SAFETY DATA SHEET (1907/2006)

R0717827

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CERAPHYL 41

ANNEX

Contents

1. Overview of exposure scenarios

Identifiers	Titles of exposure scenarios and the related contributing scenarios
ES1 - M1	Manufacture - Manufacture of propanoic acid, 2-hydroxy-, C12-15-alkyl esters - Manufacture of propanoic acid, 2-hydroxy-, C12-15-alkyl esters (ERC 1) - Worker contributing scenario: closed process (PROC 1) - Worker contributing scenario: closed process with occasional sampling (PROC 2) - Worker contributing scenario: closed batch process (PROC 3) - Worker contributing scenario: batch process with limited risk of exposure (PROC 4) - Worker contributing scenario: mixing or blending (PROC 5)
ES2 - F1	Formulation - Formulation of end-use cosmetic products - Formulation of solid cosmetic and home care products (small scale) (ERC 2) - Formulation of liquid water-borne cosmetic products - low viscosity liquids (small scale) (ERC 2) - Formulation of liquid water-borne cosmetic products - high viscosity liquids (small scale) (ERC 2) - Formulation of liquid water-borne cosmetic products - non-liquid creams (small scale) (ERC 2) - Formulation of cosmetic products which involve cleaning of manufacturing equipment with organic solvents - (small scale) (ERC 2) - Worker contributing scenario: closed batch processes (PROC 3) - Worker contributing scenario: batch wise processes with limited risk of exposure (PROC 4) - Worker contributing scenario: mixing or blending in batch processes (PROC 5) - Worker contributing scenario: Transfer of formulations to smaller containers. (PROC 9) - Worker contributing scenario: quality check of samples during formulation processes (PROC 15)
ES3 - PW1	Use by professional worker - Professional use of cosmetic products - Professional use of cosmetic products (ERC 8a) - Worker contributing scenario: Using cosmetic products by manual application (PROC 19)
ES4 - C1	Consumer Use - Consumer use of cosmetic products - Consumer use of cosmetic products (ERC 8a)
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-#.)	

2. Exposure scenario 1: Manufacture of propanoic acid, 2-hydroxy-, C12-15-alkyl esters

2.1 General scenario

Environment contributing scenario(s):	
Manufacture of propanoic acid, 2-hydroxy-, C12-15-alkyl esters	ERC 1
Worker contributing scenario(s):	
Worker contributing scenario: closed process	PROC 1
Worker contributing scenario: closed process with occasional sampling	PROC 2
Worker contributing scenario: closed batch process	PROC 3
Worker contributing scenario: batch process with limited risk of exposure	PROC 4
Worker contributing scenario: mixing or blending	PROC 5

2.2 Environmental contributing scenario 1: Manufacture of propanoic acid, 2-hydroxy-, C12-15-alkyl esters

2.2.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.99 tonnes/day *Release frequency: 100 days per year.*
• Annual use at a site: <= 99 tonnes/year
• Percentage of EU tonnage used at regional scale: = 100 %
Conditions and measures related to sewage treatment plant
• Municipal STP: No [Effectiveness Water: 0%]
Conditions and measures related to treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: Closed system required to prevent any release to the environment.
Other conditions affecting environmental exposure
• Discharge rate of effluent: >= 0 m3/d *Preferably no discharge to surface water: Closed system required or complete retaining of produced substance.*
• Receiving surface water flow rate: >= 1.8E4 m3/d

2.2.2. Releases

Release	Release factor estimation method	Explanation / Justification
Water	Release factor	**Initial release factor:** 1% **Final release factor:** 1% **Local release rate:** 9.9 kg/day **Explanation / Justification:** Closed system required to prevent any release to the environment
Air	Release factor	**Initial release factor:** 0.5% **Final release factor:** 0.5% **Local release rate:** 4.95 kg/day
Soil	Release factor	**Final release factor:** 0% **Explanation / Justification:** No application of the STP sludge on agricultural soil.

