SAFETY DATA SHEET (1907/2006)

R0717500

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Imidiazolidinyl urea (IZU)/ GERMALL® 115

ANNEX

1. OVERVIEW OF EXPOSURE SCENARIOS

1.1 General

Imidiazolidinyl urea (IZU) is used in the formulation of end-use cosmetic products. Manufacture and formulation activities involving industrial workers are covered by the joint CSR. End-use cosmetic products are used by the consumers; however, human health exposure assessment has not been performed as use of cosmetic products is not covered under the scope of REACH (1907/2006 as amended) .

Identifiers	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
ES1 - M1	Manufacture - Manufacture - Manufacture (ERC 1) - Use in closed process, no likelihood of exposure (PROC 1) - Use in closed, continuous process with occasional controlled exposure (PROC 2) - Use in closed batch process (synthesis of formulation) (PROC 3) - Use in batch or other process (synthesis) where opportunity for exposure arises (PROC 4) - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b) - Use as laboratory reagent (PROC 15)	50.0
ES2 - F1	Formulation - Formulation - Formulation (ERC 2) - Use in closed batch process (synthesis of formulation) (PROC 3) - Mixing or blending in batch processes for formulation of preparations and articles (multistage or significant contact) (PROC 5) - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a) - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b) - Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9) - Use a laboratory reagent (PROC 15)	500.0
ES3 - C1	Consumer Use - Consumer Use - Consumer Use (ERC 8a)	500.0

1.2 Environment

Protection target	Type of risk characterisation	Hazard conclusion
Freshwater	Quantitative	PNEC aqua (freshwater) = 5.78 µg/L
Sediment (freshwater)	Quantitative	PNEC sediment (freshwater) = 88.78 µg/kg sediment dw
Marine water	Quantitative	PNEC aqua (marine water) = 0.58 µg/L
Sediment (marine water)	Quantitative	PNEC sediment (marine water) = 8.88 µg/kg sediment dw
Sewage treatment plant	Quantitative	PNEC STP = 20 mg/L
Air	Not needed	No hazard identified
Agricultural soil	Quantitative	PNEC soil = 14.35 µg/kg soil dw
Predator	Not needed	No potential for bioaccumulation

Comments on assessment approach:

The local Predicted Exposure Concentrations (PECs) reported for each contributing scenario correspond to the sum of the local concentrations (Clocal) and the regional concentrations (PEC regional).

Caution: The exposure estimates have been obtained with EUSES although the following parameter(s) is/are outside the boundaries of the EUSES model:

- Half-life in Water (1.5 h)
- Half-life in Hydrolysis (12 h)
- Vapour pressure (1E-9 Pa)
- Water solubility (1E3 g/L)

A quantitative assessment was carried out for all environmental protection targets except for air and for predators, for which no hazard had been identified.

1.3 Man via environment

Scope and type of assessment

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion
Inhalation: Systemic Long Term	Qualitative	Hazard unknown (no further information necessary)
Oral: Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 5 mg/kg bw/day

Comments on assessment approach:

A quantitative assessment was carried out for potential exposure to man via environment.

1.4 Workers

Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for workers are described in the following table based on the hazard conclusions presented in section 5.11.

Route	Type of effect	Type of risk characterisation	Hazard conclusion
Inhalation	Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 20.5 mg/m³
	Systemic Acute	Quantitative	DNEL (Derived No Effect Level) = 19.5 mg/m³
	Local Long Term	Not needed	No hazard identified
	Local Acute	Not needed	No hazard identified
Dermal	Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 11.7 mg/kg bw/day
	Systemic Acute	Not needed	No hazard identified
	Local Long Term	Qualitative	Medium hazard (no threshold derived)
	Local Acute	Qualitative	Medium hazard (no threshold derived)
Eye	Local	Not needed	No hazard identified

Comments on assessment approach related to toxicological hazard:

A quantitative assessment was carried out for long term systemic hazards via skin and inhalation.

Possible adverse systemic health effects were associated with short term inhalation route. Consequently, short term and peak exposures were quantitatively assessed.

A qualitative assessment was carried out with respect to local dermal effect due to sensitisation, based on a categorisation of "medium hazard" for skins sensitisation.

The OC/RMM for safe use based on a quantitative assessment were evaluated as to whether they provide sufficient protection against possible adverse skin sensitisation effects, or whether additional measures are needed.

The criterion for selection of OC/RMM are summarized here below:

The minimum RMM necessary was applied to ensure the exposure levels are safe(covering all relevant endpoints, and the combined risk) taking into account for uncertainty of exposure estimation.

