



# SWEDS AND SUMIS GUIDANCE

Guidance for the REACH registrants of fertilizer substances, fertilizer formulators and end-users

## Abstract

This Guidance for the manufacturers and end-users of fertilizer mixtures aims to provide support in communicating safe use information as prescribed by REACH article 31.7:

*"Any DU shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses."*

# Contents

1	Fertilizers Europe Disclaimer .....	2
2	Purpose of this document.....	2
3	Safe use communication obligations in the supply chain.....	3
4	Fertilizers Europe sector Use Map.....	3
5	SWEDs .....	4
5.1	What are SWEDs? .....	4
5.2	Exposure assessment and risk characterization by SWEDs – principle .....	7
5.3	Fertilizers Europe SWEDs.....	7
6.	SWEDs and Chesar .....	10
7.	SUMIs .....	12
7.1.	Link between Fertilizers Europe SWEDs and SUMIs .....	12
8.	Formulators attach the relevant SUMIs to the SDS of the mixture.....	13
8.1.	Validation of the SUMI by the formulator .....	14
9.	SUMI provides guidance to the grower .....	15
10.	References .....	16

## 1 Fertilizers Europe Disclaimer

Fertilizers Europe represents majority of fertilizer producers in Europe and is recognized as the dedicated industry source of information on mineral fertilizers. Fertilizers Europe takes, among others, responsibility in supporting fertilizer substance manufacturers, fertilizer formulators and end users to comply with REACH regulation (EC) No 1907/2006 and to ensure the safe use of fertilizer products.

Safe Use of Mixture Information (SUMIs) have been developed by Fertilizers Europe in the framework of the CSR/ES Roadmap initiative (ref. 4), under the umbrella of ENES (Exchange Network on Exposure Scenarios). They have been developed with the aim to provide support in communicating safe use information along the supply chain, as prescribed by REACH article 31.7.

The content of the SUMIs must not be modified by the user. By using the SUMIs for fertilizers, users accept full responsibility for their further uses. The producers of this guidance document cannot take liability for any use or misuse of the results.

The SUMIs are made freely available on the Fertilizers Europe website <http://www.reachfertilizers.com/>

## 2 Purpose of this document

This document provides information about Fertilizers Europe SUMIs (Safe Use of Mixture Information) and SWEDs (Sector-specific Worker Exposure Descriptions).

In this Guidance it is described how SWEDs and SUMIs have been established and how substance manufacturers and formulators of hazardous mixtures should benefit from them and further, how the end users (professional growers and farmers) should use SUMIs in their daily work to control risks when handling fertilizers with intrinsic hazards to human health.

SWED/SUMI approach concerns fertilizer mixtures, classified as hazardous for workers for CLP and placed on the market in European Union and in EEA countries Norway, Iceland and Liechtenstein.

Fertilizers Europe SWED/SUMI concept tends to cover the most common fertilizer uses.

### 3 Safe use communication obligations in the supply chain

Suppliers of hazardous substances need to provide up-to-date Safety Data Sheets (SDSs) and Exposure Scenarios (ESs) to their customers. Customers may use these substances as components in mixtures (“formulators”).

Formulators of fertilizer mixtures have the obligation to review the (e)SDSs of the ingredient substances for the hazards to human health and to environment and assess if the mixture is classified as hazardous according to CLP. If mixture is classified, formulators need to check whether the identified uses of their downstream users are covered in the incoming SDSs/ESs of the ingredient substances (ref. 6). Formulators are obliged to communicate the information on safe use details to the customers.

If the fertilizer mixture is not classified as hazardous, no specific safe use instructions needs to be provided via Safety Data Sheet to the customers as no health or environmental risks from fertilizer use are expected.

The company placing the hazardous fertilizer mixture on the market shall communicate the safe use instructions to his customers either in the main body sections of the SDS or in a use-specific Safe Use of Mixture Information attachment, called SUMI. It is also possible to append all the Exposure Scenarios of the ingredient substances contributing to the classification of the fertilizer mixture, but this is not a practical choice for professional workers like farmers. Professional workers prefer to receive easy-to-read instructions and this is in accordance with EU Commission’s 2<sup>nd</sup> REACH Review 2018, action 3 (ref. 2). SUMIs are targeting to be practical, concrete and have a harmonized layout. This guidance introduces how the SUMI communication concept, originally developed by DUCC, 2015 (ref. 6) has been applied in fertilizer sector.

### 4 Fertilizers Europe sector Use Map

To be able to give safe use instructions for chemicals, the result of the exposure and risk assessment needs to be available for each relevant substance present in the product. Assessment needs to be made per each identified use.

Ecetoc TRA, embedded in ECHA’s Chesar tool is the commonly applied Tier1 IT tool to assess the health hazards of the uses of substances. To assist the registrants of a substance to perform the assessment properly, downstream users of the substance need to communicate the details of use practices to the registrants. ECHA’s Exchange Network on Exposure Scenarios ([ENES](#)) recommended each sector to collect the common uses into so called Use Map table.

