

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Niacinamide

Synonyms:

Nicotinamide; Vitamin B3; Niacinamide Feed Grade; Niacinamide Free Flow

Chemical Abstracts Registry No:

98-92-0

REACH Registration Number:

01-2119968268-22-0008

1.2. Relevant identified uses of the substance or mixture and uses advised against

Animal & human nutrition, chemical intermediate, personal care

1.3. Details of the supplier of the safety data sheet

Vertellus Specialty Chemicals (Nantong) Co., Ltd.
#9 Shengkai Road NETDZ
Nantong, Jiangsu, China. 226009
Phone: 86-513-83591318
Emergency Phone: 86 25 85477110
86-513-83591318

Only Representative for EU REACH Registration:

Vertellus Specialties Belgium NV
Havenlaan 86 C Bus 204
B 1000 Brussels
Belgium
REACH@Vertellus.com

e-mail Address:

1.4. Emergency telephone number

Vertellus:
CHEMTREC (USA):
CHEMTREC (International):
NRCC (China): +86 25 85477110

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture (According to Regulation (EC) No 1272/2008, 29 CFR 1910.1200 and the Globally Harmonized System)

Serious Eye Irritation Category 2
Hazard Not Otherwise Classified - Combustible Dust

2.2. Label elements

Hazard Symbols (Pictogram):



Signal Word:

Warning

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Hazard Precautions: H319 - Causes serious eye irritation.

Prevention Precautionary Statements: P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P264 - Wash hands thoroughly after handling.

First Aid Precautionary Statements: P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

Other Hazards: WARNING! MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR (DURING PROCESSING).

SECTION 3: Composition/information on ingredients

3.1. Substances or 3.2. Mixtures

Ingredient	CAS Number	Concentration (weight %)	EC Number	CLP Inventory/Annex VI	EU CLP Classification (1272/2008)
Niacinamide	98-92-0	~ 100	202-713-4	Not listed.	Eye Irrit. 2; H319

NOTE: See Section 8 for exposure limit data for these ingredients. See Section 15 for trade secret information (where applicable).

SECTION 4: First aid measures

4.1. Description of first aid measures

Skin Contact: Wash exposed area twice with soap and water. The exposed area should be examined by medical personnel if irritation or pain persists after the area has been washed.

Eye Contact: Rinse eyes immediately with large amounts of water for at least 15 minutes, occasionally lifting the eyelids. Seek medical advice if symptoms persist.

Inhalation: Remove from exposure area to fresh air immediately. If breathing has stopped, give artificial respiration. Keep affected person warm and at rest. Seek medical advice if symptoms persist.

Ingestion: If swallowed, contact physician or poison control center immediately. Give oxygen if respiration is shallow. Do not give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Acute: Niacinamide is an eye irritant, but does not irritate the skin. May cause respiratory irritation upon exposure to dusty conditions. In humans, nausea with or without vomiting was the main effect after acute exposure and was generally seen after doses in excess of 5 grams/day; no effects were persistent.

Delayed Effects: None known.

4.3. Indication of any immediate medical attention and special treatment needed

Note to Physician: No specific indications. Treatment should be based on the judgment of the physician in response to the reactions of the patient.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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Appropriate Extinguishing Media: Water fog, foam, carbon dioxide, or dry chemical

5.2. Special hazards arising from the substance or mixture

Hazardous Products of Combustion: Cyanide and nitrogen oxides may be released during thermal decomposition.

Potential for Dust Explosion: Niacinamide presents a significant dust explosion hazard unless properly handled. Maximum Explosion Pressure = 8.0 bar; Maximum Rate of Pressure Rise = 885 bar/s; Kst = 240 bar.m/s; Minimum Ignition Energy = 3 - 5 mJ; Limiting Oxygen Concentration = 13 - 14%; Minimum Explosible Concentration = 50 - 60 g/m³. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, or equivalent guidance, for safe handling. Refer to European standards: EN1127-1, EN14491, EN14797, EN14373, and EN15089 for safe handling of and controlling explosive atmospheres in the workplace.

Special Flammability Hazards: This product is an organic solid. As such, in its finely divided form, this product has the potential to present a dust explosion hazard under certain conditions. Please review the dust explosion data enclosed in this section. Handle this product in a manner that prevents dust generation and accumulation, and refer to National Fire Protection Association (NFPA) Standard 654 for further information on prevention of dust explosions.

