SAFETY DATA SHEET (1907/2006)

R0711626

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CERAPHYL 55

ANNEX

1. OVERVIEW OF EXPOSURE SCENARIOS

Identifiers	Titles of exposure scenarios and the related contributing scenarios
ES1 - F1	Formulation - Formulation - Formulation (ERC 2) - 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 dedicated facilities (PROC 8b) - Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)
ES2 - C1	Consumer Use - Consumer Use - Consumer Use (ERC 8a) - Use of Cosmetics Creams (emollients) by consumers (PC 39)

1.1 General information on risk management related to toxicological hazard

Ceraphyl 55 is classified as a skin sensitizer under CLP. Most cosmetic products containing the substance hold less than 10% wt/wt of Ceraphyl 55 and have not been reported to be sensitizers. However, the formulation process starts with pure Ceraphyl 55 process, and for the concerning workers this may be a health hazard. Therefore, a qualitative risk assessment needs to be conducted.

For skin sensitisation the qualitative risk characterisation was conducted for the neat substance. Handling and storage risk management measures that are generally identified for skin sensitisation and identified below.
A review of these RMMs indicates that if the user complies with the following generic statements, risks due to skin sensitisation can be considered to be adequately controlled with the following measurements to avoid direct skin contact with neat product.:

1. Identify potential areas for indirect skin contact;
2. Wear gloves (tested to EN374) if direct hand contact with the substance is likely;
3. Clean up contamination/spills as soon as they occur;
4. Wash off skin contamination immediately;
5. Provide basic employee training to prevent / minimise exposures and to report any skin effects that may develop.

If these conditions are adhered to, then safe use has been demonstrated. No hazard is expected in cases of handling formulations with < 10% of Ceraphyl 55.

Conditions of the use of gloves:

a. It is anticipated that companies generally define their standard glove type(s), often nitrile, and a few non-standard gloves for special chemicals or long-term/extensive risk of exposure (e.g. spills).
b. Recommendations concerning the type of material, its thickness and the typical or minimum breakthrough times of the glove material:
    1. Gloves for repeated or prolonged exposure (breakthrough time > 240 min): Material: standard thick nitrile gloves, thickness: ≥ 0.38 mm,
    2. Gloves for short term exposure/splash protection (breakthrough time > 10 min): Material: thin disposable nitrile gloves, thickness: ≥ 0.12 mm.
c. Where the scenario includes the use of inner gloves under specific situations, disposable polyethylene (PE) gloves are generally recommended. PE gloves offer excellent long-term protection for more than 95% of the

chemicals, except halogenated hydrocarbons. As PE gloves are not ergonomic and not mechanically resistant, they have to be used under other gloves offering a good grip and resistance.

d. In combination with specific training and the use of disposible PE inner gloves, gloves protection is considered to be 98% effective at further reducing any incidental or intermittent exposures. In those cases, the external dermal dose was derived applying this 98% efficiency.
e. Instructions should force operators to replace both the outer and inner gloves immediately in case of any direct contact with a chemical.

2. EXPOSURE SCENARIO 1: FORMULATION

2.1 General scenario

Environment contributing scenario(s):	
Formulation	ERC 2
Worker contributing scenario(s):	
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 dedicated facilities	PROC 8b
Transfer of preparation (< 10% Ceraphyl 55) into small containers (dedicated filling line, including weighing)	PROC 9

2.2 Environmental contributing scenario 1: Formulation

2.2.1 Conditions of use Formulation

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.077 tonnes/day *• Annual use at the site: <= 20 tonnes/year; Assumes that there is 1 site where formulation occurs. • Daily use at site: <= 0.077 tonnes/day Assumes that the formulation occurs for most of the year (260 days) at the plant.*
• Annual use at a site: <= 20 tonnes/year
• Percentage of tonnage used at regional scale: = 100 %
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes [Effectiveness Water: 95.92%]
• 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 concentration) (Particular risks from waste treatment unlikely due low concentration of substance in waste stream. Waste disposal according to national/local legislation is sufficient.) *Emission/release to waste water: - significant wastewater emissions as process operates with water contact – Assumes free product in wastewater stream. – Oil-water separation is present (e.g. via oil water separators or oil skimmers) – Site specific waste water treatment is present*
Other conditions affecting environmental exposure
• 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:** 2E-4% **Final release factor:** 2E-4% **Local release rate:** 1.54E-4 kg/day **Explanation / Justification:** Emission/release to waste water: - significant wastewater emissions as process operates with water contact – Assumes free product in wastewater stream. – Oil-water separation is present (e.g. via oil water separators or oil skimmers) – Site specific waste water treatment is present
Air	Release factor	**Initial release factor:** 0% **Final release factor:** 0% **Local release rate:** 0 kg/day **Explanation / Justification:** Negligible air emissions as process operates in a contained system.
Soil	Release factor	**Final release factor:** 0% **Explanation / Justification:** No significant emmissions relevant for potenial contamination of soil.

