

Transferring Solvents ESVOC GES Worker files into Chesar

Introduction:

The ESVOC Worker GES files are available as a start point for carrying out substance Chemical Safety Assessments for solvents and solvent-like substances under REACH using:

- a. Cefic CSA Template for liquids, and
- b. ECHA Chesar Tool

This guidance takes you through the steps necessary for using the **Worker GES files in Chesar** which have been prepared in Chesar '.CHR3' format.

It covers:

1. Pre-requisites
2. Scope
3. Importing the Worker GES files into Chesar
 - There are two options:
 - i. Chesar format 'CSA Block' – each GES/Use Title is available as a separate CSA Block for importing into Chesar on an individual basis.
 - ii. Chesar format 'Use Map' – GES/Use Titles have been grouped into a so-called Chesar 'Use Map' according to the Vapour Pressure and DNEL bands. Each 'Use Map' can be imported in one go and any GES titles not required can be readily deleted.
4. Processing the files in Chesar

Appendix 1: Worker GES/Use title v Volatility/DNEL Bands (and grouping of GES/Use title per Chesar 'Use Map')

Appendix 2: General notes on GES content and application in Chesar

Appendix 3: Qualitative Risk Assessment (QRA) – Approach for substances classified for irritation

It is assumed that users are familiar with the Solvents GES process (refer to [ESIG web site - GES Workers](#) for details) and using Chesar (refer to [Chesar web site](#)).



1. Pre-requisites

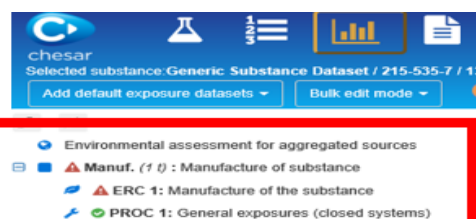
- Chesar is installed on your PC (or Server); (older Chesar v3.1 is not compatible)
- IUCLID Substance file with required Chesar inputs (IUCLID 6.1.2 and 6.1.3 are compatible with Chesar 3.2); Chesar 3.3 is compatible with IUCLID 6.2 and the IUCLID Cloud Service
- Worker GES/Use Titles for assessment are known (reference: GES Index, available for download from the ESIG GES website: <http://www.esig.org/regulatory/reach-ges/>)
- Generic Exposure Scenario Chesar files are saved to your PC (or LAN) – Chesar format ‘CSA Block’ or Chesar format ‘Use Map’. <http://www.esig.org/regulatory/reach-ges/workers/>
- Select the GES based on the Use Title and the relevant vapor pressure and Inhalation/Dermal DNEL for the substance.
 - See Appendix 1 for the GES list.
 - Not all Use Titles have a supporting GES file available in each VP/DNEL band, therefore select the VP and DNEL band closest to your substance as a start point and then refine the safety assessment as needed.

2. Scope

GES Chesar files include details for worker assessments only.

- Each GES is a use containing several contributing activities. For each contributing activity for workers a pre-defined set of conditions of use is provided which corresponds to the necessary inputs for the ECETOC *TRA model for workers*.

- ERCs are included but environmental assessments are not contained in these files. Red triangles will appear for this reason on imported data blocks.



- Tox end points for Long Term Systemic Inhalation and Dermal DNELs only have been used in GES assessments and RCR determinations. If your substance has DNELs for other hazards (e.g. short term Inhalation DNEL) or another qualitative hazard (e.g. Inhalation irritation) these substance effects must be additionally addressed by Users.

- Refer to Appendix 2 for general notes on GES content and application in Chesar.

3. Importing the GES Files into Chesar

i. Chesar Format - 'CSA Block'

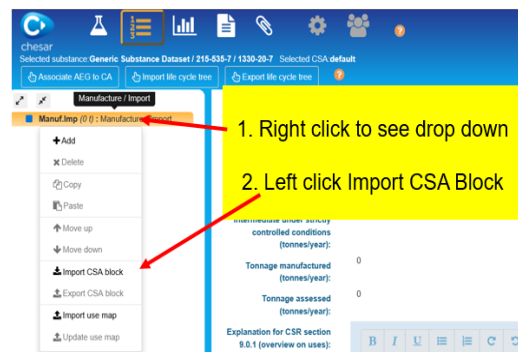
– each GES Title is available as a separate 'CSA Block' for importing into Chesar on an individual basis.

In Chesar Box 2: Import each relevant GES/Use Title in Chesar CSA Block format

Highlight the Top level of the Life Cycle i.e. 'Manuf/Import'.

Then right click:

- A Chesar Browse box will appear for you to browse to the file location where the GES CSA Blocks are saved to your PC or LAN.