5.3. Advice for firefighters

Basic Fire Fighting Guidance: Wear self-contained breathing apparatus and protective clothing. Normal firefighting procedures may be used. Avoid generating dust. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuation Procedures: Isolate the hazard area and deny entry to unnecessary and unprotected personnel.

Special Instructions: See Section 8 for personal protective equipment recommendations. Remove all contaminated clothing to prevent further absorption. Decontaminate affected personnel using the first aid procedures in Section 4. Leather shoes that have been saturated must be discarded.

6.2. Environmental precautions

Prevent releases to soils, drains, sewers and waterways.

6.3. Methods and material for containment and cleaning up

Remove all ignition sources. Ventilate the area of spill or leak. Wear protective equipment during clean-up. Material can then be collected for later disposal. After collection of material, flush area with water. Dispose of the material in accordance with standard practice for disposal of potentially hazardous materials as required by applicable federal, state or local laws. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Nonsparking tools should be used.

6.4. Reference to other sections

Refer to section 8 for information on selecting personal protective equipment. Refer to section 13 for information on spilled product, absorbent and clean up material disposal instructions.

SECTION 7: Handling and storage

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7.1. Precautions for safe handling

Precautions for Unique Hazards:	This material may present a dust explosion hazard in solid form and is sensitive to ignition by electrostatic discharge. Maintain areas below flammable vapor / explosive dust concentrations.
Practices to Minimize Risk:	Wear appropriate protective equipment when performing maintenance on contaminated equipment. Wash hands thoroughly before eating or smoking after handling this material. Do not eat, drink or smoke in work areas. Prevent contact with incompatible materials. Avoid spills and keep away from drains. Handle in a manner to prevent generation of aerosols, vapors or dust clouds. To reduce the risk of dust explosion, the recommendations for facility and process design, control of ignition sources and fugitive dust, fire protection, training and maintenance outlined in "NFPA 654: Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids", or equivalent guidance, should be followed. Implementing a housekeeping program to control the accumulation of dust on work surfaces is critical to reducing the risk of catastrophic secondary dust explosions.
Special Handling Equipment:	Not applicable.

7.2. Conditions for safe storage, including any incompatibilities

Storage Precautions & Recommendations:	Protect containers against physical damage. Maintain dry, ventilated conditions for storage. Keep away from strong acids, strong bases and oxidizing agents. Do not store with poisons. Minimize dust generation and accumulation. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Dangerous Incompatibility Reactions:	Avoid strong acids, strong bases, and oxidizing agents.
Incompatibilities with Materials of Construction:	None known

7.3. Specific end use(s)

If a chemical safety assessment has been completed an exposure scenario is attached as an annex to this Safety Data Sheet. Refer to this annex for the specific exposure scenario control parameters for uses identified in subsection 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Country	Occupational Exposure Limit
Latvia	1 mg/m ³
New Zealand	Particulates: 10 mg/mg ³ (inhalable); 3 mg/m ³ (respirable)
United States (OSHA)	Particulates: 15 mg/m ³ (total dust); 5 mg/m ³ (respirable fraction)
United States (NIOSH), Belgium, Canada (Quebec), Singapore, South Korea	Particulates: 10 mg/m ³

Air Monitoring Method: Gravimetric analysis for total particulate and respirable fraction (<10 microns).

Derived No Effect Levels (DNELs) – Workers:

	Route	DNEL

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Acute and long-term - local effects (dermal, inhalation) Long-term - systemic effects (dermal) Long-term - systemic effects (inhalation) Acute - systemic effects (dermal) Acute - systemic effects (inhalation)	No hazard identified 25 mg/kg bw/day 87.5 mg/m ³ No hazard identified No hazard identified
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Derived No Effect Levels (DNELs) – General Population:

Route	DNEL
Long-term - systemic effects (inhalation) Acute and long-term - local effects (dermal, inhalation) Acute - systemic effects (oral, dermal, inhalation) Long-term - systemic effects (dermal) Long-term - systemic effects (oral)	21.88 mg/m ³ No hazard identified No hazard identified 12.5 mg/kg bw/day No hazard identified

Predicted No Effect Concentrations (PNECs):

Route	PNEC
PNEC aqua (freshwater) PNEC aqua (marine water) PNEC aqua (STP) PNEC sediment (freshwater) PNEC sediment (marine water) PNEC soil	1 mg/L 0.1 mg/L 423.5 mg/L 1.109 mg/kg sediment dw 0.111 mg/kg sediment dw 0.33 mg/kg soil dw

8.2. Exposure controls

Also see the annex to this SDS (if applicable) for specific exposure scenario controls.

