



## **SAFETY DATA SHEET (1907/2006)**

**R0717507**

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### **SUTTOCID® A 50% SOLUTION**

### **ANNEX**

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# 1. Overview of exposure scenarios

Identifiers	Titles of exposure scenarios and the related contributing scenarios
ES1 - F1	Formulation - Formulation of cosmetic products - Environmental contributing scenario for formulation of low viscosity liquids (small scale) (ERC 2) - Environmental contributing scenario for formulation of non-liquid creams (small scale) (ERC 2) - Environmental contributing scenario for formulation of high viscosity body care products (small scale) (ERC 2) - Environmental contributing scenario formulation of solid cosmetic and home care products (ERC 2) - Environmental contributing scenario, ERC based (ERC 2) - Worker contributing scenario, closed process (PROC 1) - Worker contributing scenario, closed process with incidental sampling (PROC 2) - Worker contributing scenario, closed batch process (PROC 3) - Worker contributing scenario, mixing or blending of formulations (PROC 5) - Worker contributing scenario, charging/discharging for formulating purposes, non-dedicated facilities (PROC 8a) - Worker contributing scenario, charging/discharging for formulating purposes, dedicated facilities (PROC 8b) - Worker contributing scenario, dedicated filling line. (PROC 9) - Worker contributing scenario, use at the laboratory (PROC 15)
ES2 - PW1	Use by professional worker - Use of cosmetic products by professional workers. - Use of cosmetic products by professional workers. (ERC 8a) - Professional worker contributing scenario concerning manual application of cosmetic products (PROC 21)
ES3 - C1	Consumer Use - Consumer Use of cosmetic products containing the substance - Consumer Use of cosmetic products (ERC 8a)
<b>Manufacture: M-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial site): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)</b>	

## 2. Exposure scenario 1: Formulation of cosmetic products

Environment contributing scenario(s):	
Environmental contributing scenario for formulation of low viscosity liquids (small scale)	ERC 2 <sup>1)</sup>
Environmental contributing scenario for formulation of non-liquid creams (small scale)	ERC 2 <sup>2)</sup>
Environmental contributing scenario for formulation of high viscosity body care products (small scale)	ERC 2 <sup>3)</sup>
Environmental contributing scenario formulation of solid cosmetic and home care products	ERC 2 <sup>4)</sup>
Environmental contributing scenario, ERC based	ERC 2
Worker contributing scenario(s):	
Worker contributing scenario, closed process	PROC 1
Worker contributing scenario, closed process with incidental sampling	PROC 2
Worker contributing scenario, closed batch process	PROC 3
Worker contributing scenario, mixing or blending of formulations	PROC 5
Worker contributing scenario, charging/discharging for formulating purposes, non-dedicated facilities	PROC 8a
Worker contributing scenario, charging/discharging for formulating purposes, dedicated facilities	PROC 8b
Worker contributing scenario, dedicated filling line.	PROC 9
Worker contributing scenario, use at the laboratory	PROC 15

### Description of the activities and technical processes covered in the exposure scenario:

The substance is marketed in a 50% solution and used as a preservative in cosmetic and personal care products at concentrations < 50%.

#### <sup>1)</sup> Description of the technical process covered by the SpERC: Cosmetics Europe 2.1c.v2

For economic reasons, formulation of mixtures requires minimized losses of raw materials during the mixing and packaging of products. Losses of raw materials via volatilization are negligible. Significant losses to the environment can be the result of cleaning of mixing vessels, tubing, production/packaging lines. High viscosity products adhere more strongly to the walls of mixing vessels, tubing, production/packaging lines. They are less efficiently transferred into the packaging. Hence, emissions caused by equipment cleaning are higher and lower for high and low viscosity products, respectively. These losses occur irrespective of the physical-chemical properties of the substance employed in a cosmetic product. For that reason, this SPERC pertains to all substances.

Technical comments:

- Before treatment means: emissions as entering an on-site biological WWTP, or if absent, as leaving the site towards a municipal WWTP.
- It is assumed for simplicity that 1 kg cosmetic product (excl. water) represents ~ 1 kg COD. Actual average value for the chemical ingredients may range from 1-2.
- Emissions to soil or solid waste are not discussed here, as justified in IFRA (2009), these are considered

negligible.

2) Description of the technical process covered by the SpERC: Cosmetics Europe 2.1j.v2

For economic reasons, formulation of mixtures requires minimized losses of raw materials during the mixing and packaging of products. Losses of raw materials via volatilization are negligible. Significant losses to the environment can be the result of cleaning of mixing vessels, tubing, production/packaging lines. High viscosity products adhere more strongly to the walls of mixing vessels, tubing, production/packaging lines. They are less efficiently transferred into the packaging. Hence, emissions caused by equipment cleaning are higher and lower for high and low viscosity products, respectively. These losses occur irrespective of the physical-chemical properties of the substance employed in a cosmetic product. For that reason, this SPERC pertains to all substances.