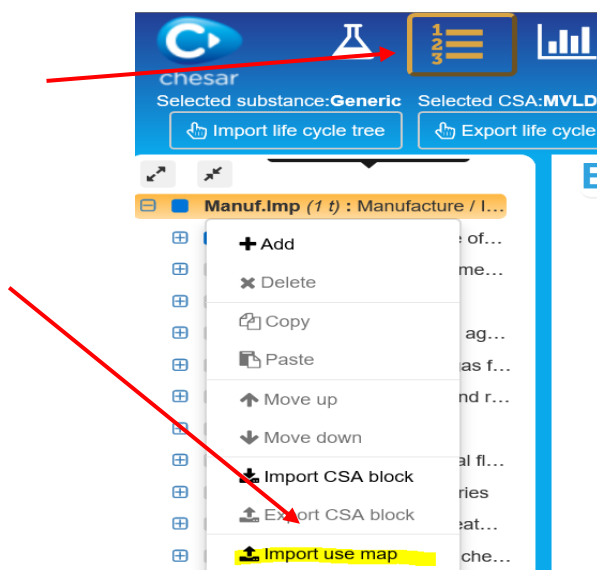


ii. Chesar Format - 'Use Map'

– GES/Use Titles have been grouped into so-called Chesar 'Use Maps' according to the Vapour Pressure and DNEL bands. Each 'Use Map' can be imported in one go and any GES/Use titles not required can be readily deleted. Not all GES/Use Titles are included within each 'Use Map'; thus, more than one 'Use Map' may be needed to cover all the required use titles. The GES/Use titles within each Chesar 'Use Map' grouping are given in Appendix 1.

In Chesar Box 2: Import each relevant GES grouping of Use titles in Chesar 'Use Map' format

In Box 2 select 'Import Use map' option (appears at bottom of the dropdown list). Any GES/Use titles not required can be readily deleted.

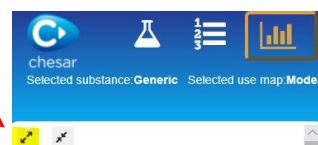


4. Processing the GES files in Chesar

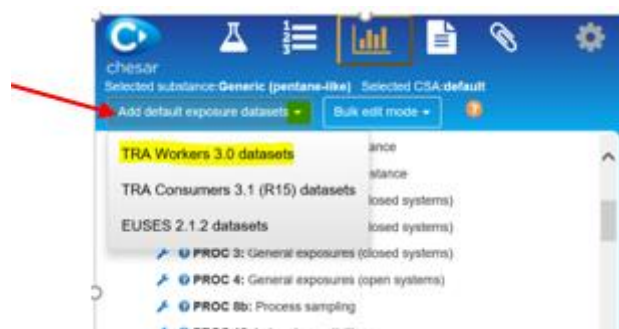
- Once the required GES/Use titles (in either the 'CSA Block' or 'Use Map' formats) are available in Chesar, the steps to adjust the GES content to generate the substance-specific CSA are similar for either format.

In Chesar Box 3:

- a. Expand all Uses by clicking on the expand button at the top lefthand corner of the list of GESs 'Use Map' Titles.



- b. Click on the dropdown menu 'Add default exposure datasets' and select 'TRA Workers 3.0 datasets' to ensure that the assigned exposure estimates are also activated in the tool.



STEP 1: Review and refine GES CSA details

The GES CSAs include OCs/RMMs to demonstrate safe use for the associated volatility and DNEL banding. The start point in the development of the GES CSA is the baseline default values for the ECETOC TRA, e.g. 8 hours duration, 100% concentration, basic general ventilation. If necessary to demonstrate safe use with an RCR <1, more stringent values have been selected based on typical conditions of use, so far as possible, with a target RCR of 0.8. Depending on the substance-specific volatility and DNEL values, the OCs/RMMs available in the GES may be unnecessary or insufficient for the demonstration of safe use and may be adjusted accordingly.

a. Check your RCRs

Are they too low/high for each Contributing Scenario?
If so adjust OC/RMMs as follows:

Route, type of effect	Hazard conclusion	Risk characterisation type	RCR	Risk control
Inhalation				
Inhalation, systemic, long term	DNEL (Derived No Effect Level) 292 mg/m ³	Quantitative	0.036	Green circle
Inhalation, systemic, short term	No hazard identified	Not needed		
Inhalation, local, long term	No hazard identified	Not needed		
Inhalation, local, short term	No hazard identified	Not needed		
Dermal				
Dermal, systemic, long term	DNEL (Derived No Effect Level) 40 mg/kg bw/day	Quantitative	0.014	Green circle
Dermal, systemic, short term	No hazard identified	Not needed		
Dermal, local, long term	No hazard identified	Not needed		
Dermal, local, short term	No hazard identified	Not needed		
Eye, local				
Eye, local	No hazard identified	Not needed		
Combined routes				
Combined, systemic, long term		Quantitative	0.05	Green circle
Combined, systemic, short term		Not needed		