2.3 Worker contributing scenario 1: Worker contributing scenario: closed process (PROC 1)

2.3.1 Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: Substance as such	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• 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
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0

Product (article) characteristics	Method
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

2.4 Worker contributing scenario 2: Worker contributing scenario: closed process with occasional sampling (PROC 2)

2.4.1 Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: Substance as such	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• 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: yes [Effectiveness Inhal: 90%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

2.5 Worker contributing scenario 3: Worker contributing scenario: closed batch process (PROC 3)

2.5.1 Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: Substance as such	TRA Workers 3.0

Product (article) characteristics	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• General ventilation: Good general ventilation (3-5 air changes per hour)	TRA Workers 3.0
• Containment: Closed batch process with occasional controlled exposure	TRA Workers 3.0
• Local exhaust ventilation: yes [Effectiveness Inhal: 90%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

2.6 Worker contributing scenario 4: Worker contributing scenario: batch process with limited risk of exposure (PROC 4)

2.6.1 Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: Substance as such	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• General ventilation: Good general ventilation (3-5 air changes per hour)	TRA Workers 3.0
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers 3.0
• Local exhaust ventilation: yes [Effectiveness Inhal: 90%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	

Product (article) characteristics	Method
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

2.7 Worker contributing scenario 5: Worker contributing scenario: mixing or blending (PROC 5)

2.7.1 Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: Substance as such	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• General ventilation: Good general ventilation (3-5 air changes per hour)	TRA Workers 3.0
• Containment: No	TRA Workers 3.0
• Local exhaust ventilation: yes [Effectiveness Inhal: 90%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

3 Exposure scenario 2: Formulation of end-use cosmetic products

Environment contributing scenario(s):	
Formulation of solid cosmetic and home care products (small scale)	ERC 2[1)]
Formulation of liquid water-borne cosmetic products - low viscosity liquids (small scale)	ERC 2[2)]
Formulation of liquid water-borne cosmetic products - high viscosity liquids (small scale)	ERC 2[3)]
Formulation of liquid water-borne cosmetic products - non-liquid creams (small scale)	ERC 2[4)]
Formulation of cosmetic products which involve cleaning of manufacturing equipment with organic solvents - (small scale)	ERC 2[5)]
Worker contributing scenario(s):	
Worker contributing scenario: closed batch processes	PROC 3
Worker contributing scenario: batch wise processes with limited risk of exposure	PROC 4
Worker contributing scenario: mixing or blending in batch processes	PROC 5
Worker contributing scenario: Transfer of formulations to smaller containers.	PROC 9
Worker contributing scenario: quality check of samples during formulation processes	PROC 15

[1)] 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)] 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.

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 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.

5) Description of the technical process covered by the SpERC: Cosmetics Europe 2.2c.v2

For economic reasons, formulation of mixtures requires optimized use of raw materials for inclusion into products. Losses of raw materials via volatilization are negligible. Manufacturing equipment is cleaned with organic solvents. The resulting solvent rinsing are collected and disposed of according to local regulations or recycled.
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.

3.1 Environmental contributing scenario 1: Formulation of solid cosmetic and home care products (small scale)

3.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.45 tonnes/day *Daily use amount is calculated as the maximum daily site tonnage (Msperc). Msperc can be used by the registrant when starting the environmental assessment. 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).*
• Annual use at a site: <= 99 tonnes/year
• Percentage of EU tonnage used at regional scale: = 100 %
Technical and organisational conditions and measures
• Type of Process: Substance applied in aqueous process solution with negligible volatilization
• Indoor/outdoor use: Indoor use (Indoor)
• Equipment cleaning: Equipment cleaned with water, washing disposed of with wastewater.
• 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)
Conditions and measures related to sewage treatment plant
• Municipal STP: No [Effectiveness Water: 0%]
Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (no waste) (No waste generated.)
Other conditions affecting environmental exposure
• Discharge rate of effluent: >= 0 m3/d *Complete retaining of substance and preventing any significant release.*
• Receiving surface water flow rate: >= 1.8E4 m3/d

3.1.2 Releases

Release	Release factor estimation method	Explanation / Justification
Water	SpERC based Cosmetics Europe / AISE 2.3c.v2 - Cosmetics Europe / AISE 2.3c.v2 Industrial use in formulation of solid cosmetic and home care products (small scale) - Formulation of solid cosmetic and home care products (small scale)	**Initial release factor:** 0.2% **Final release factor:** 0.2% **Local release rate:** 0.9 kg/day **Explanation / Justification:** 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).
Air	SpERC based same as above	**Initial release factor:** 0% **Final release factor:** 0% **Local release rate:** 0 kg/day **Explanation / Justification:** 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).
Soil	SpERC based same as above	**Final release factor:** 0% **Explanation / Justification:** Must be avoided.

Releases to waste

Release factor to waste from the process: 0%

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

3.2 Environmental contributing scenario 2: Formulation of liquid water-borne cosmetic products - low viscosity liquids (small scale)

3.2.1 Conditions of use

Not defined.