Technical comments:

- Before treatment means: emissions as entering an on-site biological WWTP, or if absent, as leaving the site towards a municipal WWTP.
- It is assumed for simplicity that 1 kg cosmetic product (excl. water) represents ~ 1 kg COD. Actual average value for the chemical ingredients may range from 1-2.
- Emissions to soil or solid waste are not discussed here, as justified in IFRA (2009), these are considered negligible.

3) Description of the technical process covered by the SpERC: Cosmetics Europe 2.1g.v2

For economic reasons, formulation of mixtures requires minimized losses of raw materials during the mixing and packaging of products. Losses of raw materials via volatilization are negligible. Significant losses to the environment can be the result of cleaning of mixing vessels, tubing, production/packaging lines. High viscosity products adhere more strongly to the walls of mixing vessels, tubing, production/packaging lines. They are less efficiently transferred into the packaging. Hence, emissions caused by equipment cleaning are higher and lower for high and low viscosity products, respectively. These losses occur irrespective of the physical-chemical properties of the substance employed in a cosmetic product. For that reason, this SPERC pertains to all substances.

Technical comments:

- Before treatment means: emissions as entering an on-site biological WWTP, or if absent, as leaving the site towards a municipal WWTP.
- It is assumed for simplicity that 1 kg cosmetic product (excl. water) represents ~ 1 kg COD. Actual average value for the chemical ingredients may range from 1-2.
- Emissions to soil or solid waste are not discussed here, as justified in IFRA (2009), these are considered negligible.

4) Description of the technical process covered by the SpERC: Cosmetics Europe / AISE 2.3c.v2

For economic reasons, formulation of mixtures requires minimized losses of raw materials during the mixing and packaging of products. Losses of raw materials via volatilization are negligible. Significant losses to the environment can be the result of cleaning of mixing vessels, tubing, production/ packaging lines. High viscosity products adhere more strongly to the walls of mixing vessels, tubing, production/packaging lines. They are less

efficiently transferred into the packaging. Hence, emissions caused by equipment cleaning are higher and lower for high and low viscosity products, respectively. These losses occur irrespective of the physical-chemical properties of the substance employed in a cosmetic product. For that reason, this SPERC pertains to all substances.

## 2.1. Environmental contributing scenario 1: Environmental contributing scenario for formulation of low viscosity liquids (small scale)

### 2.1.1. Conditions of use

<b>Amount used, frequency and duration of use (or from service life)</b>
<ul style="list-style-type: none"> <li>Daily use at site: <math>\leq 0.04</math> tonnes/day</li> </ul> <p><i>The default daily use amount is a maximum daily site tonnage (MSpERC represents an indicative worst case value for the substance use rate per site. The MSPERC values have been estimated in dependence of the size of the operation, the number of days emitting, and the concentration of the substance in a finished product (i.e. mixture)). - Emission days (days/year): 250</i></p>
<ul style="list-style-type: none"> <li>Annual use at a site: <math>\leq 10</math> tonnes/year</li> </ul>
<ul style="list-style-type: none"> <li>Percentage of EU tonnage used at regional scale: = 100 %</li> </ul>
<b>Technical and organisational conditions and measures</b>
<ul style="list-style-type: none"> <li>Type of Process: Substance applied in aqueous process solution with negligible volatilization</li> </ul>
<ul style="list-style-type: none"> <li>Indoor/outdoor use: Indoor use (Indoor)</li> </ul>
<ul style="list-style-type: none"> <li>Equipment cleaning: Equipment cleaned with water, washing disposed of with wastewater.</li> </ul>
<ul style="list-style-type: none"> <li>Process efficiency: Process with efficient use of raw materials. (Typically implemented measures for reducing emissions to waste water may include: - Closed batch systems )</li> </ul>
<b>Conditions and measures related to sewage treatment plant</b>
<ul style="list-style-type: none"> <li>Municipal STP: Yes [Effectiveness Water: 87.34%]</li> </ul>
<ul style="list-style-type: none"> <li>Discharge rate of STP: <math>\geq 2E3</math> m<sup>3</sup>/d</li> </ul>
<ul style="list-style-type: none"> <li>Application of the STP sludge on agricultural soil: Yes</li> </ul>
<b>Conditions and measures related to treatment of waste (including article waste)</b>
<ul style="list-style-type: none"> <li>Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)</li> </ul>
<b>Other conditions affecting environmental exposure</b>
<ul style="list-style-type: none"> <li>Receiving surface water flow rate: <math>\geq 1.8E4</math> m<sup>3</sup>/d</li> </ul>