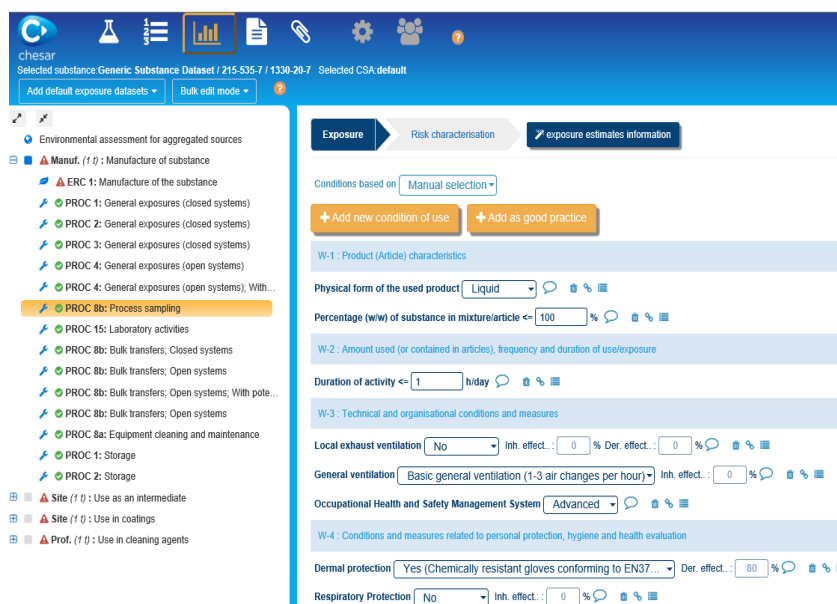


Too low:

1. Remove RPE/reduce glove
2. Increase duration
3. Increase concentration; etc.
4. Reduce ventilation

Too high:

1. Increase ventilation
2. Lower concentration
3. Lower duration
4. Advise gloves/RPE



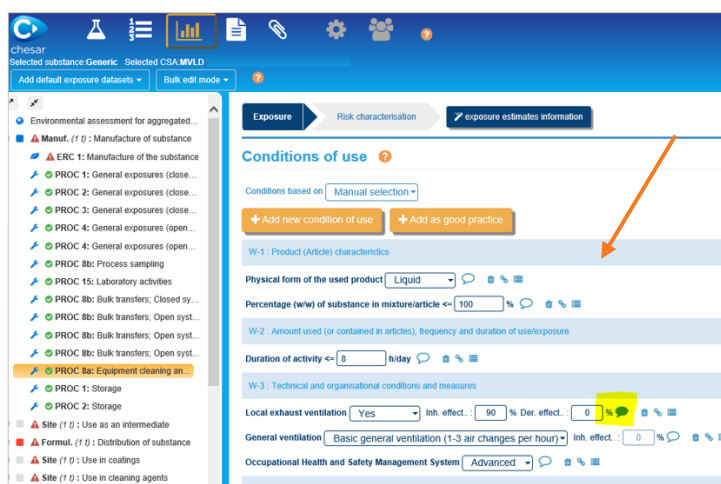
In adjusting the conditions of use, reference to the typical OCs/RMMs for the relevant DU Sector(s) covered by the GES should be taken in account. Refer to the GES Overview Use Map template showing alignment between the GES/Use titles and supporting Contributing Activities with relevant DU Sector details, where available.

b. Use of Non-Standard RMMs in Chesar

Non-standard RMMs refer to conditions of use applied that are not specifically covered by the ECETOC TRA default values. For example, the use of a drum pump to transfer a solvent is not an option within the TRA, however, it is a typical RMM.

ECHA has suggested that the TRA COU can be adjusted to accommodate non-standard RMMs in the following way:

- Provide an explanation on the adapted condition for:
 - a. the CSR using the comment 'bubble' supporting effectiveness (highlighted in yellow in the screen shot) and,
 - b. for the substance user, by adapting the default phrasing for inclusion in the ES for communication.



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- Include arguments for the CSR that the effectiveness of the specific measure can be assumed to be the same as the one suggested by the TRA. This way Chesar can calculate an exposure using the TRA.

The supporting explanation will appear in the CSR and ES for communication as shown in the Figures below. In the example given, the non-Standard RMM is a safe operating procedure for maintenance involving draining and flushing of the system prior to equipment break in or maintenance, equivalent to LEV effectiveness. Figure 1 shows the CSR output fed from the COU 'bubble' in Chesar Box 3, and Figure 2 the associated phrase for inclusion in the ES for communication added in Chesar Box 5.

