

FS Section	Content field	CSR	eSDS
1. Title	1.1 Direct application of plant protection products (granules or treated seeds) containing co-formulants to soil	Y	Y
	1.2 CLE SpERC 8d.1.v4	Y	Y
2. Scope	<b>2.1 Substance/Product Domain</b>		
	<b>Substance types / functions / properties included:</b> Solid and liquid substances used as a co-formulant	Y	Y
	<b>Additional specification of product types covered:</b> Products (substances or mixtures) applied directly to soil as granular solids or treated seeds, including substances used in seed treatment formulations.	Y	Y
	<b>Inclusion of sub-SPERCs:</b> n	N	N
	<b>2.2 Process domain</b>		
	<b>Description of activities/processes:</b> Mixing and loading of plant protection products into delivery equipment. Delivery and dispersion of plant protection products or treated seeds. Cleaning and maintenance of equipment is included.	Y	N
	<b>2.3 List of applicable Use Descriptors</b>		
	<b>LCS:</b> Widespread use by professional workers, Consumer use	Y	Y
	<b>SU:</b> 1	Y	Y
	<b>PROC:</b> 8a, 8b	Y	Y
<b>PC:</b> 27	Y	Y	
<b>ERC:</b> 8d	Y	Y	
3. Operational conditions	<b>3.1 Conditions of use</b>		
	<b>Location of use:</b> Indoor and outdoor use	Y	Y
	<b>Water contact during use:</b> n	Y	Y
	<b>Connected to a standard municipal biological STP:</b> n	Y	Y
	<b>Rigorously contained system with minimisation of release to the environment:</b> n	Y	N
	<b>Further operational conditions impacting on releases to the environment:</b> Plant protection product approvals under Regulation (EC) No. 1107/2009 include specific labelling instructions designed to prevent emission to surface water / wastewater. No intentional emission to surface water or waste water is permitted. Controlled application to agricultural crops in accordance with the product label and Good Agricultural Practice is required.	Y	Y
	<b>3.2 Waste Handling and Disposal</b>		
<b>Waste Handling and Disposal:</b> Used packaging must be disposed of in accordance with the product labelling.	Y	Y	
4. Obligatory RMMs onsite	<b>RMM limiting release to air:</b> none	Y	Y
	<b>RMM Efficiency (air):</b> n/a	Y	Y
	<b>Reference for RMM Efficiency (air):</b> n/a	Y	N
	<b>RMM limiting release to water:</b> none	Y	Y
	<b>RMM Efficiency (water):</b> n/a	Y	Y
	<b>Reference for RMM Efficiency (water):</b> n/a	Y	N
	<b>RMM limiting release to soil:</b> none	Y	Y
	<b>RMM Efficiency (soil):</b> n/a	Y	Y
<b>Reference for RMM Efficiency (soil):</b> n/a	Y	N	
5. Exposure Assessment Input	<b>5.1 Substance use rate</b>		
	<b>Amount of substance use per day:</b> not applicable	Y	Y
	<b>Fraction of EU tonnage used in region:</b> 0.1	Y	N
	<b>Fraction of Regional tonnage used locally:</b> 0	Y	N
	<b>Justification / information source:</b> The environmental risk assessment framework used for assessing chemicals under REACH (EU TGD) relies on nested multimedia mass balance models, which were developed to estimate environmental exposure arising from chemical use at industrial sites (point sources) and wide-dispersive uses in the catchment of a municipal sewage treatment plant. The EU TGD based models are mass balance ("tonnage") based and the key assumption at the local scale is that release to water will be via an industrial waste water or municipal sewage treatment plant before release to a river. Direct releases to water may be assumed, but direct releases to agricultural soil are not considered and are in fact outside the scope of the EU TGD. As a consequence, the default local exposure assessment approach does not take account of uses where substances may be directly applied onto agricultural soil, or where other direct emissions to surface water may take place. The Local Environment Tool (LET) approach developed by CropLife Europe is a standalone replacement for the local scale nested box in the models based on the EU TGD. Boundary concentrations should be calculated using the CLE SpERC (e.g. in EUSES, ECETOC TRA, CHESAR) and manually imported into CLE LET. Accordingly, the "fraction of regional tonnage used locally" is set to zero in this SpERC because the local scale output is not used. Local scale concentrations should be calculated using CLE LET.	Y	N