- Other Engineering Controls:** All operations should be conducted in well-ventilated conditions. Local exhaust ventilation should be provided. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
- Personal Protective Equipment:** Work uniform or impervious clothing. Impervious gloves and boots. Safety glasses or chemical goggles. NIOSH approved dust mask, or negative pressure respirator with dust or HEPA cartridges as necessary.
- Respirator Caution:** Observe OSHA regulations for respirator use (29 CFR 1910.134) or equivalent guidance. Air-purifying respirators must not be used in oxygen-deficient atmospheres.
- Thermal Hazards:** Not applicable.
- Environmental Exposure Controls:** The level of protection and types of controls necessary will vary depending upon potential exposure conditions. Select controls based on a risk assessment of local circumstances. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

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Appearance, State & Odor (ambient temperature):	White crystalline powder, with essentially no odor.		
Vapor Pressure:	< 1 mm Hg	Evaporation Rate:	Not applicable.
Specific Gravity or Density:	1.4 @ 25°C	Vapor Density (air = 1):	No data available.
Boiling Point:	150 - 160 °C	Freezing / Melting Point:	124 - 131 °C
Solubility in Water:	500,000 mg/L @ 25°C	Octanol / Water Coefficient:	log Kow = -0.37
pH:	pKa = 3.35 @ 20°C	Odor Threshold:	No data available.
Viscosity:	Not applicable.	Autoignition Temperature:	No data available.
Flash Point and Method:	360°F (182°C) Tag Open Cup	Flammable Limits:	No data available.
Flammability (solid, gas):	No data available.	Decomposition Temperature:	No data available.
Explosive Properties:	Not explosive.	Oxidizing Properties:	Not an oxidizer.

SECTION 10: Stability and reactivity

<u>10.1. Reactivity</u>	Not classified as dangerously reactive.
<u>10.2. Chemical stability</u>	Stable
<u>10.3. Possibility of hazardous reactions</u>	Will not occur.
<u>10.4. Conditions to avoid</u>	Avoid static discharge and generation of dust. Thermal decomposition begins at 150°C.
<u>10.5. Incompatible materials</u>	Avoid strong acids, strong bases, and oxidizing agents.
<u>10.6. Hazardous decomposition products</u>	Cyanide and nitrogen oxides may be released during thermal decomposition.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute Oral LD ₅₀ :	> 3500 mg/kg (rat) > 2500 mg/kg (mouse)	Niacinamide
Acute Dermal LD ₅₀ :	> 2000 mg/kg (rabbit)	Niacinamide
Acute Inhalation LC ₅₀ :	> 3.8 mg/L (4h rat)	Niacinamide
Skin Irritation:	Non-irritating to skin.	
Eye Irritation:	Moderately irritating to eyes.	
Skin Sensitization:	Not sensitizing (Weight of evidence)	
Mutagenicity:	This material was tested and found to be non-mutagenic in the Ames assay and Mouse Micronucleus test. Equivocal test results occurred in the Unscheduled DNA Synthesis assay in rat primary hepatocytes.	

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Reproductive / Developmental Toxicity:	In a 28-day oral toxicity test in rats, no effects on reproductive organs were observed in either sex. In a developmental toxicity study in rats using niacin, the NOAEL for maternal toxicity was 200 mg/kg/d (body weight changes) and the NOAEL on reproductive toxicity and developmental toxicity was 200 mg/kg/d (decreased placental and male pup body weight). No teratogenic effects were observed.
Carcinogenicity:	This material is not listed by IARC, NTP or OSHA as a carcinogen. No test data is available that indicates this material is a carcinogen.
Target Organs:	None Known.
Aspiration Hazard:	Based on physical properties, not likely to be an aspiration hazard.
Primary Route(s) of Exposure:	Skin contact and absorption, eye contact, and inhalation. Ingestion is not likely to be a primary route of exposure.
Most important symptoms and effects, both acute and delayed	Niacinamide is an eye irritant, but does not irritate the skin. May cause respiratory irritation upon exposure to dusty conditions. In humans, nausea with or without vomiting was the main effect after acute exposure and was generally seen after doses in excess of 5 grams/day; no effects were persistent. Delayed Effects: None known.
Additive or Synergistic effects:	None known.