## 2.1.2. Releases

Release	Release factor estimation method	Explanation / Justification
Water	SpERC based  Cosmetics Europe 2.1c.v2 - Cosmetics Europe 2.1c.v2 Industrial use in formulation of liquid water-borne cosmetic products - low viscosity liquids (small scale) - Formulation of low viscosity liquids (small scale)	<b>Initial release factor:</b> 0.4% <b>Final release factor:</b> 0.4% <b>Local release rate:</b> 0.16 kg/day <b>Explanation / Justification:</b> Releases to the wastewater can be the result of cleaning of mixing vessels, tubing, production/packaging lines with water. The spent cleaning water is discharged to the wastewater. The numbers that are presented in this SPERC originate from the study by Royal Haskoning (2009). The number for small scale manufacturing of liquid conditioner, shampoos and shower gels according to CosmeticsEurope (Cosmetics Europe 2.1.c.v2) was extrapolated by the CosmeticsEurope sector expert team based on the Royal Haskoning data. Reference: Royal Haskoning 2009 Review and evaluation of environmental emission scenarios for fragrance materials during compounding of perfume oils and formulation of consumer products (Research Institute for Fragrance Materials Ref.:9S3975.01/R0007/Nijm, 2009).
Air	SpERC based same as above	<b>Initial release factor:</b> 0% <b>Final release factor:</b> 0% <b>Local release rate:</b> 0 kg/day <b>Explanation / Justification:</b> Releases of raw materials via volatilization are quantitatively very low. For that reason, the study by Royal Haskoning (2009) does not consider to establish release factors for the use of fragrance materials in the manufacturing of detergent products. It is assumed that these findings also apply for the manufacturing of personal care and cosmetics products. For that reason, the release factor is set to zero.
Soil	SpERC based same as above	<b>Final release factor:</b> 0% <b>Explanation / Justification:</b> Direct releases to soil must be avoided.

### Releases to waste

**Release factor to waste from the process:** 0%

Not relevant – no obligatory RMM which divert substances to waste.

## 2.2. Environmental contributing scenario 2: Environmental contributing scenario for formulation of non-liquid creams (small scale)

### 2.2.1. Conditions of use

<b>Amount used, frequency and duration of use (or from service life)</b>
<ul style="list-style-type: none"> <li>Daily use at site: <math>\leq 0.024</math> tonnes/day</li> </ul> <p><i>The default daily use amount is a maximum daily site tonnage (MSPERC represents an indicative worst case value for the substance use rate per site. The MSPERC values have been estimated in dependence of the size of the operation, the number of days emitting, and the concentration of the substance in a finished product (i.e. mixture)). - Emission days (days/year): 250</i></p>
<ul style="list-style-type: none"> <li>Annual use at a site: <math>\leq 6</math> tonnes/year</li> </ul>
<ul style="list-style-type: none"> <li>Percentage of EU tonnage used at regional scale: = 100 %</li> </ul>
<b>Technical and organisational conditions and measures</b>
<ul style="list-style-type: none"> <li>Type of Process: Substance applied in aqueous process solution with negligible volatilization</li> </ul>
<ul style="list-style-type: none"> <li>Equipment cleaning: Equipment cleaned with water, washing disposed of with wastewater.</li> </ul>
<ul style="list-style-type: none"> <li>Indoor/outdoor use: Indoor use (Indoor)</li> </ul>
<ul style="list-style-type: none"> <li>Process efficiency: Process with efficient use of raw materials. (Typically implemented measures for reducing emissions to waste water may include: - Closed batch systems )</li> </ul>
<ul style="list-style-type: none"> <li>On site treatment of wastewater: Oil water separator</li> </ul>
<b>Conditions and measures related to sewage treatment plant</b>
<ul style="list-style-type: none"> <li>Municipal STP: Yes [Effectiveness Water: 87.34%]</li> </ul>
<ul style="list-style-type: none"> <li>Discharge rate of STP: <math>\geq 2E3</math> m<sup>3</sup>/d</li> </ul>
<ul style="list-style-type: none"> <li>Application of the STP sludge on agricultural soil: Yes</li> </ul>
<b>Conditions and measures related to treatment of waste (including article waste)</b>
<ul style="list-style-type: none"> <li>Particular considerations on the waste treatment operations: No (low amount) (Particular risks from waste treatment unlikely due to small fraction of used substance entering into the waste stage. Waste disposal according to national/local legislation is sufficient.)</li> </ul>
<b>Other conditions affecting environmental exposure</b>
<ul style="list-style-type: none"> <li>Receiving surface water flow rate: <math>\geq 1.8E4</math> m<sup>3</sup>/d</li> </ul>

### 2.2.2. Releases

Release	Release factor estimation method	Explanation / Justification
Water	SpERC based Cosmetics Europe 2.1j.v2 - Cosmetics Europe 2.1j.v2	Initial release factor: 4% Final release factor: 4% Local release rate: 0.96 kg/day