Fertilizers Europe coordinated the co-operation among its members under the umbrella of REACH Farm Consortium (REACH Consortium of manufacturers of Fertilizers and Related Materials) and the fertilizer sector Use Map was built. Use Map is freely available in ECHA’s use maps Library (<https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library>) and on Fertilizers Europe website (<https://www.reachfertilizers.com/#map>). Fertilizer sector Use Map describes how fertilizers are produced

by formulation or by manufacturing new substances and how fertilizers are used by professional growers and consumers. Each use is split into different contributing activities according to ECHA guidance R12 (ref. 3.). Fertilizer sector Use Map thus standardizes the use descriptions, which can be used as realistic inputs in exposure and risk assessment tools, like Ectoc TRA in Chesar.

Fertilizer sector Use Map suggests the generic exposure determinants, PROC and ERC codes to be applied when assessing the exposures and risks from handling the fertilizer ingredients in industrial setting (i.e. manufacturing or formulation of chemicals). For the professional setting sector-specific spERCs and SWEDs were generated and incorporated in the fertilizer sector Use Map. spERCs and SWEDs enable a more realistic assessment of the exposures and risks to the environment and to the workers in the professional setting.

The assessment of environmental exposures and risks arising from the use of environmentally classified fertilizers require the use of FEE tool (Fertilizers Environmental Exposure tool). FEE tool and spERCs, together with their guidance, are available on Fertilizers Europe website at <https://www.reachfertilizers.com>

The current document focuses, instead, on fertilizer sector SWEDs for the assessment of the occupational exposures and risks of fertilizer substances and mixtures.

## 5 SWEDs

Fertilizers Europe recommends all companies, who manufacture substances ending up to fertilizers, to perform the exposure and risk assessment by fertilizer sector SWEDs. SWEDs can be used as direct inputs in Chesar and thereafter registrants can update their CSRs and the Exposure Scenarios communicated down to their customers in fertilizer sector.

### 5.1 What are SWEDs?

SWEDs are **S**ector-specific **W**orker **E**xposure **D**escriptions, which can be selected as assessment inputs in Chesar (Ectoc TRA) when performing the exposure assessment for a substance. Each SWED already contains the typical use conditions (e.g. exposure time and indoor vs. outdoor conditions) and risk management measures (RMMs) of the selected use. For example, growers' procedure to empty the liquid fertilizer into a spraying tank is usually very similar (**Picture 1**). Exposure time is short but exposure to splashes is possible. If the product is not classified as hazardous via inhalation route, eye and face protection, gloves and coverall with boots will be used as RMMs.

**Picture 1.** Pouring a classified liquid fertilizer to the fertilizer spraying tank in outdoor conditions. As the product is not hazardous via inhalation route, the use of gloves and eye protection as personal protection measures (SWED3) will minimize the exposure and the risk of adverse effects to human health. Photo: Yara International ASA.



Fertilizers Europe collected the typical use conditions and RMMs of the fertilizer sector. To convert the information into SWEDs, ECHA's Template in xls format was used. For Chesar purposes the SWEDs were transformed into Chesar format, which will be available on the ECHA web site.

**Table 1** shows the elements of SWED3, illustrating the above-mentioned working conditions and RMMs. SWED3 brings the following input to the exposure and risk assessment in Chesar:

- a liquid product is handled
- outdoor conditions
- gloves and eye protection are used
- daily working time (time used for mixing and loading activities summed up) is restricted to one hour maximum
- additional specific info on temperature, effectiveness of protection etc

Table 1. Example, SWED3 content.

Field No.	Field name	SWED 3
		Field content
<b>1</b>	<b>SWED identifiers</b>	
1.1	SWED title	Mixing and loading of liquid fertilizers into the equipment by farmers, growers and contractors including analyses (outdoor, without respiratory protection).
1.2	SWED code	FE_SWED3_PW   1_o_noRPE
1.3	Short description of process/activity covered	Mixing and loading of liquid fertilizers into the equipment by farmers, growers and contractors including analyses (outdoor, without respiratory protection).
1.4.1	Short description of the applicability domain (in terms of substance properties)	Liquid materials transferred and used.
1.4.2	Short description of factors during use that may influence selection of modeling tool	
1.5	Relevant SUMI(s) for end-user communication	FE_SUMI 3
<b>1.6</b>	<b>Relevant contributing activity(ies)</b>	
1.6.1.1	Contributing activity/scenario name	Unloading and loading of fertilizer in non-dedicated facilities (e.g. farm outdoor conditions), including sampling and cleaning fertilizer residues from the equipment.
1.6.1.2	Corresponding PROC	PROC_8a
1.6.2.1	Contributing activity/scenario name	Packing solids in a dedicated filling line, including weighing.
1.6.2.2	Corresponding PROC	PROC_9
1.6.3.1	Contributing activity/scenario name	Handling of fertilizer in stages with significant contact.
1.6.3.2	Corresponding PROC	PROC_5
1.6.4.1	Contributing activity/scenario name	Unloading and loading of fertilizer in dedicated facilities (e.g. in greenhouses where dedicated engineering controls are in place), including sampling.
1.6.4.2	Corresponding PROC	PROC_8b
1.6.5.1	Contributing activity/scenario name	-
1.6.5.2	Corresponding PROC	
1.7	Last Revision date	11.10.2019
<b>2</b>	<b>Conditions of use for workers (input to CSA)</b>	
2.1	Percentage (w/w) of substance in mixture	<= 100 %
2.2	Duration of activity	<= 1 h/day
2.3	Place of use	Outdoor
2.4	Physical form of the used product	Liquid
2.5	Operating temperature (°C)	<= 40 °C
2.6	General ventilation	-
2.7	Local Exhaust Ventilation (LEV)	-
2.7.1	Effectiveness (%) for Dermal	
2.7.2	Effectiveness (%) for Inhalation	
2.8	Use of Respiratory Protection Equipment (RPE)	No
2.8.1	Effectiveness (%) for Inhalation	0.0
2.9	Use of gloves & other dermal protection	Yes (Chemically resistant gloves conforming to EN374) and (other) appropriate dermal protection
2.9.1	Effectiveness (%) for Dermal	80.0
2.10	Use of eye protection	Yes
2.11	Occupational health and safety management system	Basic
<b>3</b>	<b>Description of other conditions of use, if relevant for specified exposure assessment tool</b>	
3.1	Cabin control containment	-
3.1.1	Effectiveness (%) for Inhalation	
3.1.3	Relevant for exposure assessment tool	
<b>4</b>	<b>Rigorous containment</b>	
4.1	Rigorously contained system	No
4.2	Description of non-technical means for rigorous containment and strict control for manual intervention.	-
<b>5</b>	<b>Measured data available</b>	
<b>6</b>	<b>Additional good practice advice</b>	