SECTION 12: Ecological information

<u>12.1. Toxicity</u>	EC50 (24h) Daphnia magna > 1000 mg/L LC50 (96h) Poecilia reticulata (guppy) > 1000 mg/L EC50 (72h) Scenedesmus subspicatus > 1000 mg/L	Niacinamide
<u>12.2. Persistence and degradability</u>	Material is readily biodegradable under aerobic conditions.	
<u>12.3. Bioaccumulative potential</u>	Not expected to bioconcentrate in aquatic species.	
<u>12.4. Mobility in soil</u>	This material is soluble in water. Its adsorption to soil and sediment should not be significant.	
<u>12.5. Results of PBT and vPvB assessment</u>	This substance is not a PBT or vPvB.	
<u>12.6. Other adverse effects</u>	No data available.	

SECTION 13: Disposal considerations

<u>13.1. Waste treatment methods</u>	
US EPA Waste Number:	Non-Hazardous
Waste Classification: (per US regulations)	The waste may be classified as "special" or hazardous per State regulations.
Waste Disposal:	NOTE: Generator is responsible for proper waste characterization. State hazardous waste regulations may differ substantially from federal regulations. Dispose of this material responsibly, and in accordance with standard practice for disposal of potentially hazardous materials as required by applicable international, national, regional, state or local laws, and environmental protection duty of care principles. Do NOT dump into any sewers, on the ground, or into any body of water. For disposal within the EC, the appropriate classification code according to the European Community List of Wastes should be used. Note that disposal regulations may also apply to empty containers and equipment rinsates.

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SECTION 14: Transport information

The following information applies to all shipping modes (DOT/IATA/ICAO/IMDG/ADR/RID/ADN), unless otherwise indicated:

14.1. UN number	Not applicable	14.2. UN proper shipping name	Chemicals, n.o.s. (Niacinamide)
14.3. Transport hazard class(es)	Not applicable	14.4. Packing group	Not applicable
14.5. Environmental hazards	Not applicable		
14.6. Special precautions for user	Cannot be stored or shipped with TOXIC materials		
NA Emergency Guidebook Numbers:	Not applicable	IMDG EMS:	Not applicable
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.		

SECTION 15: Regulatory information

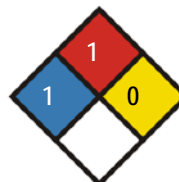
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Chemical Inventory Lists:	Status:		
USA TSCA:	Listed	EC / list No.:	202-713-4
Canada(DSL/NDL):	DSL	Japan:	(5)-736
Korea:	KE-29935	Australia:	Listed
China:	Listed	Philippines:	Listed
Taiwan:	Listed	New Zealand:	Listed
German Water Hazard Classification:	ID Number 2244, hazard class 1 - low hazard to waters (<i>Nicotinamid</i>)		
SARA 313:	Not listed.		
Reportable Quantities:	Not applicable.		
Other Regulatory Listings:	- Included in US Food and Drug Administration's (US FDA) Priority-Based Assessment of Food Additives database. - "Generally Regarded as Safe" (GRAS) by US Food and Drug Administration (21 CFR 184.1). - Approved as cosmetic product additive under European Cosmetic Products Directive 76/768/EEC, Section I listing.		

HMIS IV:

HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0

NFPA:



15.2. Chemical safety assessment

A chemical safety assessment is not required as this substance is not classified as hazardous.

SECTION 16: Other information

- Key Data Sources:
- Select Committee on GRAS Substances (SCOGS) (1979). Opinion: Niacinamide (nicotinamide), SCOGS-

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Report Number: 108

- European Food Safety Authority, 2012. Scientific Opinion on the safety and efficacy of niacin (nicotinic acid and nicotinamide) as a feed additive for all animal species based on a dossier submitted by Vertellus Specialties Belgium BV1, 2. EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)3, 4
- OECD SIDS, UNEP Publications (2002). 3-Pyridinecarboxaldehyde (Nicotinamide): SIDS Initial Assessment Report for SIAM 15.

Classification Method: On basis of test data

Legend of Abbreviations:

ACGIH = American Conference on Governmental Industrial Hygienists.

CAS = Chemical Abstracts Service.

CFR = Code of Federal Regulations.

DSL/NDSL = Domestic Substances List/Non-Domestic Substances List.

EC = European Community.

EINECS = European Inventory of Existing Commercial Chemical Substances.

ELINCS = European List of Notified Chemical Substances.

EU = European Union.

GHS = Globally Harmonized System.