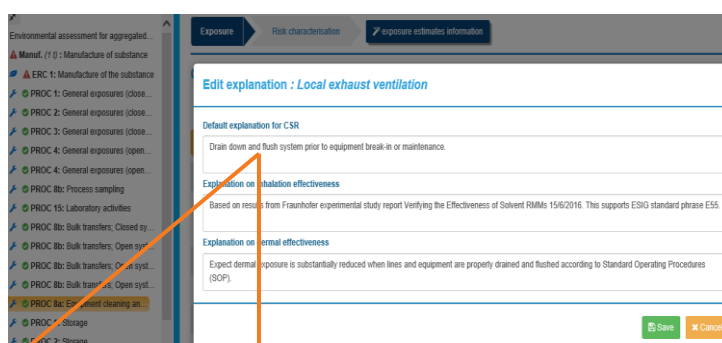


Figure 1: Example Output in CSR Section 9

Figure 2: Example Output in ES for communication

9.1.13. Worker CS 13: Equipment cleaning and maintenance (PROC 8a, PROC 28)

9.1.13.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of the used product: Liquid	TRA Workers 3.0
• Percentage (w/w) of substance in mixture/article: <= 100.0 %	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Local exhaust ventilation: Yes [Effectiveness Inhalation: 90%, Dermal: 0%] Drain down and flush system prior to equipment break-in or maintenance. Inhalation explanation: <i>Based on results from Fraunhofer experimental study report Verifying the Effectiveness of Solvent RMMs 15/6/2016. This supports ESIG standard phrase E55.</i> Dermal explanation: <i>Expect dermal exposure is substantially reduced when lines and equipment are properly drained and flushed according to Standard Operating Procedures (SOP).</i>	TRA Workers 3.0
• General ventilation: Basic general ventilation (1-3 air changes per hour) [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with basic	TRA Workers 3.0

Bulk transfers; Open systems (PROC 8b)	Covers use up to 4.0 h/day Wear suitable gloves tested to EN374.; For further specification, refer to section 8 of the SDS. Wear a respirator providing a minimum efficiency of 90.0 %; For further specification, refer to section 8 of the SDS. No other specific measures identified.
Equipment cleaning and maintenance (PROC 8a, PROC 28)	Covers use up to 8.0 h/day Drain down and flush system prior to equipment break-in or maintenance. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.; For further specification, refer to section 8 of the SDS.
Storage (PROC 1)	Covers use up to 8.0 h/day Store substance within a closed system.



c. AEROSOL Assessment

Certain GESs include parallel assessments to cover exposure to aerosol in addition to vapour. The aerosol assessment accounts for those substances with potential for aerosol generation from high energy conditions or the result of condensation following heating (PROC 4, 5, 6, 7, 10, 11, 17, 18).

Delete the Aerosol assessment if not applicable by right clicking CA in Box 2 and selecting 'delete'.

d. GENERAL MEASURES (Skin Irritants and Eye Irritants)

Assessment for substances that are skin/eye irritants require to be done on a qualitative basis as typically it is not possible to assign a DNEL. For these hazards qualitative RMM phrases resulting from the supporting qualitative assessment have been generically added to all CAs for each GES as a COU.

When not applicable, the assessor must bulk delete the GENERAL MEASURES phrase if the substance assessed is not classified as a Skin or Eye irritant.

If Skin or Eye irritation applies retain the COU. The risk control advice will display in the CSR and ES. See yellow highlighted text in Figures 3 & 4.

The screenshot displays the software interface for exposure assessment. On the left, a list of PROCs (Process Control Operations) is shown, with 'PROC 8a: Equipment cleaning and maintenance' highlighted in yellow. On the right, the 'Exposure' section is active, showing 'W3: Technical and organisational conditions and measures' and 'W4: Conditions and measures related to personal protection, hygiene and health evaluation'. The 'W4' section includes 'Dermal protection' (set to 'Yes') and 'Respiratory Protection' (set to 'No'). A red box highlights the 'Bulk delete' option in a dropdown menu for 'General Measures (skin irritants)'. A red text box on the right states: 'Bulk delete function can remove from all PROC CAs'.