## 5.2. Exposure assessment and risk characterization by SWEDs – principle

If the assessment by a SWED in Chesar ends up to an exposure value which is lower than the substance's safe exposure limit, DNEL (mg/kg body weight/day or mg/m<sup>3</sup>), the use can be regarded as safe (**Risk Characterization Ratio, RCR<1**). The DNEL is based on the scientific data collected for the substance and by applying the safety assessment factors.

Fertilizers Europe SWEDs are highly recommended to be used in the exposure and risk assessment by the manufacturers of all substances, which will be used as ingredients in fertilizer products.

Formulators of fertilizer mixtures need to assess the Exposure Scenarios of the mixture ingredient substances and to deduct if the substances in the mixture can be used safely by the customers down in the supply chain. If fertilizer formulator, after examining the suppliers' eSDSs, concludes that SWED-based assessment has been performed for the relevant substances in his classified mixture with RCR<1, he can communicate the conditions of use contained in the SWED to the professional growers. Communication can be made by the SUMI document appended to the mixture SDS. More about Fertilizers Europe SUMIs and about the link between the SWED and SUMI can be read in later chapters.

If the registrant of the ingredient substance has assessed the uses by applying sector specific SWEDs, it is easy for the formulator to see if all his professional customers' uses are covered. In special situations, formulator can prepare a specific Downstream User CSR if the SWED conditions are not covered by the registrant.

## 5.3. Fertilizers Europe SWEDs

The design of Fertilizers Europe SWEDs is shown in **Table 2**.

Fertilizers Europe SWEDs were first split into two main use scenarios:

1. Transfers, mixing, loading, cleaning, laboratory use
2. Application for the crop

Secondly the SWEDs were differentiated between the activities happening in indoor and in outdoor conditions. SWEDs in indoor conditions expect the air exchange ratio 1-3 times per hour. In outdoor conditions air exchange happens on a natural way.

Next the SWEDs were split into scenarios where respiratory protection is either needed or not needed (to protect from particles (dust, aerosols) or from acid vapors).

Gloves and eye protection, likewise the coverall with long sleeves and boots are always advised to be used when handling fertilizer products with a classification for a health hazard, even if the product gets heavily diluted before spreading. However, if the spreading of the classified fertilizer happens by a tractor with contained cabin or if fertilizer is applied via irrigation or is placed into soil by special equipment (App. 2a.), none of these risk management measures are required as the exposure is regarded as negligible.



Further, the SWEDs were categorized between solids and liquids.

Mixing, loading, cleaning, laboratory use scenario covers the operations described in ECHA R12 guidance (ref. 3) by PROC5, 8a, 8b, 9 and 15. Solid or liquid fertilizers are poured from bags or containers to spreaders and tanks and are in some cases diluted by water (see App 1). Samples for analyses may be taken. At the end of the operations the equipment will be cleaned and empty packages with traces of product handled. It is expected that the worker may become exposed in such preparatory activities maximum 1 hour per day.

Application scenario covers the application of the fertilizer to the crop by a technique which may expose the worker to dust (product is solid during application) or to spray mist (product is in liquid form during application). This happens for example when solid or liquid fertilizers are spread by a tractor without any contained cabin (see App 2b) or if liquid sprays are applied by using a backpack sprayer. ECHA R12 Guidance (ref. 3) describes this kind of exposure by PROC11. Eight (8) hours working time is considered.