LC = Lethal Concentration.

LD = Lethal Dose.

NFPA = National Fire Protection Association.

NIOSH = National Institute of Occupational Safety and Health.

NTP = National Toxicology Program.

OSHA = Occupational Safety and Health Administration

PEL = Permissible Exposure Limit.

RQ = Reportable Quantity.

SARA = Superfund Amendments and Reauthorization Act of 1986.

TLV = Threshold Limit Value.

WHMIS = Workplace Hazardous Materials Information System.

Important Note: Please note that the information contained herein is furnished without warranty of any kind. Users should consider these data only as a supplement to other information gathered by them and must make independent determinations of suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers. Recipients are advised to confirm in advance of need that the information is current, applicable, and suitable to their circumstances. The information contained herein may change without prior notice. **THIS SAFETY DATA SHEET SUPERSEDES ALL PREVIOUS EDITIONS.**

Revision Date:	19 Feb 2019	Original Date of Issue:	13 July 1995
Issued by:	Regulatory Management Department	Email:	SDS@Vertellus.com
Revision Details:	Revised classification and applicable data in accordance with REACH registration.		

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Annex to the safety data sheet

Product exposure scenario(s)

ES Type	ES title
Environment - Worker	Formulation (cosmetics)
Environment - Worker	Use by professional worker (cosmetics)
Consumer	Use by consumers (cosmetics)

1. Exposure scenario ES2 - F2

Formulation (cosmetics)	ES Ref.: ES2 - F2 ES Type: Environment - Worker Version: 1.0	Company ES code: ES2 - F2 Date of issue: 19/10/2018
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Use descriptors	PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC13, PROC14, PROC15 ERC2
Processes, tasks, activities covered	Formulation into mixture
Assessment method	Cosmetics Europe SPERC 2.1.a.v2 Cosmetics Europe SPERC 2.1.b.v2 Cosmetics Europe SPERC 2.1.c.v2 Cosmetics Europe SPERC 2.1.f.v2 Cosmetics Europe SPERC 2.1.g.v2 Cosmetics Europe SPERC 2.1.h.v2 Cosmetics Europe SPERC 2.1.i.v2 Cosmetics Europe SPERC 2.1.j.v2 Cosmetics Europe / AISE SPERC 2.3.a.v2 Cosmetics Europe / AISE SPERC 2.3.b.v2 Cosmetics Europe / AISE SPERC 2.3.c.v2 ECETOC TRA worker v3

2. Operational conditions and risk management measures

2.1.1 Contributing scenario controlling worker exposure (PROC1) (General exposures (closed systems))

Worker contributing scenario (Proc 1)		
PROC1	Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,one hand,face	240 cm ²
Other given operational conditions affecting workers exposure	Indoor,Assumes activities are at room temperature,Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
Risk Management Measures		

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Technical conditions and measures at process level (source) to prevent release	Handle substance within a closed system	
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear suitable gloves tested to EN374	80 % Effectiveness Dermal
	Conditions and measures related to personal protection, hygiene and health evaluation Wear safety glasses with side shields.	

2.1.2 Contributing scenario controlling worker exposure (PROC2) (General exposures (closed systems))

Worker contributing scenario (Proc 2)		
PROC2	Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands,face	480 cm ²
Other given operational conditions affecting workers exposure	Indoor,Assumes activities are at room temperature,Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Use in closed, continuous process with occasional controlled exposure	
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear suitable gloves tested to EN374	80 % Effectiveness Dermal
	Conditions and measures related to personal protection, hygiene and health evaluation Wear safety glasses with side shields.	

2.1.3 Contributing scenario controlling worker exposure (PROC3)

Worker contributing scenario (Proc 3)		
PROC3	Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,one hand,face	240 cm ²
Other given operational conditions affecting workers exposure	Same as above	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Use in closed batch process (synthesis or formulation). With occasional controlled exposure	
	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No

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Organisational measures to prevent /limit releases, dispersion and exposure	Same as above	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear safety glasses with side shields.	
	Conditions and measures related to personal protection, hygiene and health evaluation Wear suitable gloves tested to EN374	80 % Effectiveness Dermal