Release	Release factor estimation method	Explanation / Justification
	Industrial use in formulation of liquid water-borne cosmetic products - non-liquid creams (small scale) - Formulation of non-liquid creams (small scale)	<b>Explanation / Justification:</b> Releases to the wastewater can be the result of cleaning of mixing vessels, tubing, production/packaging lines with water. The spent cleaning water is discharged to the wastewater. The numbers that are presented in this SPERC originate from the study by Royal Haskoning (2009). For Cosmetics Europe 2.1.h.v2, Cosmetics Europe 2.1.i.v2. and Cosmetics Europe 2.1.j.v2 (non-liquid creams) Royal Haskoning (2009) did not distinguish between scales of production. The release factors in these spERCs have been extrapolated (in a conservative approach) by the CosmeticsEurope sector expert team from the Royal Haskoning (2009) data based on the increasing degree of control of the manufacturing process from large to small scale. Reference: Royal Haskoning 2009 Review and evaluation of environmental emission scenarios for fragrance materials during compounding of perfume oils and formulation of consumer products (Research Institute for Fragrance Materials Ref.:9S3975.01/R0007/Nijm, 2009).
<b>Air</b>	SpERC based same as above	<b>Initial release factor:</b> 0% <b>Final release factor:</b> 0% <b>Local release rate:</b> 0 kg/day <b>Explanation / Justification:</b> Releases of raw materials via volatilization are quantitatively very low. For that reason, the study by Royal Haskoning (2009) does not consider to establish release factors for the use of fragrance materials in the manufacturing of detergent products. It is assumed that these findings also apply for the manufacturing of personal care and cosmetics products. For that reason, the release factor is set to zero.
<b>Soil</b>	SpERC based same as above	<b>Final release factor:</b> 0% <b>Explanation / Justification:</b> Direct releases to soil must be avoided.

### Releases to waste

**Release factor to waste from the process:** 0%

Not relevant – no obligatory RMM which divert substances to waste.

## 2.3. Environmental contributing scenario 3: Environmental contributing scenario for formulation of high viscosity body care products (small scale)

### 2.3.1. Conditions of use

<b>Amount used, frequency and duration of use (or from service life)</b>
<ul style="list-style-type: none"> <li>Daily use at site: <math>\leq 0.04</math> tonnes/day</li> </ul> <p><i>The default daily use amount is a maximum daily site tonnage (MSPERC represents an indicative worst case value for the substance use rate per site. The MSPERC values have been estimated in dependence of the size of the operation, the number of days emitting, and the concentration of the substance in a finished product (i.e. mixture)). - Emission days (days/year): 250</i></p>
<ul style="list-style-type: none"> <li>Annual use at a site: <math>\leq 10</math> tonnes/year</li> </ul>
<ul style="list-style-type: none"> <li>Percentage of EU tonnage used at regional scale: = 100 %</li> </ul>
<b>Technical and organisational conditions and measures</b>
<ul style="list-style-type: none"> <li>Type of Process: Substance applied in aqueous process solution with negligible volatilization</li> </ul>
<ul style="list-style-type: none"> <li>Equipment cleaning: Equipment cleaned with water, washing disposed of with wastewater.</li> </ul>
<ul style="list-style-type: none"> <li>Indoor/outdoor use: Indoor use (Indoor)</li> </ul>
<ul style="list-style-type: none"> <li>Process efficiency: Process with efficient use of raw materials. (Typically implemented measures for reducing emissions to waste water may include: - Closed batch systems )</li> </ul>
<b>Conditions and measures related to sewage treatment plant</b>
<ul style="list-style-type: none"> <li>Municipal STP: Yes [Effectiveness Water: 87.34%]</li> </ul>
<ul style="list-style-type: none"> <li>Discharge rate of STP: <math>\geq 2E3</math> m<sup>3</sup>/d</li> </ul>
<ul style="list-style-type: none"> <li>Application of the STP sludge on agricultural soil: Yes</li> </ul>
<b>Conditions and measures related to treatment of waste (including article waste)</b>
<ul style="list-style-type: none"> <li>Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)</li> </ul>
<b>Other conditions affecting environmental exposure</b>
<ul style="list-style-type: none"> <li>Receiving surface water flow rate: <math>\geq 1.8E4</math> m<sup>3</sup>/d</li> </ul>

### 2.3.2. Releases

Release	Release factor estimation method	Explanation / Justification
Water	SpERC based Cosmetics Europe 2.1g.v2 - Cosmetics Europe 2.1g.v2	<p><b>Initial release factor:</b> 2%</p> <p><b>Final release factor:</b> 2%</p> <p><b>Local release rate:</b> 0.8 kg/day</p>