Comments on assessment approach related to physicochemical hazard:

A risk assessment of physico-chemical hazard is not applicable for this substance.

General information on risk management related to toxicological hazard:

The main specifications for personal protective equipment (PPE) appropriate for IZU are as follows:
Gloves: chemically resistant gloves conforming to EN374
Eye protection: safety goggles

In addition to the above, as a minimum personal protection equipment selected for each use should prevent exposure to the skin and mucous membranes.

General information on risk management related to physicochemical hazard:

None required. The substance is not classified for any physico-chemical hazards.

1.5 Consumers

Scope and type of assessment

Route	Type of effect	Type of risk characterisation	Hazard conclusion
Inhalation	Systemic Long Term	Qualitative	Hazard unknown (no further information necessary)
	Systemic Acute	Qualitative	Hazard unknown (no further information necessary)
	Local Long Term	Qualitative	Hazard unknown (no further information necessary)
	Local Acute	Qualitative	Hazard unknown (no further information necessary)
Dermal	Systemic Long Term	Qualitative	Hazard unknown (no further information necessary)
	Systemic Acute	Qualitative	Hazard unknown (no further information necessary)
	Local Long Term	Qualitative	Hazard unknown (no further information necessary)
	Local Acute	Qualitative	Hazard unknown (no further information necessary)

Route	Type of effect	Type of risk characterisation	Hazard conclusion
Eye	Local	Qualitative	Hazard unknown (no further information necessary)
Oral	Systemic Long Term	Quantitative	DNEL (Derived No Effect Level) = 5 mg/kg bw/day

Comments on assessment approach:

No consumer human health exposure assessment has not been performed as use of cosmetic products is not covered under the scope of REACH (1907/2006 as amended). General population DNEL was derived only to complete an exposure assessment for man via the environment.

2. EXPOSURE SCENARIO 1: MANUFACTURE

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

Environment contributing scenario(s):	
Manufacture	ERC 1
Worker contributing scenario(s):	
Use in closed process, no likelihood of exposure	PROC 1
Use in closed, continuous process with occasional controlled exposure	PROC 2
Use in closed batch process (synthesis of formulation)	PROC 3
Use in batch or other process (synthesis) where opportunity for exposure arises	PROC 4
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b
Use as laboratory reagent	PROC 15

Manufacture of up to 50 tonnes per annum included in the joint CSR for potential follow-on registrant manufacture in the EU; not a Lead Registrant use.

2.1 Environmental contributing scenario 1: Manufacture

2.1.1 Conditions of use Manufacture

Manufacture occurs at a dedicated site where all processes are performed in dedicated facilities with dedicated equipment and any contaminated waste or water (after only incidental cleaning) is treated as chemical waste and incinerated. This means that there is no potential for release to the aquatic environment.

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.227 tonnes/day (*based on 220 days per year)*
• Annual use at a site: <= 50 tonnes/year
• Percentage of tonnage used at regional scale: = 100 %
Technical and organisational conditions and measures
• Collect water from equipment/drums cleaning as waste: Yes [Effectiveness Water: 100%] *all processes are performed in dedicated facilities with dedicated equipment and any contaminated waste or water (after only incidental cleaning) is treated as chemical waste and incinerated. No release to the aquatic environment is expected.*
• Exhaust air treatment (scrubbers): Yes [Effectiveness Air: 99%]

Conditions and measures related to sewage treatment plant
• Municipal STP: No [Effectiveness Water: 0%] *Not applicable as all wastes must be collected and disposed on site*
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: >= 2E3 m3/d
• Receiving surface water flow rate: >= 1.8E4 m3/d

2.1.2 Releases Manufacture

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 6% **Final release factor:** 0% **Local release rate:** 0 kg/day
Air	ERC based	**Initial release factor:** 5% **Final release factor:** 0.05% **Local release rate:** 0.114 kg/day
Soil	ERC based	**Final release factor:** 0.01%

Releases to waste

Release factor to waste from the process: 6%

Initial estimate of release to waste water conservatively based on ERC default figures

Release factor to waste from on site treatment: 0%

All processes are performed in dedicated facilities with dedicated equipment and any contaminated waste or water (after only incidental cleaning) is treated as chemical waste and incinerated. No release to the aquatic environment is expected and therefore releases to waste water set at 0%.