2.1.4 Contributing scenario controlling worker exposure (PROC4)

Worker contributing scenario (PROC 4)		
PROC4	Chemical production where opportunity for exposure arises	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands,face	480 cm ²
Other given operational conditions affecting workers exposure	Indoor,Assumes activities are at room temperature	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Local exhaust ventilation. None	
	Technical conditions and measures at process level (source) to prevent release Semi-closed system. With occasional controlled exposure	
	Technical conditions and measures at process level (source) to prevent release Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour)	
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear safety glasses with side shields.	
	Conditions and measures related to personal protection, hygiene and health evaluation Wear suitable gloves tested to EN374	80 % Effectiveness Dermal

2.1.5 Contributing scenario controlling worker exposure (PROC5)

Worker contributing scenario (PROC 5)		
PROC5	Mixing or blending in batch processes	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands,face	480 cm ²
Other given operational conditions affecting workers exposure	Indoor,Assumes activities are at room temperature	
	Other given operational conditions affecting workers exposure Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
Risk Management Measures		

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Technical conditions and measures at process level (source) to prevent release	Local exhaust ventilation	No
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear safety glasses with side shields.	
	Conditions and measures related to personal protection, hygiene and health evaluation Wear suitable gloves tested to EN374	80 % Effectiveness Dermal

2.1.6 Contributing scenario controlling worker exposure (PROC8a)

Worker contributing scenario (PROC 8a)		
PROC8a	Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Both hands	960 cm ²
Other given operational conditions affecting workers exposure	Indoor, Assumes activities are at room temperature	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Provide a good standard of controlled ventilation (5 to 10 air changes per hour)	
	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear safety glasses with side shields.	
	Conditions and measures related to personal protection, hygiene and health evaluation Wear suitable gloves tested to EN374	80 % Effectiveness Dermal

2.1.7 Contributing scenario controlling worker exposure (PROC8b)

Worker contributing scenario (PROC 8b)		
PROC8b	Transfer of substance or mixture (charging and discharging) at dedicated facilities	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands	960 cm ²
Other given operational conditions affecting workers exposure	Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
	Other given operational conditions affecting workers exposure Indoor, Assumes activities are at room temperature	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Semi-closed system. With occasional controlled exposure	
	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No

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Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear safety glasses with side shields.	
	Conditions and measures related to personal protection, hygiene and health evaluation	80 % Effectiveness Dermal
	Wear suitable gloves tested to EN374	

2.1.8 Contributing scenario controlling worker exposure (PROC9)

Worker contributing scenario (PROC 9)		
PROC9	Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands,face	480 cm ²
Other given operational conditions affecting workers exposure	Indoor,Assumes activities are at room temperature	
	Other given operational conditions affecting workers exposure Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Semi-closed system. With occasional controlled exposure	
	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear safety glasses with side shields.	
	Conditions and measures related to personal protection, hygiene and health evaluation	80 % Effectiveness Dermal
	Wear suitable gloves tested to EN374	

2.1.9 Contributing scenario controlling worker exposure (PROC13)

Worker contributing scenario (PROC 13)		
PROC13	Treatment of articles by dipping and pouring	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands,face	480 cm ²
Other given operational conditions affecting workers exposure	Indoor,Assumes activities are at room temperature	
	Other given operational conditions affecting workers exposure Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
Risk Management Measures		
	Containment	No

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Technical conditions and measures at process level (source) to prevent release	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear suitable gloves tested to EN374	80 % Effectiveness Dermal
	Conditions and measures related to personal protection, hygiene and health evaluation Wear safety glasses with side shields.	

2.1.10 Contributing scenario controlling worker exposure (PROC14)

Worker contributing scenario (PROC 14)		
PROC14	Tabletting, compression, extrusion, pelettisation, granulation	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands,face	480 cm ²
Other given operational conditions affecting workers exposure	Indoor,Assumes activities are at room temperature	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Containment	No
	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No
	Technical conditions and measures at process level (source) to prevent release Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour)	
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear safety glasses with side shields.	
	Conditions and measures related to personal protection, hygiene and health evaluation Wear suitable gloves tested to EN374	80 % Effectiveness Dermal

2.1.11 Contributing scenario controlling worker exposure (PROC15)

Worker contributing scenario (PROC 15)		
PROC15	Use as laboratory reagent	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,one hand,face	240 cm ²
Other given operational conditions affecting workers exposure	Indoor,Assumes activities are at room temperature,Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
Risk Management Measures		
	Containment	No

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Technical conditions and measures at process level (source) to prevent release	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear safety glasses with side shields.	
	Conditions and measures related to personal protection, hygiene and health evaluation Wear suitable gloves tested to EN374	80 % Effectiveness Dermal