Figure 3 – CSR Section 9 Output with Dermal quantitative + qualitative advice

9.2.4. Worker CS 4: Material transfers; Dedicated facility (PROC 8b)

9.2.4.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of the used product: Liquid	TRA Workers 3.0
• Percentage (w/w) of substance in mixture/article: <= 100.0 %	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: <= 8.0 h/day	TRA Workers 3.0
Technical and organisational conditions and measures	
• Occupational Health and Safety Management System: Basic	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal protection: Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection [Effectiveness Dermal: 80%]	TRA Workers 3.0
• Respiratory Protection: No [Effectiveness Inhalation: 0%]	TRA Workers 3.0
• General Measures (skin irritants) <i>Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN374) if hand contact with substance likely. Clean up contamination/spills as soon as they occur. Wash off any skin contamination immediately. Provide basic employee training to prevent / minimise exposures and to report any skin problems that may develop [E3].</i>	
• General measures (eye irritants) <i>Use suitable eye protection. Avoid direct eye contact with product, also via contamination on hands.</i>	
Other conditions affecting workers exposure	
• Operating temperature: <= 20.0 °C	TRA Workers 3.0
• Place of use: Outdoor	TRA Workers 3.0
• Good Hygiene <i>Assumes a good basic standard of occupational hygiene is implemented.</i>	
• No other specific measures identified [E120]	

Figure 4 – ES Narrative Output with Dermal quant + qual advice

1.2.3. Control of worker exposure

Conditions of use applicable to all contributing scenarios

Product (Article) characteristics	
Covers concentrations up to 100.0 %	
Amount used (or contained in articles), frequency and duration of use/exposure	
Covers use up to 8.0 h/day	
Conditions and measures related to personal protection, hygiene and health evaluation	
General measures (skin irritants): Ensure that direct skin contact is avoided; Identify potential areas for indirect skin contact; Wear suitable gloves tested to EN374; Clear spills immediately; Wash off any skin contamination immediately; For further specification, refer to section 8 of the SDS.	
General measures (eye irritants): Use suitable eye protection; Avoid direct eye contact with product, also via contamination on hands.	
Other conditions affecting workers exposure	
Assumes use at not more than 20°C above ambient temperature.	
Assumes a good basic standard of occupational hygiene is implemented	

Specific conditions of use per contributing scenario

Contributing scenario	Specific conditions of use
Drum batch transfers; Non-dedicated facility (PROC 8a)	No other specific measures identified.
Material transfers; Dedicated facility (PROC 8b)	Wear suitable gloves tested to EN374; For further specification, refer to section 8 of the SDS.
Small scale weighing (PROC 9)	Outdoor use No other specific measures identified.
Rolling, Brushing (PROC 10)	Outdoor use No other specific measures identified.
Spraying or fogging; Machines (PROC 11)	No other specific measures identified.
Dipping, immersion and pouring (PROC 13)	Outdoor use No other specific measures identified.
Storage (PROC 1)	Store substance within a closed system. No other specific measures identified.
Storage (PROC 2)	Store substance within a closed system. No other specific measures identified.

NB 1: When a substance has both a Dermal DNEL **and** a qualitative skin irritant hazard then glove advice is duplicated. The Assessor must decide whether to keep: a. qualitative advice, b. quantitative advice, or c. retain both.





The Chesar bulk edit function can be used to delete the qualitative General Measures phrases or set Dermal protection 'Yes' to all CAs. For the latter, first select the value 'basic glove with 80% effectiveness' and adapt the type of gloves required on a case by case basis for each CS in case the RCR remains >1 for the quantitative assessment.

NB 2: Additionally, qualitative hazards (e.g. skin, eye irritant) require a qualitative risk assessment justification for how the risk is controlled and included in Box 3 'Risk Characterization' tab (see figure below). Assessors will need to add these conclusions which can be managed via the bulk edit function. An example of justification statements used in existing registrations can be found in Appendix 3.





Risk characterisation

Route, type of effect	Hazard conclusion	Risk characterisation type	RCR	Risk controlled
Inhalation				
Inhalation, systemic, long term	No hazard identified	Not needed		
Inhalation, systemic, short term	No hazard identified	Not needed		
Inhalation, local, long term	No hazard identified	Not needed		
Inhalation, local, short term	No hazard identified	Not needed		
Dermal				
Dermal, systemic, long term	No hazard identified	Not needed		
Dermal, systemic, short term	No hazard identified	Not needed		
Dermal, local, long term	No hazard identified	Not needed		
Dermal, local, short term	Low hazard (no threshold derived)	Qualitative		<input checked="" type="checkbox"/>  
Eye				
Eye, local	Low hazard (no threshold derived)	Qualitative		<input checked="" type="checkbox"/>  
Combined routes				
Combined, systemic, long term		Not needed		
Combined, systemic, short term		Not needed		

STEP 2: FINISH OFF

- Generate the Chesar CSR (Box 4) and ES for communication (Box 5) and review to verify outputs.
- Edit to display information as needed in Box 4 and 5.
- Visit the Chesar webpage for application-specific support
<https://chesar.echa.europa.eu/web/chesar/support/manuals-tutorials>



Appendix 1: Worker GES/Use title v Volatility/DNEL Bands (and grouping of GES/Use title per Chesar ‘Use Map’)

There are numerous applications for solvents through the supply chain. The handling associated with these applications have been consolidated into approx. 40 Generic Exposure Scenario (GES) titles, covering Workers (Industrial and Professional), Consumers and the Environment.