Release	Release factor estimation method	Explanation / Justification
	Industrial use in formulation of liquid water-borne cosmetic products - high viscosity body care products (small scale) - Formulation of high viscosity body care products (small scale)	<b>Explanation / Justification:</b> Releases to the wastewater can be the result of cleaning of mixing vessels, tubing, production/packaging lines with water. The spent cleaning water is discharged to the wastewater. The numbers that are presented in this SPERC originate from the study by Royal Haskoning (2009). The spERCs for Cosmetics Europe 2.1.f.v2 and Cosmetics Europe 2.1.g.v2 (high viscosity body care) reflect emission values between the product type of liquid conditioner, shampoos and shower gels (low viscosity) and non-liquid creams. Hence, these emission factors were interpolated between these values. Reference: Royal Haskoning 2009 Review and evaluation of environmental emission scenarios for fragrance materials during compounding of perfume oils and formulation of consumer products (Research Institute for Fragrance Materials Ref.:9S3975.01/R0007/Nijm, 2009).
<b>Air</b>	SpERC based same as above	<b>Initial release factor:</b> 0% <b>Final release factor:</b> 0% <b>Local release rate:</b> 0 kg/day <b>Explanation / Justification:</b> Releases of raw materials via volatilization are quantitatively very low. For that reason, the study by Royal Haskoning (2009) does not consider to establish release factors for the use of fragrance materials in the manufacturing of detergent products. It is assumed that these findings also apply for the manufacturing of personal care and cosmetics products. For that reason, the release factor is set to zero.
<b>Soil</b>	SpERC based same as above	<b>Final release factor:</b> 0% <b>Explanation / Justification:</b> Direct releases to soil must be avoided.

### Releases to waste

**Release factor to waste from the process:** 0%

Not relevant – no obligatory RMM which divert substances to waste.

## 2.4. Environmental contributing scenario 4: Environmental contributing scenario formulation of solid cosmetic and home care products

### 2.4.1. Conditions of use

<b>Amount used, frequency and duration of use (or from service life)</b>
<ul style="list-style-type: none"> <li>Daily use at site: <math>\leq 0.04</math> tonnes/day</li> </ul> <p><i>Daily use amount is calculated as the maximum daily site tonnage (M<sub>sperc</sub>). M<sub>sperc</sub> can be used by the registrant when starting the environmental assessment. M<sub>sperc</sub>-represents an indicative worst case value for the substance use rate per site. The M<sub>sperc</sub> values have been estimated in dependence of the size of the operation, the number of days emitting, and the concentration of the substance in a finished product (i.e. mixture).</i></p>
<ul style="list-style-type: none"> <li>Annual use at a site: <math>\leq 10</math> tonnes/year</li> </ul>
<ul style="list-style-type: none"> <li>Percentage of EU tonnage used at regional scale: = 100 %</li> </ul>
<b>Technical and organisational conditions and measures</b>
<ul style="list-style-type: none"> <li>Type of Process: Substance applied in aqueous process solution with negligible volatilization</li> </ul>
<ul style="list-style-type: none"> <li>Indoor/outdoor use: Indoor use (Indoor)</li> </ul>
<ul style="list-style-type: none"> <li>Equipment cleaning: Equipment cleaned with water, washing disposed of with wastewater.</li> </ul>
<ul style="list-style-type: none"> <li>Process efficiency: Process optimized for efficient use of raw materials. (Typical measures may include e.g. - Closed batch systems and / or - Semi-closed transfer system and/or - Batch production of final product Reduced number of transfer and cleaning operations through e.g. - Dedicated storage tanks for raw materials, premixes and final products)</li> </ul>
<b>Conditions and measures related to sewage treatment plant</b>
<ul style="list-style-type: none"> <li>Municipal STP: Yes [Effectiveness Water: 87.34%]</li> </ul>
<ul style="list-style-type: none"> <li>Discharge rate of STP: <math>\geq 2E3</math> m<sup>3</sup>/d</li> </ul>
<ul style="list-style-type: none"> <li>Application of the STP sludge on agricultural soil: Yes</li> </ul>
<b>Conditions and measures related to treatment of waste (including article waste)</b>
<ul style="list-style-type: none"> <li>Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)</li> </ul>
<b>Other conditions affecting environmental exposure</b>
<ul style="list-style-type: none"> <li>Receiving surface water flow rate: <math>\geq 1.8E4</math> m<sup>3</sup>/d</li> </ul>

### 2.4.2. Releases

Release	Release factor estimation method	Explanation / Justification
Water	SpERC based	Initial release factor: 0.2%