2.2.1 Contributing scenario controlling environmental exposure (ERC2)

Formulation (COLIPA 1) (ERC 2)		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe SPERC 2.1.a.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	16.7 t/d
	Amounts used	<= 100 t/yr
	Annual site tonnage	
Frequency and duration of use		250 days/yr
Environmental factors not influenced by risk management		
Other given operational conditions affecting environmental exposure	Indoor use	Product applied in aqueous process solution with negligible volatilization
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Process optimized for highly efficient use of raw materials	
	Technical conditions and measures at process level (source) to prevent release Equipment cleaning with minimized emissions to wastewater	Typically implemented measures for reducing emissions to waste water may include: - Dry cleaning of equipment (Use of absorbent materials and vacuum cleaning including incineration of resulting solid waste) - Cleaning involving so-called pigs - Cleaning involving so-called "cleaning in place" (CIP System) - Steam cleaning and/or - Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.) - use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste).
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant	8 m³/d

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	Assumed effluent discharge flow from site	
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

2.2.2 Contributing scenario controlling environmental exposure (ERC2)

COLIPA 2		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe SPERC 2.1.b.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	4.5 t/d
	Amounts used	≤ 100 t/yr
	Annual amount per site	
Frequency and duration of use	250 days/yr	
Other given operational conditions affecting environmental exposure	Indoor use	Product applied in aqueous process solution with negligible volatilization
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Process with 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.
	Technical conditions and measures at process level (source) to prevent release Equipment cleaning with reduced emissions to wastewater	Typically implemented measures for reducing emissions to waste water may include: - Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.) - use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste).
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes

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Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	
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2.2.3 Contributing scenario controlling environmental exposure (ERC2)

COLIPA 3		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe SPERC 2.1.c.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	≤ 0.45 t/d
	Amounts used	≤ 100 t/yr
	Annual site tonnage	
Frequency and duration of use	Emission days	250 days/yr
Other given operational conditions affecting environmental exposure	Indoor use	Product applied in aqueous process solution with negligible volatilization
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Equipment cleaning	Equipment cleaned with water, washing disposed of with wastewater. Worst case assumption for solvent-borne products
	Technical conditions and measures at process level (source) to prevent release Process with efficient use of raw materials	Typically implemented measures for reducing emissions to waste water may include: Use in closed batch process (synthesis or formulation)
Conditions and measures related to sewage treatment plant	Refer to CS 1.	

2.2.4 Contributing scenario controlling environmental exposure (ERC2)

Formulation (COLIPA 6)		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe SPERC 2.1.f.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	≤ 3 t/d
	Amounts used	≤ 100 t/yr
	Annual site tonnage	
Frequency and duration of use		250 days/yr
Other given operational conditions affecting environmental exposure	Indoor use	Product applied in aqueous process solution with negligible volatilization
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Equipment cleaning with reduced emissions to wastewater	Typically implemented measures for reducing emissions to waste water may

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		include: - Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.) - use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste).
	Technical conditions and measures at process level (source) to prevent release 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 Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

2.2.5 Contributing scenario controlling environmental exposure (ERC2)

Formulation (COLIPA 7)		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe SPERC 2.1.g.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	< 0.45 t/d
	Amounts used	< 100 t/yr
	Annual site tonnage	
Frequency and duration of use	250 days/yr	
Other given operational conditions affecting environmental exposure	Indoor use	Product applied in aqueous process solution with negligible volatilization
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Process with efficient use of raw materials	
	Technical conditions and measures at process level (source) to prevent release Equipment cleaned with water, washing disposed of with wastewater. Worst case assumption for solvent-borne products	

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Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 % Effectiveness Water:
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

2.2.6 Contributing scenario controlling environmental exposure (ERC2)

Formulation (COLIPA 8)		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe SPERC 2.1.h.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	< 3 t/d
	Amounts used	≤ 100 t/yr
	Annual site tonnage	
Frequency and duration of use		250 days/yr
Other given operational conditions affecting environmental exposure	Indoor use	Product applied in aqueous process solution with negligible volatilization
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Equipment cleaning with minimized emissions to wastewater	Typically implemented measures for reducing emissions to waste water may include: - Dry cleaning of equipment (Use of absorbent materials and vacuum cleaning including incineration of resulting solid waste) - Cleaning involving so-called pigs - Cleaning involving so-called "cleaning in place" (CIP System) - Steam cleaning and/or - Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.) - use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste).
	Technical conditions and measures at process level (source) to prevent release Process optimized for highly efficient use of raw materials	Typical measures may include e.g. - Closed automated process and/or - Closed transfer system and/or - Centralized process control and/or - re-use of process grey water for cleaning - optimized and/or automated systems for the transport and handling of raw materials, that minimize overall exposure levels and incidental spills - Reduced number of transfer and cleaning operations through e.g. - Manufacturing of different products from one