**Table 2.** The design of fertilizer sector SWEDs.

	Mixing, loading, cleaning, laboratory use (PROC5, 8a, 8b, 9,15)				Application activities (PROC11). Exposure potential.				Application activities (PROC11). No exposure potential.
	Indoors		Outdoors		Indoors		Outdoors		Outdoors
	No respiratory protection	Yes respiratory protection	No respiratory protection	Yes respiratory protection	No respiratory protection	Yes respiratory protection	No respiratory protection	Yes respiratory protection	No respiratory protection
	Yes gloves				Yes gloves				No gloves
	Yes eye protection				Yes eye protection				No eye protection
SWEDs for LIQUID	1	2	3	4	5	6	7	8	9
SWEDs for SOLID	10	11	12	13	14	15	16	17	18
Explanation	RPE not required because -the product is <b>not classified for inhalation hazard</b> OR -if SWED assessment shows that the inhalation exposure and risks thereof are considered as negligible		RPE not required because -the product is <b>not classified for inhalation hazard</b> OR -if SWED assessment shows that the inhalation exposure and risks thereof are considered as negligible		RPE not required because -the product is <b>not classified for inhalation hazard</b> OR -if SWED assessment shows that the inhalation exposure and risks thereof are considered as negligible e.g. due to the dilution of the product before application		RPE not required because -the product is <b>not classified for inhalation hazard</b> OR -if SWED assessment shows that the inhalation exposure and risks thereof are considered as negligible e.g. due to the dilution of the product before application		PPE not required, because: - grower is protected when sitting in closed tractor cabin - there is no exposure as application of fertilizer happens by placement or irrigation

In the Fertilizers Europe Use Map each SWED has a specific code and title (contributing activity name) (**Table 3**).

SWED codes have been built by using the following abbreviations for the use conditions:

- FE: Fertilizers Europe
- SWED: Sector-specific Worker Exposure Descriptions
- PW: professional worker
- l: liquid
- s: solid
- 1: duration 1 hour per day max
- 8: duration 8 hours per day max
- i: indoors
- o: outdoors
- RPE: Respiratory Protection Equipment
- RMM: Risk Management Measures
- cabin: tractor is equipped with contained cabin
- diluted: product is diluted down to non-classification

**Table 3.** Coding and naming of fertilizer sector SWEDs

<b>SWED code</b>	<b>SWED title</b>
FE_SWED01_PW_l_1_i_noRPE	Mixing and loading of liquid fertilizers into the equipment by farmers, growers and contractors including analyses (indoor, without respiratory protection).
FE_SWED02_PW_l_1_i_RPE	Mixing and loading of liquid fertilizers into the equipment by farmers, growers and contractors including analyses (indoor, with respiratory protection).
FE_SWED03_PW_l_1_o_noRPE	Mixing and loading of liquid fertilizers into the equipment by farmers, growers and contractors including analyses (outdoor, without respiratory protection).
FE_SWED04_PW_l_1_o_RPE	Mixing and loading of liquid fertilizers into the equipment by farmers, growers and contractors including analyses (outdoor, respiratory protection).
FE_SWED05_PW_l_8_i_noRPE	Applying liquid fertilizers by spraying for the crop by farmers, growers and contractors (indoor, without respiratory protection).
FE_SWED06_PW_l_8_i_RPE	Applying liquid fertilizers by spraying for the crop by farmers, growers and contractors (indoor, with respiratory protection).
FE_SWED07_PW_l_8_o_noRPE	Applying liquid fertilizers by spraying for the crop by farmers, growers and contractors (outdoor, without respiratory protection).
FE_SWED08_PW_l_8_o_RPE	Applying liquid fertilizers by spraying for the crop by farmers, growers and contractors (outdoor, with respiratory protection).
FE_SWED09_PW_l_8_o_cabin	Applying liquid fertilizers by spraying for the crop by farmers, growers and contractors (outdoor, tractor with contained cabin, placement etc.).
FE_SWED10_PW_s_1_i_noRPE	Mixing and loading of solid fertilizers into the equipment by farmers, growers and contractors including analyses (indoor, without respiratory protection).
FE_SWED11_PW_s_1_i_RPE	Mixing and loading of solid fertilizers into the equipment by farmers, growers and contractors including analyses (indoor, with respiratory protection).
FE_SWED12_PW_s_1_o_noRPE	Mixing and loading of solid fertilizers into the equipment by farmers, growers and contractors including analyses (outdoor, without respiratory protection).
FE_SWED13_PW_s_1_o_RPE	Mixing and loading of solid fertilizers into the equipment by farmers, growers and contractors including analyses (outdoor, with respiratory protection).
FE_SWED14_PW_s_8_i_noRPE	Applying solid fertilizers for the crop by farmers, growers and contractors (indoor, without respiratory protection).
FE_SWED15_PW_s_8_i_RPE	Applying solid fertilizers for the crop by farmers, growers and contractors (indoor, with respiratory protection).
FE_SWED16_PW_s_8_o_noRPE	Applying solid fertilizers for the crop by farmers, growers and contractors (outdoor, without respiratory protection).
FE_SWED17_PW_s_8_o_RPE	Applying solid fertilizers for the crop by farmers, growers and contractors (outdoor, with respiratory protection).
FE_SWED18_PW_s_8_o_cabin	Applying solid fertilizers for the crop by farmers, growers and contractors (outdoor, tractor with contained cabin, placement etc.).