The GES comprise a start point for Chemical Safety Assessments for solvents and aim to provide a consistent basis for use by Registrants in developing substance-specific exposure scenarios in support of their substance registrations.

The Table below lists the GES/Use titles available for Workers. It indicates the relevant Life Cycle Stage(s) per title and the available Volatility and DNEL Bands per Chesar ‘CSA Block’ or ‘Use Map’ format. **For details of the Volatility and DNEL Bands refer to Notes 1 and 2 located after the table.**

Having selected the relevant GES/Use Titles for your substance to be assessed (refer to the supporting GES Index and ESIG GES guidance), this Table will help you to identify the relevant Chesar ‘CSA Block’ or ‘Use Map’.

Not all Use Titles have a supporting GES file available in each VP/DNEL band. In this case, select the VP and DNEL band closest to your substance as a start point and then refine the safety assessment as needed.

GES #	GES/USE TITLE	Life Cycle Stage IS = Industrial Site PW = Professional Worker	VOLATILITY BAND (Note1) Numbering indicates available GES and grouping for ‘Chesar Use Map’ format			DNEL BAND (Note 2)
			LOW	MED	HIGH	
ESVOC_M_001	Manufacture	Manufacture	1	2	3	LOW
ESVOC_F_001	Formulation	Formulation	1	2	3	LOW
ESVOC_IS_001	Use as an Intermediate	IS	1	2	3	LOW
ESVOC_IS_002	Use as a Process Chemical	IS	1	2	3	LOW
ESVOC_IS_003	Coatings	IS		2		LOW
ESVOC_PW_001	Coatings	PW		2		LOW
ESVOC_IS_004	Cleaning	IS		2		LOW
ESVOC_PW_002	Cleaning	PW		2		LOW
ESVOC_IS_005	Oil & Gas field chemicals	IS	1	2		LOW
ESVOC_PW_003	Oil & Gas field chemicals	PW	1	2		LOW
ESVOC_IS_006	Lubricants	IS	1			LOW
ESVOC_PW_004	Lubricants	PW	1			LOW
ESVOC_IS_007	Metal working fluids	IS	1			LOW
ESVOC_PW_005	Metal working fluids	PW	1			LOW
ESVOC_IS_008	Blowing agents	IS			4	HIGH



ESVOC_IS_009	Binders	IS		2		LOW
ESVOC_PW_006	Binders	PW		2		LOW
ESVOC_PW_007	Agrochem	PW		2		LOW
ESVOC_IS_010	Fuel use	IS	1	2		LOW
ESVOC_PW_008	Fuel use	PW	1	2		LOW
ESVOC_IS_011	Functional fluids	IS		2		LOW
ESVOC_PW_009	Functional fluids	PW		2		LOW
ESVOC_PW_010	De-icing fluids	PW	5			HIGH
ESVOC_PW_011	Road construction	PW	1			LOW
ESVOC_IS_012	Laboratories	IS		2		LOW
ESVOC_PW_012	Laboratories	PW		2		LOW
ESVOC_PW_013	Explosives	PW	1			LOW
ESVOC_IS_013	Rubber production	IS	1			LOW
ESVOC_IS_014	Water treatment	IS		2		LOW
ESVOC_PW_014	Water treatment	PW		2		LOW
ESVOC_IS_015	Mining chemicals	IS	1			LOW
ESVOC_IS_016	Polymer processing	IS	1			LOW
ESVOC_PW_015	Polymer processing	PW	1			LOW

Note 1:

Volatility Bands - ECETOC TRA Worker Exposure Modelling Tool	
Low Vapour Pressure	0.01 Pa - 0.5 kPa at STP
Medium Vapour Pressure	0.5 - 10 kPa at STP
High Vapour Pressure	> 10 kPa at STP

GES 'Chesar Use Map' groupings:

- 1 = Low VP/Low DNEL
- 2 = Medium VP/Low DNEL
- 3 = High VP/Low DNEL
- 4 = High VP/High DNEL (Blowing Agents)
- 5 = Low VP/High DNEL (De-icing Fluids)

Note 2:

DNEL Bands	Inhalation (ppm)	Dermal (mg/kg/day)
Low	≤ 10	≤ 5
Medium	≥ 10 to 50	≤ 25
High	≥ 50 to 100	≤ 40

