGORIES (SPERC) – BACKGROUND

REACH requires manufacturers to complete a chemical safety assessment (CSA) for substances that carry a hazard classification. For the environment, the CSA involves determining the hazard posed by the substance and estimating the concentration of substance that could reach the environment through its various uses.



These are the so-called predicted no effect concentration (PNEC) and predicted environmental concentration (PEC), respectively.

Estimation of the PEC requires a number of inputs into an exposure model. Some inputs are based on chemical properties, such as physical chemistry and biodegradability. Others relate to the use, such as tonnage, number of emission days, release fractions to air, soil and water, and dilution factors. ECHA has provided default values for the use inputs, and these defaults are known as environmental release categories or ERCs and based on pattern of use for each life cycle stage.

However, ERC release fractions tend to be unrealistic and very conservative. For example, ERC 4 'Use of non-reactive processing aid at industrial site', assumes that 100% of substance is lost to each of air, soil and water compartments.

In response, industry has developed specific environmental release categories (SpERCs). Based on industry knowledge, SpERCs give assessors more realistic inputs for PEC derivation. However, they are still considered to be conservative, and therefore protective, when related to hazard in risk assessment.

Industry sectors developed SpERCs independently, which meant that the initiative needed guidance and consistency. Therefore, a SpERC core team of experts from a number of industry sector groups, including ESIG, developed SpERC factsheets containing the key values as inputs to exposure assessment. Each factsheet should be supported by a background document where the values are explained with references. This approach has been published in the open literature (<http://onlinelibrary.wiley.com/doi/10.1002/ieam.1745/pdf>) and as ECHA guidance within the CSR/ES Roadmap initiative. It is available at: https://echa.europa.eu/documents/10162/15669641/sperc_factsheet_guidance_en.pdf/4c94f0fb-07dd-4e9f-842a-3f21a63bd3fe

Many industry sectors' SpERCs, including ESIG SpERCs, have been mapped to GESs in ECHA's use map library and values programmed into ECHA's ChESAR assessment tool.

www.echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library

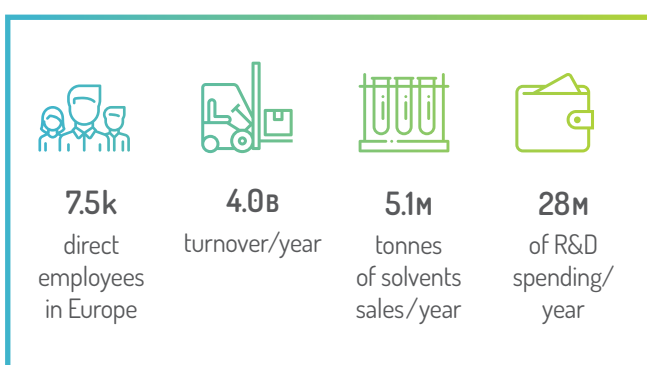
Over the last year, the SpERC core team have been working, in close cooperation with ECHA, to develop a quality control matrix, which is a tool to facilitate quality checking of SpERC documentation in a consistent manner. These quality checks (QC) can be conducted by industry sectors on their own SpERCs and by external reviewers (other industry sectors, consultants or Member States). The QC matrix should be finalised by the end of the year.

ESIG SpERCs were developed ahead of the first round of REACH registrations in 2010, and the documentation now needs to be updated according to initiatives described above. Supported by a consultant we are currently revising factsheets and preparing background documents. As well as updating documents, there are plans to consolidate information to take account of the overlap between ESIG and other industry sector SpERCs. ESIG SpERC updates should be completed in time for an anticipated external, third party review of SpERCs in 2019-2020.

DID YOU KNOW?

We have updated our facts and figures on the EU solvents industry. The new figures will be included in ESIG presentations and available on our website's homepage.

Here they are below!



CHANGES TO THE ESIG WEBSITE

Section on Occupational Exposure Limits (OELs) and new video explaining RCP (Reciprocal Calculation Procedure)

The Regulatory Section of the ESIG website has been updated to streamline information. The chapter on REACH has been split into two: a first part provides generic information and a second part is dedicated to the Generic Exposure Scenarios (GES). A new page has been added for Occupational Exposure Limits (OELs), providing an overview and links to databases where OELs can be found. It also dives into the issue of Hydrocarbon Solvents for which the so-called RCP method has been developed.

In addition, we have posted two short instructional videos made by the Hydrocarbon Solvents Producer Association (HSPA) to explain the Reciprocal Calculation Procedure (RCP) method and the RCP-calculations.