## 6. SWEDs and Chesar

Fertilizers Europe covers in the sector Use Map all the contributing activities for workers and the environment in the different life cycle stages (formulation, industrial, professional and consumer uses). spERCs are available for both professional and consumer fertilizer uses and SWEDs for professional uses. All SWEDs are compatible with Chesar (SWED 9 and 18 must be assessed by a higher tier tool but can thereafter be imported to Chesar and continue the work there). For spERCs a separate FEE tool needs to be used.

Chesar 3.6 links each PROC to one or more SWEDs. In fertilizer sector map PROC 11 is linked to ten different SWEDs (SWED 5-9 and SWED 14-18; table 2.). Conversely, mixing, loading and cleaning activities (PROC5, 8a, 8b, 9, 15) are grouped in fertilizer sector use map. Technically in Chesar 3.6 each of these five PROCs requires a separate assessment for the comparable SWED (SWED 1-4 and SWED 10-13).

Fertilizers contain nutrients but may contain in low concentrations also co-formulants (coatings, colors, surfactants etc.). Fertilizers Europe SWEDs can be used to assess the exposures and risks of both nutrient and co-formulant substances, which are classified for hazards to human health.

For a substance, present in fertilizers, the exposure assessment starts by importing the substance data from IUCLID (Box1) and thereafter the Fertilizers Europe Use Map to Chesar (Box2). The non-relevant set of uses (Examples: *Use of monomers in polymer coating of fertilizers*; *Professional use of solid fertilizers* if substance is always liquid by nature; *Consumer use of fertilizers* if the substance will not be sold to consumers in fertilizer products etc.) should be deleted after importing into Chesar.

**Picture 2.** Imported Fertilizers Europe Use Map in Chesar (Box 2)

The screenshot displays the Chesar software interface for configuring a 'Use map'. The top navigation bar includes icons for home, search, and settings. Below the navigation bar, the 'Use map: Fertilizers Europe Use Map' is selected. A list of use categories is shown on the left, including 'Formul.', 'Site', 'Prof.', and 'Consum'. The main area contains a 'Name' field with 'Fertilizers Europe Use Map', an 'Advice to assessor' field with a rich text editor toolbar, and an 'Internal remarks' field with a dropdown arrow.

The assessment should be performed for the substance both in solid and in liquid form, if applicable. For solids this is important as solid salts may end up to liquid fertilizer products, placed on the market. Also solid fertilizer mixtures might be dissolved into water by growers and applied for the crop in liquid form by

spraying. In such cases registrant needs to benefit from the refinement options of Ecetoc TRA in Chesar by selecting high dustiness property for the solid substance in a liquid product (worst-case scenario).

The assessment should start using the SWEDs 1, 3, 5 and 7 (substance used in liquid form, no RPE) and / or SWEDs 10, 12, 14 and 16 (substance used in solid form, if applicable for the substance, no RPE). If safe use conditions can be reached, assessment is ready and the OC and RMM of the SWED can be communicated down the supply chain. If assessment does not demonstrate safe use, the concentration of the substance can be adapted (**Picture 3**) as the concentration of hazardous substances is usually well below 100% in fertilizer mixtures. Concentration is the parameter, which can be modified in Chesar for Fertilizers Europe SWEDs. The maximum concentrations of safe use per each SWED in liquid and solid form are recommended to be obtained by the registrants and communicated in the eSDS to the formulators.

**Picture 3.** Modification of substance concentration in Chesar (Box 3)

The screenshot displays the Chesar software interface. On the left, a navigation menu lists various SWEDs, with 'PROC 5: Handling of liquid fertilizer in st...' highlighted. The main panel shows the 'Exposure' tab selected, with 'Conditions based on' set to 'SWED'. The 'Selected SWED' section shows the title 'Mixing and loading of liquid fertilizers into the equipment by farmers, growers and contractors including analyses (indoor, w...' and the code 'FE\_SWED01\_PW\_L\_1\_i\_noRPE'. Below this, the 'W-1: Product (article) characteristics' section is visible, where the 'Percentage (w/w) of substance in mixture/article' is set to 3%. The 'Physical form of the used product' is set to 'Liquid'. The 'W-2: Amount used (or contained in articles), frequency and duration of use/exposure' section shows 'Duration of activity' set to 1 h/day.

If safe use for inhalation route wasn't achieved, SWEDs 2, 4, 6 and 8 (substance used in liquid form, with RPE) and / or 11, 13, 15 and 17 (substance used in solid form, if applicable for the substance, with RPE) need to be used. SWEDs 2, 4, 6, 8, 11, 13, 15 and 17 include the use of respiratory protection. Concentration can again be reduced if safe use can't be demonstrated for 100% substance. The maximum concentration of safe use is recommended to be obtained by the registrant and communicated for the mentioned SWEDs for the substance both in liquid and solid form.

If safe use can't be demonstrated by a SWED after adjusting the concentration of the substance, SWED/SUMI approach is not suitable for the use in object. In this case, higher tier tools are needed for the chemical safety assessment. The obtained results can be imported into Chesar in order to generate the Exposure Scenarios.

## 7. SUMIs

SUMIs, are attachments for the mixture SDSs. Downstream Users of Chemicals co-ordination Group (DUCC) guidance (2017, ref. 5) stresses that SUMIs are for the end users of the mixture.