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	Instead of "Amount of substance use per day", the maximum use rate [kg/ha] output of CLE LET should be communicated as an outcome of the risk assessment in the extended Safety Data Sheet as an operational condition.		
	<b>5.2 Days emitting</b>		
	<b>Number of emission days per year:</b> not applicable	Y	Y
	<b>Justification / information source:</b> The default local exposure assessment approach is not applicable to substances used as a co-formulant in plant protection products. This assessment should be performed with the CLE LET, by using the default parameters and conditions of use implemented in and reported by the tool. For further details please consult the CLE guidance document.	Y	N
	<b>5.3 Release factors</b>		
	<b>5.3.1 Release factors for solid and liquid substances used as a co-formulant in granular products and treated seeds, including solid substances with vapour pressure <math>\geq 0.01</math> and <math>&lt; 0.01</math> Pa and liquid substances with vapour pressure <math>&lt; 0.01</math> Pa used as a co-formulant in seed treatment formulations</b>		
	<b>SPERC identifier:</b> CLE SpERC 8d.1.v4	Y	Y
	<b>5.3.1.1 Release Factor – air</b>		
	<b>Numeric value / percent of input amount (Air):</b> 0	Y	Y
	<b>Justification of RFs (Air):</b> For granular products and treated seeds it can be assumed use of co-formulants with significant volatility is unlikely, because these are typically liquids, and as such cannot be added in significant concentrations in a solid product without modifying the physical state. Furthermore, solid substances with low melting points or prone to sublimation would pose product storage/stability issues. Due to these reasons, potential volatilisation of co-formulants from granular products and treated seeds on the timescale relevant for the emission fraction (during and shortly after initial application) was considered unrealistic.	Y	N
	<b>5.3.1.2 Release Factor – water</b>		
	<b>Numeric value / percent of input amount (Water):</b> 0	Y	Y
	<b>Justification of RFs (Water):</b> Plant protection products approvals under Regulation (EC) No. 1107/2009 include specific labelling instructions designed to prevent emission to surface water / waste water. No intentional emission to surface water or waste water is permitted. Furthermore, the physical properties of granules and treated seeds limits the potential for direct release to surface water.	Y	N
	<b>5.3.1.3 Release Factor – soil</b>		
	<b>Numeric value / percent of input amount (Soil):</b> 1	Y	Y
	<b>Justification of RFs (Soil):</b> For granular products and treated seeds, the worst case is that the total applied fraction reaches the soil. The emission fraction to soil was accordingly set to 1.	Y	N
	<b>5.3.1.4 Release Factor – waste</b>		
	<b>Percent of input amount disposed as waste:</b> 0.0001	Y	N
	<b>Justification of RFs:</b> Product labels provide guidance for users on how to dispose of plant protection products. Specific estimates of residual product remaining in packaging for granular formulations or treated seeds are not available. The OECD emission scenario document for plastic additives (OECD 2009) gives a reasonable number for powders of particle size $> 40 \mu\text{m}$ of 0.01% remaining in the package. Based on this analogous scenario (i.e. solid substance of relatively large particle size in a plastic container) this value was adopted without modification.	Y	N
	<b>References to SPERC Background Document <sup>1</sup></b>		
	<b>Reference to Background Document:</b> The background document "REACH Specific Environmental Release Categories for plant protection product applications" has been published in the scientific journal "Integrated Environmental Assessment and Management" and is accessible via DOI:10.1002/ieam.4251.	Y	N

<sup>1</sup> The objective of this factsheet is to summarize the SPERC key facts provided in the corresponding SPERC background documents. It gives an overview of the SPERC essentials for the chemical safety assessment. A SPERC background document is a reference document, which provides the description of the emission situation(s) for a use specified by an industrial sector, the justification and applicability domain of the environmental release factors, and the references/information sources/methods used in the derivation of the release factors.