2.1.3 Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	1.985E-5 mg/kg bw/day	6.949E-4 mg/L
Fish	1.342E-8 mg/kg bw/day	8.168E-6 mg/kg ww
Leaf crops	1.414E-4 mg/kg bw/day	0.008 mg/kg ww
Root crops	3.93E-6 mg/kg bw/day	7.163E-4 mg/kg ww
Meat	2.691E-9 mg/kg bw/day	6.259E-7 mg/kg ww
Milk	5.016E-8 mg/kg bw/day	6.259E-6 mg/kg ww

2.2 Human Health contributing scenarios: Manufacture

2.2.1 General conditions

Product (article) characteristics
• Dustiness of material: High

• Concentration of substance in mixture: Substance as such
Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: < 8 hours
Technical and organisational conditions and measures
• General ventilation: Basic general ventilation (1-3 air changes per hour)
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]
• Local exhaust ventilation (for dermal): no [Effectiveness Dermal: 0%]
• Occupational Health and Safety Management System: Advanced
Conditions and measures related to personal protection, hygiene and health evaluation
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *Substance is treated as hazardous and as such workers are supplied with PPE and appropriate training, covering skin and mucous membranes (gloves, eyes protection and dust masks).*
• Respiratory Protection: No [Effectiveness Inhal: 0%]
Other conditions affecting workers exposure
• Place of use: Indoor
• Process temperature (for solid): Ambient

2.2.2 Worker contributing scenario 1: Use in closed process, no likelihood of exposure (PROC 1)

Additional or deviating conditions

Technical and organisational conditions and measures
• Containment: Closed system (minimal contact during routine operations)
Other conditions affecting workers exposure
• Skin surface potentially exposed: One hand face only (240 cm2)

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled.

2.2.3 Worker contributing scenario 2: Use in closed, continuous process with occasional controlled exposure (PROC 2)

Additional or deviating conditions

Technical and organisational conditions and measures	
• Containment: Closed continuous process with occasional controlled exposure	
Other conditions affecting workers exposure	
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled.

2.2.4 Worker contributing scenario 3: Use in closed batch process (synthesis of formulation) (PROC 3)

Additional or deviating conditions

Technical and organisational conditions and measures
• Containment: Closed batch process with occasional controlled exposure
Other conditions affecting workers exposure
• Skin surface potentially exposed: Two hands face (240 cm2)

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled.

2.2.5 Worker contributing scenario 4: Use in batch or other process (synthesis) where opportunity for exposure arises (PROC 4)

Additional or deviating conditions

Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours (*Workers exposed for less than 4 hours)*	
Technical and organisational conditions and measures	
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: yes [Effectiveness Inhal: 90%] *LEV in place for this type of operation (minimum 90% efficiency)*	TRA Worker v3
Other conditions affecting workers exposure	
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled.

2.2.6 Worker contributing scenario 5: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

Additional or deviating conditions

Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: < 1 hour *Workers exposed for less than 1 hour for this type of operation*
Technical and organisational conditions and measures
• Containment: Semi-closed process with occasional controlled exposure
• Local exhaust ventilation: yes [Effectiveness Inhal: 95%] *LEV in place for this type of operation (minimum 95% efficiency)*
Other conditions affecting workers exposure
• Skin surface potentially exposed: Two hands (960 cm2)

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled.

2.2.7 Worker contributing scenario 6: Use as laboratory reagent (PROC 15)

Additional or deviating conditions

Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: < 1 hour
Technical and organisational conditions and measures
• Containment: No (Sampling of product for QA checks)
• Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhal: 90%] *Dust mask/respirator to APF 10 recommended for workers involved in this activity.*
Other conditions affecting workers exposure
• Skin surface potentially exposed: One hand face only (240 cm2)

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled.

3. EXPOSURE SCENARIO 2: FORMULATION

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

Environment contributing scenario(s):	
Formulation	ERC 2
Worker contributing scenario(s):	
Use in closed batch process (synthesis of formulation)	PROC 3
Mixing or blending in batch processes for formulation of preparations and articles (multistage or significant contact)	PROC 5
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	PROC 8a
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC 9
Use a laboratory reagent	PROC 15

The substance is used in formulations to make end-use cosmetic products at various sites in the EU.

3.1 Environmental contributing scenario 1: Formulation

3.1.1 Conditions of use Formulation

Formulation of the substance into end-use cosmetic products. The largest single site is considered to use 50 tpa.