3.2.2. 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)	**Initial release factor:** 0.4% **Final release factor:** 0.4% **Local release rate:** 1.8 kg/day **Explanation / Justification:** 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	**Initial release factor:** 0% **Final release factor:** 0% **Local release rate:** 0 kg/day **Explanation / Justification:** 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

Release	Release factor estimation method	Explanation / Justification
		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	**Final release factor:** 0% **Explanation / Justification:** 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.

3.3 Environmental contributing scenario 3: Formulation of liquid water-borne cosmetic products - high viscosity liquids (small scale)

3.3.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.45 tonnes/day *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*
• Annual use at a site: <= 99 tonnes/year
• Percentage of EU tonnage used at regional scale: = 100 %
Technical and organisational conditions and measures
• Type of Process: Substance applied in aqueous process solution with negligible volatilization
• Equipment cleaning: Equipment cleaned with water, washing disposed of with wastewater.
• Indoor/outdoor use: Indoor use (Indoor)
• Process efficiency: Process with efficient use of raw materials. (Typically implemented measures for reducing emissions to waste water may include: - Closed batch systems)
Conditions and measures related to sewage treatment plant
• Municipal STP: No [Effectiveness Water: 0%]
Conditions and measures related to treatment of waste (including article waste)

• 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.)
Other conditions affecting environmental exposure
• Discharge rate of effluent: >= 0 m3/d
• Receiving surface water flow rate: >= 1.8E4 m3/d

3.3.2 Releases

Release	Release factor estimation method	Explanation / Justification
Water	SpERC based Cosmetics Europe 2.1g.v2 - Cosmetics Europe 2.1g.v2 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)	**Initial release factor:** 2% **Final release factor:** 2% **Local release rate:** 9 kg/day **Explanation / Justification:** 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).
Air	SpERC based same as above	**Initial release factor:** 0% **Final release factor:** 0% **Local release rate:** 0 kg/day **Explanation / Justification:** 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.

Release	Release factor estimation method	Explanation / Justification
Soil	SpERC based same as above	**Final release factor:** 0% **Explanation / Justification:** 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.

Milk	2.148E-8 mg/kg bw/day	2.68E-6 mg/kg ww

3.4 Environmental contributing scenario 4: Formulation of liquid water-borne cosmetic products - non-liquid creams (small scale)

3.4.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.45 tonnes/day *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*
• Annual use at a site: <= 99 tonnes/year
• Percentage of EU tonnage used at regional scale: = 100 %
Technical and organisational conditions and measures
• Type of Process: Substance applied in aqueous process solution with negligible volatilization
• Equipment cleaning: Equipment cleaned with water, washing disposed of with wastewater.
• Indoor/outdoor use: Indoor use (Indoor)
• Process efficiency: Process with efficient use of raw materials. (Typically implemented measures for reducing emissions to waste water may include: - Closed batch systems)
• On site treatment of wastewater: Oil water separator
Conditions and measures related to sewage treatment plant
• Municipal STP: No [Effectiveness Water: 0%]
Conditions and measures related to treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (no waste) (No waste generated.)
Other conditions affecting environmental exposure

• Discharge rate of effluent: >= 0 m3/d
• Receiving surface water flow rate: >= 1.8E4 m3/d

3.4.2 Releases

Release	Release factor estimation method	Explanation / Justification
Water	SpERC based Cosmetics Europe 2.1j.v2 - Cosmetics Europe 2.1j.v2 Industrial use in formulation of liquid water-borne cosmetic products - non-liquid creams (small scale) - Formulation of non-liquid creams (small scale)	**Initial release factor:** 4% **Final release factor:** 4% **Local release rate:** 18 kg/day **Explanation / Justification:** 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).
Air	SpERC based same as above	**Initial release factor:** 0% **Final release factor:** 0% **Local release rate:** 0 kg/day **Explanation / Justification:** 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	**Final release factor:** 0%

Release	Release factor estimation method	Explanation / Justification
		Explanation / Justification: 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.

3.5. Environmental contributing scenario 5: Formulation of cosmetic products which involve cleaning of manufacturing equipment with organic solvents - (small scale)

3.5.1. Conditions of use

Not defined.