Release	Release factor estimation method	Explanation / Justification
	<p>Cosmetics Europe / AISE 2.3c.v2 - Cosmetics Europe / AISE 2.3c.v2</p> <p>Industrial use in formulation of solid cosmetic and home care products (small scale) - Formulation of solid cosmetic and home care products (small scale)</p>	<p><b>Final release factor:</b> 0.2%</p> <p><b>Local release rate:</b> 0.08 kg/day</p> <p><b>Explanation / Justification:</b> Releases to the wastewater can be the result of cleaning of mixing vessels, tubing, production/packaging lines with water. The spent cleaning water is discharged to the wastewater. The number is equal to that for large production of soap in the study by Royal Haskoning (2009). Royal Haskoning 2009 Review and evaluation of environmental emission scenarios for fragrance materials during compounding of perfume oils and formulation of consumer products (Research Institute for Fragrance Materials Ref.:9S3975.01/R0007/Nijm, 2009).</p>
<b>Air</b>	SpERC based same as above	<p><b>Initial release factor:</b> 0%</p> <p><b>Final release factor:</b> 0%</p> <p><b>Local release rate:</b> 0 kg/day</p> <p><b>Explanation / Justification:</b> Releases of raw materials via volatilization are quantitatively very low. For that reason, the study by Royal Haskoning (2009) does not consider to establish release factors for the use of fragrance materials in the manufacturing of detergent products. For that reason, the release factor is set to zero. Royal Haskoning 2009 Review and evaluation of environmental emission scenarios for fragrance materials during compounding of perfume oils and formulation of consumer products (Research Institute for Fragrance Materials Ref.:9S3975.01/R0007/Nijm, 2009).</p>
<b>Soil</b>	SpERC based same as above	<p><b>Final release factor:</b> 0%</p> <p><b>Explanation / Justification:</b> Must be avoided.</p>

### Releases to waste

**Release factor to waste from the process:** 0%

Not relevant – no obligatory RMM which divert substances to waste.

## 2.5. Environmental contributing scenario 5: Environmental contributing scenario, ERC based

### 2.5.1. Conditions of use

<b>Amount used, frequency and duration of use (or from service life)</b>
• Daily use at site: <= 0.04 tonnes/day
• Annual use at a site: <= 10 tonnes/year
• Percentage of EU tonnage used at regional scale: = 100 %
<b>Conditions and measures related to sewage treatment plant</b>
• Municipal STP: Yes [Effectiveness Water: 87.34%]
• Discharge rate of STP: >= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
<b>Conditions and measures related to treatment of waste (including article waste)</b>
• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)
<b>Other conditions affecting environmental exposure</b>
• Receiving surface water flow rate: >= 1.8E4 m3/d

### 2.5.2. Releases

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	Initial release factor: 2% Final release factor: 2% Local release rate: 0.8 kg/day
Air	ERC based	Initial release factor: 2.5% Final release factor: 2.5% Local release rate: 1 kg/day
Soil	ERC based	Final release factor: 0.01%

## 2.6. Worker contributing scenario 1: closed process (PROC 1)

### 2.6.1. Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: >25% <i>The substance is applied in the formulation process as a 50% solution in water (Suttocide A).</i>	TRA Workers 3.0

Product (article) characteristics	Method
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>	
• Duration of activity: < 8 hours	TRA Workers 3.0
<b>Technical and organisational conditions and measures</b>	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers 3.0
• Containment: Closed system (minimal contact during routine operations)	TRA Workers 3.0
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Workers 3.0
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
<b>Other conditions affecting workers exposure</b>	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0
• Skin surface potentially exposed: One hand face only (240 cm <sup>2</sup> )	TRA Workers 3.0

### Conclusion on risk characterisation

For workers there is no or only a low health risk in case of exposure.

## **2.7. Worker contributing scenario 2: closed process with incidental sampling (PROC 2)**

### **2.7.1. Conditions of use**

Product (article) characteristics	Method
• Concentration of substance in mixture: >25% <i>The substance is applied in the formulation process as a 50% solution in water (Suttocide A).</i>	TRA Workers 3.0
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>	
• Duration of activity: < 8 hours	TRA Workers 3.0
<b>Technical and organisational conditions and measures</b>	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers 3.0
• Containment: Closed continuous process with occasional controlled exposure	TRA Workers 3.0
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0

Product (article) characteristics	Method
<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Workers 3.0
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
<b>Other conditions affecting workers exposure</b>	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Workers 3.0

### Conclusion on risk characterisation

For workers there is no or only a low health risk in case of exposure.

## 2.8. Worker contributing scenario 3: closed batch process (PROC 3)

### 2.8.1. Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: >25% <i>The substance is applied in the formulation process as a 50% solution in water (Suttocide A).</i>	TRA Workers 3.0
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>	
• Duration of activity: < 8 hours	TRA Workers 3.0
<b>Technical and organisational conditions and measures</b>	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers 3.0
• Containment: Closed batch process with occasional controlled exposure	TRA Workers 3.0
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Workers 3.0
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
<b>Other conditions affecting workers exposure</b>	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Workers 3.0

### Conclusion on risk characterisation



For workers there is no or only a low health risk in case of exposure.