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Appendix 2: General notes on GES content and application in Chesar

Item	Clarification and Application in Chesar for GES Worker
<p>1. Operating (Process) Temperature</p>	<p>Default value in Chesar is 40 deg C. This has been amended to NTP 20 Deg C. This is aligned with ECETOC TR114 Table 3.</p> <p>Operating temperature is not to be confused with ambient temperature. Operating temperature expected to cover ambient temperature up to +/- 20 deg.</p> <p>For Contributing Activities (CAs) at 'elevated temperature', Chesar Operating Temperature has been adjusted to reflect this with associated adjustment in the exposure estimate.</p>
<p>2. Phrase: 'No other specific measures identified.'</p>	<p>This phrase is applied to all GES CAs where there are no RMMs assigned to demonstrate safe use. This is to avoid that there is a blank space in the Exposure Scenario which may worry readers that an assessment has been missed. In addition, the phrasing 'no other specific measures identified' points to the fact that some basic level of control is expected and is supported by the general phrase 'Assumes a good basic standard of occupational hygiene is implemented' (included as a standard phrase in Section 2.1) and that controls for flammability are applied where needed.</p> <p>Phrase applied in Chesar as an ESIG 'Condition of Use'.</p>
<p>3. Phrase: 'Assumes a good basic standard of occupational hygiene is implemented.'</p>	<p>This phrase is applied to all Worker GES. It refers to measures that are routinely encountered and applied to meet the requirements of relevant workplace legislation such as regulations supporting the EU Framework Directive, in addition to specific RMM identified in the ES. It is reflective of the Chesar field 'Occupational Health and Safety Management System' requirement. These may include, but are not limited to:</p> <ul style="list-style-type: none"> - Risk assessment of local workplace activities - Procedures supporting safe handling and maintenance of controls - Education and training of workers in understanding the hazards and control measures relevant to their activities - Provision of basic general ventilation (1 – 3 ACH) <p>Phrase applied in Chesar as an ESIG 'Condition of Use'.</p>



<p>4. Non-standard RMMs, i.e. RMMs not integrated into ECETOC TRA tool. E.g. Maintenance Safe Operating Procedure (SOP)</p>	<p>Currently Chesar does not auto-calculate exposure reduction for new non-Standard RMMs with a justified supporting efficiency value. To include such RMMs, a workaround has been agreed with the Chesar team to use an existing 'standard' RMM with the required efficiency value, allowing auto-calculation of exposure using that efficiency/effectiveness value. The appropriate non-standard RMM can be described for the CSR by editing the COU 'bubble' in Box 3 and by adapting the text for communication in Box 5 (see Step 1, b. Applying Non-Standard RMMs within Chesar, above)</p>
<p>5. Approach for Qualitative Risk Assessment</p>	<p>General Measures phrases for skin and eye irritants have been pre-populated as a COU to all Contributing Activities. Choose the ES template 'Use alternative template with common conditions of use per ES for workers', and the General Measures advice will appear in the CSR and ES for communication documents only once in the ES 'header' section. If not applicable (i.e. the substance does NOT have a skin or eye irritant classification) then the Assessor must bulk delete.</p> <p>Reasons this approach:</p> <ol style="list-style-type: none"> 1. Substances may only have a qualitative hazard, e.g. skin irritation, which needs to be clearly distinguished from a quantitative skin hazard requiring Dermal DNEL risk assessment. 2. This approach allows the inclusion/deletion of related phrases to be managed in an efficient manner in the CSR and ES. <p>The disadvantage with this approach is when these qualitative phrases are not applicable users must bulk delete. When the substance has both a Dermal DNEL and Qualitative irritation hazard the glove advice is duplicated.</p>

APPENDIX 3: QUALITATIVE RISK ASSESSMENT (QRA) APPROACH FOR IRRITATING SUBSTANCES

This Appendix includes existing templates for use in documenting a qualitative risk assessment for substances classified as eye (H319) and skin (H315) irritants. These may be used as a reference for developing the QRA justification for such substances for inclusion within Chesar Box 3.

3.1. EYE IRRITATION (H319) QUALITATIVE CSA

The purpose of the qualitative risk characterisation is to assess "... the likelihood that effects are avoided when implementing the exposure scenario..." (REACH Annex 1, Section 6.5).

This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The endpoints for which the available data may trigger a qualitative risk characterisation include eye irritation (H319).

This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Eye irritation is considered a low hazard. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.

For eye irritation a qualitative risk characterisation was conducted. Handling and storage risk management measures that are generally identified for eye irritation are given in the table below.