DUCC developed the SWED-SUMI concept and they also published a draft for the SUMI template (2015, ref. 6). Thereafter, sector organizations have modified the template slightly, targeting to create a harmonized template which fulfills the sector-specific requirements. All formulator companies belonging to the same sector are expected to append to the mixture SDSs the same SUMIs with the standard lay-out. This will make the SUMIs easy-to-read. An example of Fertilizers Europe SUMI can be viewed in **Appendix 1**.

As said, Fertilizers Europe SUMIs need to maintain the same lay-out and content, independent on who has published the eSDS. Fertilizer formulators will use different software to create SDSs and this may require breaking the SUMIs down to standard sentences which would then be used to establish the SUMIs in company's own publishing system. Formulators need to take good care that the resulting SUMIs will be in full harmony with the original Fertilizers Europe SUMIs, published in <https://www.reachfertilizers.com>.

### 7.1. Link between Fertilizers Europe SWEDs and SUMIs

SWEDs provide the information on use conditions to the exposure and risk assessment, which results will be communicated down the supply chain in the standard-format SUMI document. SWEDs and SUMIs are thus directly linked to each other.

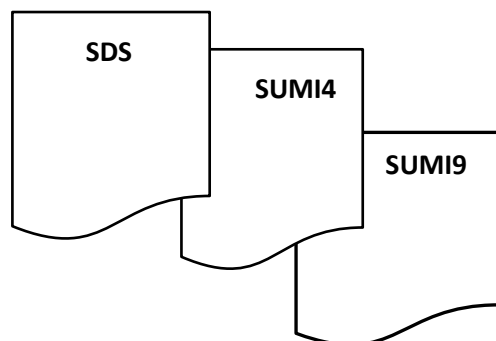
Each Fertilizer Fertilizers Europe SUMI covers two SWEDs (**Table 5.** and **Appendix2.**).

**Table 5.** Fertilizer sector SWEDs - link to SUMIs.

	Mixing, loading, cleaning, laboratory use (PROCS, 8a, 8b, 9,15)				Application activities (PROCI1). Exposure potential.				Application activities (PROCI1).
	Indoors		Outdoors		Indoors		Outdoors		No exposure potential.
	No respiratory protection	Yes respiratory protection	No respiratory protection	Yes respiratory protection	No respiratory protection	Yes respiratory protection	No respiratory protection	Yes respiratory protection	Outdoors
	Yes gloves				Yes gloves				No gloves
Yes eye protection				Yes eye protection				No eye protection	
SWEDs for LIQUID	1	2	3	4	5	6	7	8	9
SWEDs for SOLID	10	11	12	13	14	15	16	17	18
Explanation	RPE not required because -the product is <b>not classified for inhalation hazard</b> OR -if SWED assessment shows that the inhalation exposure and risks thereof are considered as negligible		RPE not required because -the product is <b>not classified for inhalation hazard</b> OR -if SWED assessment shows that the inhalation exposure and risks thereof are considered as negligible		RPE not required because -the product is <b>not classified for inhalation hazard</b> OR -if SWED assessment shows that the inhalation exposure and risks thereof are considered as negligible e.g. due to the dilution of the product before application		RPE not required because -the product is <b>not classified for inhalation hazard</b> OR -if SWED assessment shows that the inhalation exposure and risks thereof are considered as negligible e.g. due to the dilution of the product before application		PPE not required, because: - grower is protected when sitting in closed tractor cabin - there is no exposure as application of fertilizer happens by placement or irrigation
SUMI nr for LIQUID and SOLID	SUMI 1	SUMI 2	SUMI 3	SUMI 4	SUMI 5	SUMI 6	SUMI 7	SUMI 8	SUMI 9

Grower needs to receive an SDS with separate SUMIs instructing each of the steps required when using the product (**Picture 4.**) For easy understanding and consistency also the activities requiring no RMMs should be included. Grower might need respiratory protection when pouring the product to the tank for dilution (SUMI 4) but does not require any RMM when applying the diluted product by his tractor with the contained cabin (SUMI 9).

**Picture 4.** Fertilizer SDS may have multiple SUMIs.



## 8. Formulators attach the relevant SUMIs to the SDS of the mixture

If the fertilizer product is not classified for any hazard, formulator does not need to provide any specific safe use instructions in the SDS for the growers.

If the fertilizer product contains hazardous substances in concentrations which will make the mixture classified as hazardous to human health, the formulator needs to provide the SDS with safe use instructions to the grower. As mentioned in Chapter 3, SUMIs are a good option for professional grower SDSs.

Ready-made SUMIs are available for fertilizer formulators in Fertilizers Europe webpage. Each formulator is fully responsible for selecting the correct SUMI, which fits with the use conditions proven safe for his mixture (see next chapter). Formulators shall never change the factual contents of the SUMI.

Formulator can add his company logo and the name of the product to the left corner of the SUMI. Company can use this area to indicate which use concentration the SUMI applies to (example: “spraying if the dilution is below 10%”). Fertilizers Europe logo shall be maintained in the right upper corner.

A SUMI shall never be delivered to the customer as an independent document. A SUMI shall always be given to the customer as an appendix to the relevant product’s Safety Data Sheet.