3.5.2. Releases

Release	Release factor estimation method	Explanation / Justification
Water	SpERC based Cosmetics Europe 2.2c.v2 - Cosmetics Europe 2.2c.v2 Industrial use in formulation of cosmetic products which involve cleaning of manufacturing equipment with organic solvents - (small scale) - Formulation of cosmetic products involving cleaning with organic solvents (small scale)	**Initial release factor:** 0% **Final release factor:** 0% **Local release rate:** 0 kg/day **Explanation / Justification:** No wastewater treatment required.
Air	SpERC based same as above	**Initial release factor:** 0% **Final release factor:** 0% **Local release rate:** 0 kg/day **Explanation / Justification:** Air emission controls are not applicable as there is no direct release to air.
Soil	SpERC based same as above	**Final release factor:** 0% **Explanation / Justification:** Must be avoided

Releases to waste

Release factor to waste from the process: 0%

Not relevant - no obligatory RMM which divert substances to waste

3.6. Worker contributing scenario 1: Worker contributing scenario: closed batch processes (PROC 3)

3.6.1. Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: Substance as such	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• General ventilation: Good general ventilation (3-5 air changes per hour)	TRA Workers 3.0
• Containment: Closed batch process with occasional controlled exposure	TRA Workers 3.0
• Local exhaust ventilation: yes [Effectiveness Inhal: 90%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

3.7. Worker contributing scenario 2: Worker contributing scenario: batch wise processes with limited risk of exposure (PROC 4)

3.7.1. Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: Substance as such	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	

Product (article) characteristics	Method
• Duration of activity: < 4 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• General ventilation: Good general ventilation (3-5 air changes per hour)	TRA Workers 3.0
• Containment: Semi-closed process with occasional controlled exposure	TRA Workers 3.0
• Local exhaust ventilation: yes [Effectiveness Inhal: 90%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

3.8. Worker contributing scenario 3: Worker contributing scenario: mixing or blending in batch processes (PROC 5)

3.8.1. Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: <1%	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• General ventilation: Good general ventilation (3-5 air changes per hour)	TRA Workers 3.0
• Containment: No	TRA Workers 3.0
• Local exhaust ventilation: yes [Effectiveness Inhal: 90%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	

Product (article) characteristics	Method
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

3.9. Worker contributing scenario 4: Worker contributing scenario: Transfer of formulations to smaller containers. (PROC 9)

3.9.1. Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: <1%	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• 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
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

3.10. Worker contributing scenario 5: Worker contributing scenario: quality check of samples during formulation processes (PROC 15)

3.10.1. Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: <1%	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• 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: 90%]	TRA Workers 3.0
• Occupational Health and Safety Management System: Advanced	TRA Workers 3.0
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

4. Exposure scenario 3: Use by professional worker - Professional use of cosmetic products

Sector of use:

SU 0, Other (Cosmetic products)

Environment contributing scenario(s):	
Professional use of cosmetic products	ERC 8a
Worker contributing scenario(s):	
Worker contributing scenario: Using cosmetic products by manual application	PROC 19

4.1. Environmental contributing scenario 1: Professional use of cosmetic products

4.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 3.63E-5 tonnes/day
• Percentage of EU tonnage used at regional scale: = 10 %
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes [Effectiveness Water: 90.4%]
• Discharge rate of STP: >= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to treatment of waste (including article waste)
• 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.)
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/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:** 0.036 kg/day
Air	ERC based	**Initial release factor:** 100% **Final release factor:** 100%

Release	Release factor estimation method	Explanation / Justification
Soil	ERC based	**Final release factor:** 0%

4.2. Worker contributing scenario 1: Worker contributing scenario: Using cosmetic products by manual application (PROC 19)

4.2.1 Conditions of use

Product (article) characteristics	Method
• Concentration of substance in mixture: <1%	TRA Workers 3.0
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers 3.0
Technical and organisational conditions and measures	
• General ventilation: Good general ventilation (3-5 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
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Workers 3.0
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Workers 3.0
• Process temperature (for liquid): <= 40 °C	TRA Workers 3.0

Conclusion on risk characterisation

This application does not pose significant risk for workers.

5. Exposure scenario 4: Consumer Use - Consumer use of cosmetic products

Environment contributing scenario(s):	
Consumer use of cosmetic products	ERC 8a

5.1. Environmental contributing scenario 1: Consumer use of cosmetic products

5.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 1.815E-5 tonnes/day
• Percentage of EU tonnage used at regional scale: = 10 %
Conditions and measures related to treatment of waste (including article waste)
• 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.)
Other conditions affecting environmental exposure
• Municipal STP: Yes [Effectiveness Water: 90.4%]
• Discharge rate of STP: >= 2E3 m3/d
• Application of the STP sludge on agricultural soil: Yes
• Receiving surface water flow rate: >= 1.8E4 m3/d

5.1.2 Releases

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 100% **Final release factor:** 100% **Local release rate:** 0.018 kg/day
Air	ERC based	**Initial release factor:** 100% **Final release factor:** 100%
Soil	ERC based	**Final release factor:** 0%