## 2.9. Worker contributing scenario 4: mixing or blending of formulations (PROC 5)

### 2.9.1. Conditions of use

Product (article) characteristics	Method
<ul style="list-style-type: none"> <li>Concentration of substance in mixture: &gt;25%</li> </ul> <i>The substance is applied in the formulation process as a 50% solution in water (Suttocide A).</i>	TRA Workers 3.0
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>	
<ul style="list-style-type: none"> <li>Duration of activity: &lt; 8 hours</li> </ul>	TRA Workers 3.0
<b>Technical and organisational conditions and measures</b>	
<ul style="list-style-type: none"> <li>General ventilation: Basic general ventilation (1-3 air changes per hour)</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Containment: No</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Local exhaust ventilation: no [Effectiveness Inhal: 0%]</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Occupational Health and Safety Management System: Advanced</li> </ul>	TRA Workers 3.0
<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>	
<ul style="list-style-type: none"> <li>Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%]</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Respiratory Protection: No [Effectiveness Inhal: 0%]</li> </ul>	TRA Workers 3.0
<b>Other conditions affecting workers exposure</b>	
<ul style="list-style-type: none"> <li>Place of use: Indoor</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Process temperature (for liquid): &lt;= 40 °C</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Skin surface potentially exposed: Two hands face (480 cm<sup>2</sup>)</li> </ul>	TRA Workers 3.0

#### Conclusion on risk characterisation

For workers there is no or only a low health risk in case of exposure.

## 2.10. Worker contributing scenario 5: charging/discharging for formulating purposes, non-dedicated facilities (PROC 8a)

### 2.10.1. Conditions of use

Product (article) characteristics	Method
<ul style="list-style-type: none"> <li>Concentration of substance in mixture: &gt;25%</li> </ul> <i>The substance is applied in the formulation process as a 50% solution in water (Suttocide A).</i>	TRA Workers 3.0

Product (article) characteristics	Method
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>	
• Duration of activity: < 8 hours	TRA Workers 3.0
<b>Technical and organisational conditions and measures</b>	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers 3.0
• Containment: No	TRA Workers 3.0
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%]	TRA Workers 3.0
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
<b>Other conditions affecting workers exposure</b>	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0
• Skin surface potentially exposed: Two hands (960 cm <sup>2</sup> )	TRA Workers 3.0

### Conclusion on risk characterisation

For workers there is no or only a low health risk in case of exposure.

## **2.11. Worker contributing scenario 6: charging/discharging for formulating purposes, dedicated facilities (PROC 8b)**

### **2.11.1. Conditions of use**

Product (article) characteristics	Method
• Concentration of substance in mixture: >25% <i>The substance is applied in the formulation process as a 50% solution in water (Suttocide A).</i>	TRA Workers 3.0
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>	
• Duration of activity: < 8 hours	TRA Workers 3.0
<b>Technical and organisational conditions and measures</b>	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers 3.0
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers 3.0
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0

Product (article) characteristics	Method
<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%]	TRA Workers 3.0
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
<b>Other conditions affecting workers exposure</b>	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0
• Skin surface potentially exposed: Two hands (960 cm <sup>2</sup> )	TRA Workers 3.0

### Conclusion on risk characterisation

For workers there is no or only a low health risk in case of exposure.

## **2.12. Worker contributing scenario 7: dedicated filling line (PROC 9)**

### **2.12.1. Conditions of use**

Product (article) characteristics	Method
• Concentration of substance in mixture: <1% <i>The substance is applied in the formulation process as a 50% solution in water (Suttocide A).</i>	TRA Workers 3.0
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>	
• Duration of activity: < 8 hours	TRA Workers 3.0
<b>Technical and organisational conditions and measures</b>	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers 3.0
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers 3.0
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Workers 3.0
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
<b>Other conditions affecting workers exposure</b>	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0
• Skin surface potentially exposed: Two hands face (480 cm <sup>2</sup> )	TRA Workers 3.0

### Conclusion on risk characterisation

For workers there is no or only a low health risk in case of exposure.