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.227 tonnes/day *220 days per year.*
• Annual use at a site: <= 50 tonnes/year *F main source 0.1*
• Percentage of tonnage used at regional scale: = 100 %
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes [Effectiveness Water: 0.383%]
• 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

3.1.2 Releases Formulation

Release	Release factor estimation method	Explanation / Justification
Water	Release factor	**Initial release factor:** 0.02% **Final release factor:** 0.02% **Local release rate:** 0.045 kg/day **Explanation / Justification:** IZU is used at a concentration of 1% in end-use cosmetic formulations and as such it is appropriate to reduce the default emissions to water, air and soil at formulation sites.
Air	Release factor	**Initial release factor:** 0.025% **Final release factor:** 0.025% **Local release rate:** 0.057 kg/day **Explanation / Justification:** IZU is used at a concentration of 1% in end-use cosmetic formulations and as such it is appropriate to reduce the default emissions to water, air and soil at formulation sites.
Soil	ERC based	**Final release factor:** 0.01%

Releases to waste

Release factor to waste from the process: 0.02%

The substance is only used at concentrations at or below 1% during the main part of the formulation process. In addition, when the equipment for the formulation is cleaned, the actual concentration in the water is well below 1%. Therefore the final release percentage has been reduced from the ERC default of 2% to 0.02%.

3.1.3 Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	3.915E-5 mg/kg bw/day	0.001 mg/L
Fish	3.18E-6 mg/kg bw/day	0.002 mg/kg ww
Leaf crops	1.556E-4 mg/kg bw/day	0.009 mg/kg ww
Root crops	4.37E-6 mg/kg bw/day	7.966E-4 mg/kg ww
Meat	1.891E-9 mg/kg bw/day	4.397E-7 mg/kg ww
Milk	3.524E-8 mg/kg bw/day	4.397E-6 mg/kg ww

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled.

3.2 Human Health contributing scenarios: Formulation

3.2.1 General conditions

Product (article) characteristics
• Dustiness of material: High
• Concentration of substance in mixture: Substance as such
Technical and organisational conditions and measures
• General ventilation: Basic general ventilation (1-3 air changes per hour)
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]
• Local exhaust ventilation (for dermal): no [Effectiveness Dermal: 0%]
• Occupational Health and Safety Management System: Advanced
Conditions and measures related to personal protection, hygiene and health evaluation
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *Substance is treated as hazardous and as such workers are supplied with PPE and appropriate training, covering skin and mucous membranes (gloves, eyes protection and dust masks).*
• Respiratory Protection: No [Effectiveness Inhal: 0%]
Other conditions affecting workers exposure
• Place of use: Indoor
• Process temperature (for solid): Ambient

3.2.2 Worker contributing scenario 1: Use in closed batch process (synthesis of formulation) (PROC 3)

Additional or deviating conditions

Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	
Technical and organisational conditions and measures	
• Containment: Closed batch process with occasional controlled exposure	
Other conditions affecting workers exposure	
• Skin surface potentially exposed: One hand face only (240 cm2)	

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled.

9.2.3. Worker contributing scenario 2: Mixing or blending in batch processes for formulation of preparations and articles (multistage or significant contact) (PROC 5)

Additional or deviating conditions

Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: < 4 hours *Workers engaged in this type of activity for less than 4 hours per day*
Technical and organisational conditions and measures
• Containment: No

• Local exhaust ventilation: yes [Effectiveness Inhal: 90%] *(LEV in place for this type of operation (minimum 90% efficiency)*
Other conditions affecting workers exposure
• Skin surface potentially exposed: Two hands face (480 cm2)

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled.

3.2.3 Worker contributing scenario 3: Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

Additional or deviating conditions

Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: < 1 hour *Workers engaged in this type of activity for less than 1 hour per day*
Technical and organisational conditions and measures
• Containment: No
• Local exhaust ventilation: yes [Effectiveness Inhal: 90%] *LEV in place for this type of operation (minimum 90% efficiency)*
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhal: 90%]. *Dust masks/respirators to APF 10 required for workers involved in this activity.*
Other conditions affecting workers exposure
• Skin surface potentially exposed: Two hands (960 cm2)

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled

3.2.4 Worker contributing scenario 4: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

Additional or deviating conditions

Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour *Workers engaged in this type of activity for less than 1 hour per day*	TRA Worker v3
Technical and organisational conditions and measures	
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: yes [Effectiveness Inhal: 95%] *LEV in place for this type of operation (minimum 95% efficiency)*	TRA Worker v3
Other conditions affecting workers exposure	
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled

3.2.5 Worker contributing scenario 5: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

Additional or deviating conditions

Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	
Technical and organisational conditions and measures	
• Containment: Semi-closed process with occasional controlled exposure	
• Local exhaust ventilation: yes [Effectiveness Inhal: 90%] *LEV in place for this type of operation (minimum 90% efficiency)*	
Other conditions affecting workers exposure	
• Skin surface potentially exposed: Two hands face (480 cm2)	