By time the hazard information of the substance may be sharpened and for example the DNEL limit value may change. SWED assessment result calculated by Chesar might change from safe to unsafe. In such cases,

the SUMI related to this SWED can't be used any more as an instruction for safe use. A more conservative SWED and the respective SUMI must be selected. This means that the SDSs with SUMIs require update.

## 8.1. Validation of the SUMI by the formulator

First the formulator of a fertilizer mixture, classified for a health hazard, should know, how his product will be used by the growers and which RMMs will be available in practice. Knowing the uses and available RMMs, the formulator will be able to select the proper SWEDs for his validation assessment.

Thereafter the formulator needs to study the incoming ESs of the ingredient substances contributing to the health hazard for the product. For example, if fertilizer product is classified for acute toxicity, formulator needs to check the SWED coverage of all substances, which are listed in section 3 of mixture SDS and classified for acute toxicity.

SWED validation is easy if the registrants of the ingredient substances have performed the exposure and risk assessment by using fertilizer sector SWEDs and if the maximum safe use concentration has been given. If relevant SWEDs are present in the ESs and safe use is indicated, no deeper check of use conditions or RMM is required. Formulator can directly select the respective SUMIs for his product's SDS.

Validation should be started from the SWED with the least stringent set of RMM.

### **Example on validation:**

Formulator places on the market a solid foliar fertilizer mixture with a health hazard. After dissolving and dilution the product will not be classified as hazardous for human health

Grower's first activity is to pour the solid fertilizer to the spreader tank in outdoor conditions for dilution: SWED 12 is applicable (see **Tables 2. and 5**)

-> cross-check the proper ESs of all ingredients contributing to hazard: is SWED 12 without RPE registered and regarded as safe?

-> If yes, SUMI 3 to be attached to the SDS (see **Table 5**)

-> If not, cross-check the proper ESs of all ingredients contributing to hazard: is SWED 13 registered and with RPE regarded as safe?

-> If yes, SUMI 4 to be attached to SDS (see **Table 5**)

Grower's next activity is to spray the diluted non-classified liquid for the crop by a back-pack sprayer. Gloves and eye protection are instructed for all fertilizer products, which have originally been classified as hazardous for human health.

For this reason SWED 7 is applicable (**Table 4**)

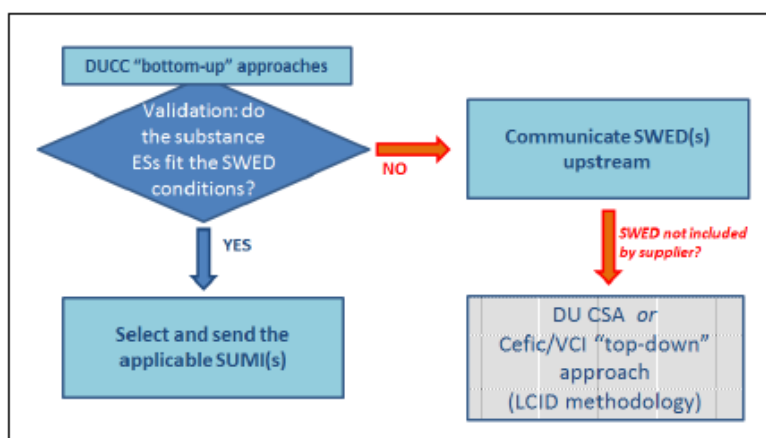
->SUMI 7 to be attached to SDS (see **Table 5**)

SWED validation requires more work if the ESs of the hazardous ingredient substances contain no fertiliser sector SWEDs and the assessment has been made by using PROC codes. In such cases the formulator can try to cross-check the ESs of the relevant ingredient substances for the operational conditions, concentrations and the RMM contained in the relevant SWED. If the conditions of SWEDs have been assessed and if safe use

has been indicated, the corresponding SUMIs can be appended to the SDS of the mixture. For more information, consult DUCC guidance on SUMIs (ref. 6).

If one or more of the registrants of the relevant ingredients have not assessed the required use properly in their ESs, fertilizer formulator should first ask the registrants of the substances to make the assessment by the missing SWED (Picture 5.). If this is not feasible, formulator can use the fertilizer SWED to perform his own CSA for the substance in Chesar. Further, if supplier has assessed only 100% concentration, which did not indicate safe use, fertilizer formulator can redo the assessment by a lower concentration. If SWED/SUMI approach does not work for the mixture, safe use conditions should be calculated by the LCID method (Picture 5.).

**Picture 5.** DUCC (2015, ref. 6) process in selecting the methodology to define the safe use information for a hazardous mixture.



## 9. SUMI provides guidance to the grower

For the grower SUMIs provide a simple guidance, how to use the product on a safe way. As the SUMI format and content have been agreed within the fertilizer sector, growers will always receive SUMIs with similar layout. SUMIs cover the real uses of the product and recommend realistic operational conditions and risk management methods and speak the sector specific language. This improves the readability and the acceptance of SDSs by growers.

DUCC guidance (ref. 5) emphasizes that SUMIs never replace the SDS. DUCC guidance also reminds that the operational conditions and risk management measures provided in the SUMI must not be altered by the end user or by his supervisor.