## 2.13. Worker contributing scenario 8: use at the laboratory (PROC 15)

### 2.13.1. Conditions of use

Product (article) characteristics	Method
<ul style="list-style-type: none"> <li>Concentration of substance in mixture: &gt;25%</li> </ul> <i>The substance is applied in the formulation process as a 50% solution in water (Suttocide A).</i>	TRA Workers 3.0
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>	
<ul style="list-style-type: none"> <li>Duration of activity: &lt; 8 hours</li> </ul>	TRA Workers 3.0
<b>Technical and organisational conditions and measures</b>	
<ul style="list-style-type: none"> <li>General ventilation: Basic general ventilation (1-3 air changes per hour)</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Containment: No</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Local exhaust ventilation: no [Effectiveness Inhal: 0%]</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Occupational Health and Safety Management System: Advanced</li> </ul>	TRA Workers 3.0
<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>	
<ul style="list-style-type: none"> <li>Dermal Protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Respiratory Protection: No [Effectiveness Inhal: 0%]</li> </ul>	TRA Workers 3.0
<b>Other conditions affecting workers exposure</b>	
<ul style="list-style-type: none"> <li>Place of use: Indoor</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Process temperature (for liquid): &lt;= 40 °C</li> </ul>	TRA Workers 3.0
<ul style="list-style-type: none"> <li>Skin surface potentially exposed: One hand face only (240 cm<sup>2</sup>)</li> </ul>	TRA Workers 3.0

### Conclusion on risk characterisation

For workers there is no or only a low health risk in case of exposure.

### 3. Exposure scenario 2: Use by professional worker - Use of cosmetic products by professional workers.

<b>Environment contributing scenario(s):</b>	
Use of cosmetic products by professional workers.	ERC 8a
<b>Worker contributing scenario(s):</b>	
Professional worker contributing scenario concerning manual application of cosmetic products	PROC 21

#### Description of the activities and technical processes covered in the exposure scenario:

Sodium n-(hydroxymethyl)glycinate is an approved cosmetic preservative which releases very low levels of formaldehyde and is authorized in Europe up to 0.5 % active as per Annex V, entry no. 51 of the Cosmetics Regulation ((EC) no. 1223/2009).

### 3.1. Environmental contributing scenario 1: Use of cosmetic products by professional workers.

#### 3.1.1. Conditions of use

<b>Amount used, frequency and duration of use (or from service life)</b>
• Daily wide dispersive use: $\leq 8.25E-6$ tonnes/day
• Percentage of EU tonnage used at regional scale: = 10 %
<b>Conditions and measures related to sewage treatment plant</b>
• Municipal STP: Yes [Effectiveness Water: 87.34%]
• Discharge rate of STP: $\geq 2E3$ m <sup>3</sup> /d
• Application of the STP sludge on agricultural soil: Yes
<b>Conditions and measures related to treatment of waste (including article waste)</b>
• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)
<b>Other conditions affecting environmental exposure</b>
• Receiving surface water flow rate: $\geq 1.8E4$ m <sup>3</sup> /d

#### 3.1.2. Releases

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	Initial release factor: 100% Final release factor: 100% Local release rate: 0.008 kg/day

Release	Release factor estimation method	Explanation / Justification
Air	ERC based	Initial release factor: 100% Final release factor: 100%
Soil	ERC based	Final release factor: 0%

## 3.2. Worker contributing scenario 1: Professional worker contributing scenario concerning manual application of cosmetic products (PROC 21)

### 3.2.1. Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: <1%	TRA Workers 3.0
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>	
• Duration of activity: < 8 hours	TRA Workers 3.0
<b>Technical and organisational conditions and measures</b>	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Workers 3.0
• Containment: No	TRA Workers 3.0
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Basic	TRA Workers 3.0
<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Workers 3.0
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
<b>Other conditions affecting workers exposure</b>	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): ≤ 40 °C	TRA Workers 3.0
• Skin surface potentially exposed: One hand face only (240 cm <sup>2</sup> )	TRA Workers 3.0

### Conclusion on risk characterisation

The concentrations of sodium hydroxymethyl glycinate in the final cosmetic products are below levels that may induce or significantly contribute to irritancy of the skin or eyes (< 1%).

## 4. Exposure scenario 3: Consumer Use - Consumer Use of cosmetic products containing the substance

<b>Environment contributing scenario(s):</b>	
Consumer Use of cosmetic products	ERC 8a

### 4.1. Environmental contributing scenario 1: Consumer Use of cosmetic products

#### 4.1.1. Conditions of use

<b>Amount used, frequency and duration of use (or from service life)</b>
• Daily wide dispersive use: $\leq 2.75E-6$ tonnes/day
• Percentage of EU tonnage used at regional scale: = 10 %
<b>Conditions and measures related to treatment of waste (including article waste)</b>
• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)
<b>Other conditions affecting environmental exposure</b>
• Municipal STP: Yes [Effectiveness Water: 87.34%]
• Discharge rate of STP: $\geq 2E3$ m <sup>3</sup> /d
• Application of the STP sludge on agricultural soil: Yes
• Receiving surface water flow rate: $\geq 1.8E4$ m <sup>3</sup> /d

#### 4.1.2. Releases

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	Initial release factor: 100% Final release factor: 100% Local release rate: 0.003 kg/day
Air	ERC based	Initial release factor: 100% Final release factor: 100%
Soil	ERC based	Final release factor: 0%