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled

3.2.6 Worker contributing scenario 6: Use a laboratory reagent (PROC 15)

Additional or deviating conditions

Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: < 1 hour *Workers engaged in this type of activity for less than 1 hour per day*
Technical and organisational conditions and measures
• Containment: No (Sampling of product for QA checks)
• Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhal: 90%] *Dust masks/respirators to APF 10 required for workers involved in this activity.*
Other conditions affecting workers exposure
• Skin surface potentially exposed: One hand face only (240 cm2)

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of direct dermal exposure to workers is controlled

3.2.7 Worker contributing scenario 7: Production of preparations or articles by tabletting, compression, extrusion, pelletisation (PROC 14)

Additional or deviating conditions

Product (article) characteristics
• Concentration of substance in mixture: 1-5%
• Solid in solid mixtures: Yes
Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: < 8 hours
Technical and organisational conditions and measures
• Containment: No
Conditions and measures related to personal protection, hygiene and health evaluation
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]

• Respiratory Protection: No [Effectiveness Inhal: 0%]
Other conditions affecting workers exposure
• Skin surface potentially exposed: Two hands face (480 cm2)

Conclusion on risk characterisation

Appropriate OC/RMMs have been specified to ensure that any risk of eye irritation or direct dermal exposure to workers is controlled

4. EXPOSURE SCENARIO 3: CONSUMER USE

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

Environment contributing scenario(s):	
Consumer Use	ERC 8a

Consumer use of cosmetic products; only the environmental exposures need to be covered as human exposure is regulated by the Cosmetics Directive.

4.1 Environmental contributing scenario 1: Consumer Use

4.1.1 Conditions of use Consumer Use

Consumer use of end-use cosmetics; 100% of substance is considered to be discharged to waste water by washing after application.

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 5E-5 tonnes/day *WARNING: According to this SPERC, the default daily use amount can be refined from the default. To that end, divide the default value of the amount used locally by a factor of 5 and substitute the result for the default value. In case of refinement, keep only the following explanation: The default value of the amount used locally has been divided by a factor of 5. This is justified by refined information on the consumption pattern of cosmetics and personal care products. According to this information, the Fraction of EU tonnage used in region (FRegion) is 0.053 (default: 0.1) and the Fraction of Regional tonnage used locally (FMainLocalSource) is 0.00075 (default is 0.002).*
• Percentage of 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: 0.383%]
• 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
• Type of process: Substance applied in aqueous process solution with negligible volatilization
• Indoor/outdoor use: Indoor Use

4.1.2 Releases Consumer Use

Release	Release factor estimation method	Explanation / Justification
Water	SpERC based Cosmetics Europe 8a.1a.v2 - Cosmetics Europe 8a.1a.v2 Wide Dispersive Use of Cosmetic Products - 'Down the drain' products - hair and skin care products (Consumers and Professionals) - Wide dispersive use in 'Down the drain' products - hair and skin care products (Consumers and Professionals)	**Initial release factor:** 100% **Final release factor:** 100% **Local release rate:** 0.05 kg/day **Explanation / Justification:** Rinse-off products such as shampoo and soap products that are disposed of with the waste water such that 100 % of the product ingredients enter the waste water system. Product residues remaining on the substrate are likely to be washed off in the next washing event.
Air	SpERC based same as above	**Initial release factor:** 0% **Final release factor:** 0% **Explanation / Justification:** Rinse-off products such as shampoo and soap products that are disposed of with the waste water such that 100 % of the product ingredients enter the waste water system. Product residues remaining on the substrate are likely to be washed off in the next washing event.
Soil	SpERC based same as above	**Final release factor:** 0% **Explanation / Justification:** Rinse-off products such as shampoo and soap products that are disposed of with the waste water such that 100 % of the product ingredients enter the waste water system. Product residues remaining on the substrate are likely to be washed off in the next washing event.

Releases to waste

Release factor to waste from the process: 0%

Rinse-off products such as shampoo and soap products that are disposed of with the waste water such that 100 % of the product ingredients enter the waste water system. Product residues remaining on the substrate are likely to be washed off in the next washing event.

4.1.3 Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	7.132E-5 mg/kg bw/day	0.002 mg/L
Fish	5.792E-6 mg/kg bw/day	0.004 mg/kg ww
Leaf crops	9.438E-5 mg/kg bw/day	0.006 mg/kg ww
Root crops	2.673E-6 mg/kg bw/day	4.872E-4 mg/kg ww
Meat	8.687E-10 mg/kg bw/day	2.02E-7 mg/kg ww
Milk	1.619E-8 mg/kg bw/day	2.02E-6 mg/kg ww

Conclusion on risk characterisation

RCRs for all compartments are < 1, indicating little risk to the environment from the uses modelled in this CSR.