SUMIs need to be read together with the Safety Data Sheet and the label of the product. Recommendations for crop-specific application rates, spreading intervals and timings need to be followed, when given by the supplier.



Growers may mix the foliar fertilizer product with plant protection products. Growers must be made aware of that the use conditions and RMMs in fertilizer product SUMIs are valid only for the fertilizer product itself. If the fertilizer product is mixed with more hazardous products, fertilizer product SUMIs do not apply for the mixture. In such cases the grower shall always apply the most stringent use conditions and personal protection equipment given for the products which he uses for mixing. A remark has been added to the Fertilizers Europe SUMIs on this.

## 10. References

1. Cefic (2018) ESCOM Guidance <https://cefic.org/guidance/reach-implementation/escom-guidance/>
2. ECHA (2018) 2 nd Commission General Report on the operation of REACH / Evaluation of ECHA (REACH review) 49th Meeting of the Management Board 22-23 March 2018  
[https://echa.europa.eu/documents/10162/3048539/FINAL\\_MB\\_07\\_2018\\_Reach\\_Review\\_MB49.pdf/25727c6a-eb9b-c533-bdae-eb83e6fc83e](https://echa.europa.eu/documents/10162/3048539/FINAL_MB_07_2018_Reach_Review_MB49.pdf/25727c6a-eb9b-c533-bdae-eb83e6fc83e)
3. ECHA (2015) Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description. Version 3.0  
[https://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r12\\_en.pdf](https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf)
4. ECHA (2013) The CSR/ES roadmap. A cross-stakeholder plan of actions to 2018 Towards good quality information on the safe use of chemicals in the REACH chemical safety report and the extended safety data sheet. [https://echa.europa.eu/documents/10162/15669641/csr\\_es\\_roadmap\\_en.pdf/5e5051df-f0ec-4017-b5d7-68218790c802](https://echa.europa.eu/documents/10162/15669641/csr_es_roadmap_en.pdf/5e5051df-f0ec-4017-b5d7-68218790c802)
5. DUCC (2017) How to use SUMIs: operational framework.  
[https://www.ducc.eu/documents/How%20to%20use%20SUMIs\\_operational%20framework\\_18%2007%202017.pdf](https://www.ducc.eu/documents/How%20to%20use%20SUMIs_operational%20framework_18%2007%202017.pdf)
6. DUCC (2015) Sector-specific approaches towards developing and communicating information for the safe use of mixtures.  
<https://www.ducc.eu/documents/Sector%20specific%20approaches%20towards%20developing%20and%20communicating%20information%20for%20the%20safe%20use%20of%20mixtures%20FINAL.pdf>

Company specific details, e.g. -LOGO - Concentration SUMI applies etc.	
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**Safe Use of Mixture Information**

SUMI 7 - v 1.0 based on: FE\_SWED07\_PW\_I\_8\_o\_noRPE & FE\_SWED16\_PW\_s\_8\_o\_noRPE

**This safe use information is for the guidance of professional growers and workers who handle the product in outdoor conditions. This safe use information describes how to safely:**

- spread the product by using a tractor without contained cabin
- spread the product by a hand-held device

**Operational conditions**

Maximum duration of the work	8 hours per day altogether
Working conditions	Outdoor



**Risk management measures**

Personal protective equipment	<p>Wear suitable eye protection Wear suitable gloves. Wear suitable coveralls to prevent exposure to the skin. Wear protective shoes.</p>  <p>Consult section 8 of Safety Data Sheet for the proper type of personal protective equipment. Pictograms are for illustrative purposes only.</p>
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**Environmental measures**

Comply with EU and national statutory rules on environment.  
Follow supplier’s recommendations for the application rates, spreading intervals and timings if given for the product.

**Good practice advice**

Do not eat or drink during use Do not smoke Do not use in proximity of open flame	
Wash hands after use	
<p>When mixing the product with other products: -check the suppliers’ information for the compatibility of the products -check the safe working conditions and personal protective equipment instructed for each product separately and apply the most stringent ones to perform the mixing on a safe way (e.g. pesticides)</p>	

**Additional information**

Follow the product use instructions as specified on the label of the package. Follow the product/crop specific recommendations, if available from the manufacturer of the product. Apply good occupational hygiene practices as specified in section 7 of the product Safety Data Sheet.

**Purpose of SUMI**

The purpose of this SUMI document is to communicate the conditions of safe use of the product to the professional growers and workers. This SUMI should be passed forward in the supply chain as an attachment of the Safety Data Sheet of the product. This SUMI should be read only in combination with the relevant product’s Safety Data Sheet, package label and product/crop specific recommendations given by the supplier.

**Disclaimer**

This SUMI has been developed by Fertilizers Europe in the framework of the CSR/ES Roadmap initiative, under the umbrella of ENES (Exchange Network on Exposure Scenarios).  
The content of the SUMI must not be modified by the user. Fertilizers’ companies placing the product on the market are responsible for the validity of the SUMI for the product, which requires them to assess its applicability for their products. Fertilizers Europe cannot take liability for any use or misuse of the SUMI content.

**App 1.**

**Example on Fertilizers Europe SUMI**