The video addresses setting OELs for hydrocarbon solvents, a challenging issue since these solvents have complex and variable hydrocarbon compositions. This means that the worker will inhale not only one but many types of hydrocarbons from the solvent at the same time. Some of these hydrocarbons are well known and have their own OELs, but for others, there is only limited information. It is thus vital to define an OEL that accounts for all the relevant types of hydrocarbons and provides consistent occupational advice.

A new approach was needed: it had to calculate a unique OEL for each hydrocarbon solvent, based on relatively simple compositional information. It also had to recognise that some components in hydrocarbon solvents cannot be identified, and that most of the existing toxicology data relates to representative hydrocarbon solvents rather than their individual components.

Therefore, the RCP approach was developed by hydrocarbon solvent manufacturers, which groups all hydrocarbons of similar physical, chemical and toxicological properties and assigns them a group guidance value (GGV) to cover existing OELs of representative hydrocarbons within a group. Using GGV values in the RCP calculation ensures that the hydrocarbons in the group do not exceed their own individual OELs. In practice this means measuring a single OEL that reflects the solvent's hydrocarbon composition.

www.esig.org/regulatory/oel/

CEFIC BOX

Industrial value chain: A bridge towards carbon neutral Europe

The EU needs a new and integrated industrial strategy for energy-intensive industries to complete a transition to a low-carbon EU economy, according to a report published by the Institute for European Studies (IES) and Vrije Universiteit Brussel (VUB) in cooperation with the European Commission. The report was commissioned by 11 energy-intensive industries including Cefic, the European Chemical Industry Council, to which ESIG belongs. It describes a combination of possible solutions that could help them reduce emission while remaining competitive, innovative and pivotal in the transition to a low-carbon economy.

The report analyses over 80 low-CO2 technology options available for energy-intensive industries and outlines the following conditions to design an efficient EU industrial policy:

- An ambitious RD&I programme providing adequate support for advanced low-CO2 technologies
- Globally competitive energy prices including a reliable and competitively priced low-carbon electricity supply
- Financed mechanisms to help companies refurbish old industrial facilities and modernise production processes
- Support for the creation of industrial clusters and synergy to improve resource efficiency and reduce CO2 emissions
- Incentives to use of public procurement and low-CO2 standards for products, so as to develop the market for low CO2 products and processes

For further information, please read the report:

www.ies.be/files/Industrial_Value_Chain_25sept.pdf



ONGOING SUCCESS OF SOLVENTS TRAINING

Our introductory training course on the solvents industry organised together with our UK sister association (SIA) continues to spark a lot of interest. The latest course (21st November) was booked up soon after opening the registrations – apologies for those who could not join!

However, a new training session has already been fixed next year for anyone seeking to learn about the history and types of solvents, the regulations, and their safe handling. This next workshop is on 14th May 2019 in Brussels. Register early at www.esig.org/product-stewardship/training/ or contact Véronique Schoune at vsc@cefic.be / +32 2 676 7269 for more information.

Outlook

A more advanced training course will be offered in co-operation with SIA in 2019. This second course will focus entirely on the uses of solvents in different industries and applications. It has been developed using feedback from those who participated in the first course. Watch out for further announcements!

MOVE

As of 1st January 2019, ESIG will move along with its mother organisation, Cefic, to its new offices: Rue Belliard 40, BE - 1040 Belgium.

We look forward to welcoming you there!



DOWNSTREAM USER BOX

ESIG joins the packaging ink joint industry task force

The Packaging Ink Joint Industry Task Force (PIJITF) was founded in 2006 as a collective industry response to public discussions on unexpected findings of a printing ink ingredient in food.

The PIJITF represents the value chain for printed food contact materials, from manufacturers of ink raw materials to food business operators. It currently gathers 14 European professional organisations, and welcomed ESIG as its most recent member.

The two goals of all involved in the industry chain are the production of safely packed food and the maintenance of high levels of consumer confidence in food safety. The PIJITF enables further collaboration along the value chain by creating model processes that ensure that the final printed food contact material is safe for its intended use. This includes guidelines, good practice guides, procedures and recommendations for those operating within the supply chain. It also provides a forum for identifying, discussing and sharing emerging issues that could have an impact on food safety.

The PIJITF has been recognized as a reference group for printed food contact materials. At the invitation of the EU Commission, the PIJITF has developed key elements, which should be considered when drafting legislation on printed food contact materials. These elements ensure a high degree of consumer safety whilst they are pragmatic and workable for industry.

SEASON'S GREETINGS

Merry Christmas and Happy New Year to all our readers!



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