Releases to waste

Release factor to waste from the process: 0%

Release factor to waste from on site treatment: 0%

2.2.3 Exposure of man via the environment

Type of food	Estimated daily dose	Concentration in food
Drinking water	3.256E-8 mg/kg bw/day	1.139E-6 mg/L
Fish	6.831E-6 mg/kg bw/day	0.004 mg/kg ww
Leaf crops	8.447E-7 mg/kg bw/day	4.927E-5 mg/kg ww
Root crops	8.349E-5 mg/kg bw/day	0.015 mg/kg ww
Meat	8.772E-7 mg/kg bw/day	2.04E-4 mg/kg ww
Milk	5.17E-7 mg/kg bw/day	6.451E-5 mg/kg ww

2.3 Worker contributing scenario 1: Mixing or blending in batch processes for formulation of preparations and articles (multistage or significant contact) (PROC 5)

Product (article) characteristics
• Concentration of substance in mixture: Substance as such
Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: < 4 hours
Technical and organisational conditions and measures
• General ventilation: Enhanced general ventilation (5-10 air changes per hour)
• Containment: No
• Local exhaust ventilation: yes [Effectiveness Inhal: 90%]
• 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%]
• Respiratory Protection: No [Effectiveness Inhal: 0%]
Other conditions affecting workers exposure
• Place of use: Indoor
• Process temperature (for liquid): <= 40 °C
• Skin surface potentially exposed: Two hands face (480 cm2)

2.4 Worker contributing scenario 2: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

Product (article) characteristics
• Concentration of substance in mixture: 5-25% (*8%*)
Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: < 4 hours (*1 h*)
Technical and organisational conditions and measures
• General ventilation: Enhanced general ventilation (5-10 air changes per hour)
• Containment: Semi-closed process with occasional controlled exposure
• Local exhaust ventilation: yes [Effectiveness Inhal: 95%]
• 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%]
• Respiratory Protection: No [Effectiveness Inhal: 0%]
Other conditions affecting workers exposure
• Place of use: Indoor
• Process temperature (for liquid): <= 40 °C
• Skin surface potentially exposed: Two hands (960 cm2)

2.5 Worker contributing scenario 3: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

Product (article) characteristics
• Concentration of substance in mixture: 5-25% (*8%*)
Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: < 4 hours (*1 h*)
Technical and organisational conditions and measures
• General ventilation: Good general ventilation (3-5 air changes per hour)
• Containment: Semi-closed process with occasional controlled exposure

• Local exhaust ventilation: yes [Effectiveness Inhal: 90%]
• 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: No [Effectiveness Dermal: 0%]
• Respiratory Protection: No [Effectiveness Inhal: 0%]
Other conditions affecting workers exposure
• Place of use: Indoor
• Process temperature (for liquid): <= 40 °C
• Skin surface potentially exposed: Two hands face (480 cm2)

3. EXPOSURE SCENARIO 2: CONSUMER USE

3.1 General scenario

Environment contributing scenario(s):	
Consumer Use	ERC 8a
Consumer contributing scenario(s):	
Use of Cosmetics Creams (emollients) by consumers	PC 39

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

Substance used as an emollient in skin care products

3.2 Environmental contributing scenario 1: Consumer Use

3.2.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 1.1E-6 tonnes/day
• 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 concentration) (Particular risks from waste treatment unlikely due low concentration of substance in waste stream. Waste disposal according to national/local legislation is sufficient.)
Other conditions affecting environmental exposure
• Municipal STP: Yes [Effectiveness Water: 95.92%]
• 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

3.2.2 Releases

Release	Release factor estimation method	Explanation / Justification
Water	Release factor	**Initial release factor:** 100%

Release	Release factor estimation method	Explanation / Justification
		Final release factor: 100% **Local release rate:** 0.001 kg/day
Air	Release factor	**Initial release factor:** 0% **Final release factor:** 0%
Soil	Release factor	**Final release factor:** 0.1%

3.2.3 Exposure of man via the environment

Type of food	Estimated daily dose	Concentration in food
Drinking water	2.237E-7 mg/kg bw/day	7.83E-6 mg/L
Fish	1.218E-5 mg/kg bw/day	0.007 mg/kg ww
Leaf crops	8.614E-7 mg/kg bw/day	5.025E-5 mg/kg ww
Root crops	5.737E-4 mg/kg bw/day	0.105 mg/kg ww
Meat	1.025E-6 mg/kg bw/day	2.383E-4 mg/kg ww
Milk	6.039E-7 mg/kg bw/day	7.535E-5 mg/kg ww