Liquid eye irritating substances, classified H319 (Causes serious eye irritation)

Examples of relevant Precautionary (P) Statements and Safety (S) Phrases	Components of the Qualitative Risk Assessment
<p>Prevention:</p> <ul style="list-style-type: none"> • P264: Wash with water thoroughly after handling. • P280: Wear protective gloves/protective clothing/eye protection/face protection. • S25: Avoid contact with eyes • S39: Wear eye/face protection <p>Response:</p>	<ul style="list-style-type: none"> • Implementation of basic standards of occupational hygiene; • Avoid direct contact with product; • Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately; • Wear protective gloves and suitable eye protection at all times when handling the substance • Avoid splashes and spills; • Avoidance of contact with contaminated tools and objects; • Clean up contamination/spills as soon as they occur; • Regular cleaning of equipment and work area;



<ul style="list-style-type: none"> • P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. • P337 + P313: If eye irritation persists: Get medical advice/attention. • S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice 	<ul style="list-style-type: none"> • Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed; • Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop; • Adopt good standards of personal hygiene. • Where activities may lead to aerosol release e.g. spraying, then additional skin and eye protection measures such as impervious suits and face shields may be required.
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A review of these RMMs indicates that if the user complies with the generic statements listed below, risks due to eye irritation can be considered to be adequately controlled. As eye exposure may also arise via skin (people rub their eyes with fingers) skin hygiene is also taken into account.

The outcome of the CSA is displayed within the relevant Exposure Scenarios by the inclusion of the following standard phrases at the start of Section 2.2 as they are applicable to as follows:

- [G44]: General measures (eye irritants)
- [PPE26]: Use suitable eye protection.
- [E73]: Avoid direct eye contact with product, also via contamination on hands.

Note: All ES's for R36 substances will also contain in section 2.1 the phrase G1, 'Assumes a good basic standard of occupational hygiene is implemented', which accounts for many of the elements described in the table above.

3.2. SKIN IRRITATION (H315) QUALITATIVE CSA

The purpose of the qualitative risk characterisation is to assess: "the likelihood that effects are avoided when implementing the exposure scenario..." (REACH Annex 1, Section 6.5). The qualitative risk characterisation has to be completed when there is no basis for setting a DNEL or DMEL for a certain human health endpoint, i.e. when the available data for this effect do not provide quantitative dose-response information, but there exist toxicity data of a qualitative nature. One of the endpoints for which the available data may trigger a qualitative risk characterisation includes irritation.

When no DNEL for an endpoint is needed the general approach aims at reducing/avoiding contact with the substance. This is achieved by implementation of risk management measures (RMMs) and operational conditions (OCs) – these need to be proportional to the degree of concern for the health hazard presented by the substance. The control strategy must be sufficient to support the conclusion that risk is controlled to a level of no concern.

Implementation of a selection of these RMMs will ensure that the likelihood of an event occurring due to the irritation hazard of the substance is negligible and the risk is considered to be controlled to a level of no concern.

Hazard	Material	Risk / Hazard Phrase	P Phrase	Qualitative Risk Assessment
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Skin Irritation	<ul style="list-style-type: none"> • Gas • Liquid 	H315	<p>Prevention:</p> <ul style="list-style-type: none"> • P264: Wash ... thoroughly after handling. • P280 : Wear protective gloves. <p>Response:</p> <ul style="list-style-type: none"> • P302 + P352 : IF ON SKIN: Wash with plenty of soap and water. • P321 : Specific treatment (see ... on this label). • P332 + P313 : If skin irritation occurs: Get medical advice/attention. • P362 : Take off contaminated clothing and wash before re-use. 	<p>Implementation of basic standards of occupational hygiene; Avoid all skin contact with product; Wear gloves (tested to EN374) if hand contamination likely, wash off any skin contamination immediately; Minimisation of splashes and spills; Avoidance of contact with contaminated tools and objects; Clean up contamination/spills as soon as they occur; Regular cleaning of equipment and work area; Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; Training for staff on good practice to prevent / minimise exposures and to report any skin problems that may develop; Good standard of personal hygiene. Where activities may lead to aerosol release e.g. spraying; additional skin protection measures such as impervious suits and face shields are required.</p>
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The outcome of the CSA is displayed within the relevant ES by the inclusion of the general phrase:

- E3: Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN374) if direct hand contact with substance likely. Clean up contamination/spills as soon as they occur. Wash off skin contamination immediately. Provide basic employee training to prevent / minimise exposures and to report any skin effects that may develop.

Together with (where there is the potential for additional and significant exposure):

- E4: Other skin protection measures such as impervious suits and face shields may be required during high dispersion activities which are likely to lead to substantial aerosol release, e.g. spraying.

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