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		premix (masterbatch), to which certain ingredients are added to yield the final products. - Dedicated storage tanks for raw materials, premixes and final products Recovery of materials through e.g. - Recycling Residues of granular detergents in cleaning steps at packaging or transfer lines into the slurries.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Provide onsite wastewater treatment.	Oil-Water Separation
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 %
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes

2.2.7 Contributing scenario controlling environmental exposure (ERC2)

Formulation (COLIPA 9)		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe SPERC 2.1.i.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	≤ 1.5 t/d
	Amounts used	≤ 100 t/yr
	Annual site tonnage	
Frequency and duration of use	250 days/yr	
Other given operational conditions affecting environmental exposure	Indoor use, Product applied in aqueous process solution with negligible volatilization	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Equipment cleaning with reduced emissions to wastewater	Typically implemented measures for reducing emissions to waste water may include: - Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.) - use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste).
	Technical conditions and measures at process level (source) to prevent release 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

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		through e.g. - Dedicated storage tanks for raw materials, premixes and final products.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Provide onsite wastewater treatment.	Oil-Water Separation
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes

2.2.8 Contributing scenario controlling environmental exposure (ERC2)

Formulation (COLIPA 10)		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe SPERC 2.1.j.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	< 0.45 t/d
	Amounts used	<= 100 t/yr
	Annual site tonnage	
Frequency and duration of use	Emission days	250 days/yr
Other given operational conditions affecting environmental exposure	Indoor use	Product applied in aqueous process solution with negligible volatilization
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Equipment cleaned with water, washing disposed of with wastewater. Worst case assumption for solvent-borne products	
	Technical conditions and measures at process level (source) to prevent release Process with efficient use of raw materials	Typically implemented measures for reducing emissions to waste water may include: Use in closed batch process (synthesis or formulation)
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Provide onsite wastewater treatment.	Oil-Water Separation
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

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2.2.9 Contributing scenario controlling environmental exposure (ERC2)

Formulation (COLIPA 14)		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe / AISE SPERC 2.3.a.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	≤ 16.7 t/d
	Amounts used	≤ 100 t/yr
	Annual site tonnage	
Frequency and duration of use	Emission days	250 days/yr
Other given operational conditions affecting environmental exposure	Indoor use, Product applied in aqueous process solution with negligible volatilization	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Equipment cleaning with minimized emissions to wastewater	Typically implemented measures for reducing emissions to waste water may include: - Dry cleaning of equipment (Use of absorbent materials and vacuum cleaning including incineration of resulting solid waste) - Cleaning involving so-called pigs - Cleaning involving so-called "cleaning in place" (CIP System) - Steam cleaning and/or - Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.) - use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste).
	Technical conditions and measures at process level (source) to prevent release Process optimized for highly efficient use of raw materials	Typical measures may include e.g. - Closed automated process and/or - Closed transfer system and/or - Centralized process control and/or - re-use of process grey water for cleaning - optimized and/or automated systems for the transport and handling of raw materials, that minimize overall exposure levels and incidental spills - Reduced number of transfer and cleaning operations through e.g. - Manufacturing of different products from one premix (masterbatch), to which certain ingredients are added to yield the final products. - Dedicated storage tanks for raw materials, premixes and final products Recovery of

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		materials through e.g. - Recycling Residues of granular detergents in cleaning steps at packaging or transfer lines into the slurries.
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m³/d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

2.2.10 Contributing scenario controlling environmental exposure (ERC2)

Formulation (COLIPA 15)		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe / AISE SPERC 2.3.b.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	≤ 4.5 t/d
	Amounts used	≤ 100 t/yr
	Annual site tonnage	
Frequency and duration of use	Emission days	250 days/yr
Other given operational conditions affecting environmental exposure	Indoor use, Product applied in aqueous process solution with negligible volatilization	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Equipment cleaning with reduced emissions to wastewater	Typically implemented measures for reducing emissions to waste water may include: - Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.) - use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste).
	Technical conditions and measures at process level (source) to prevent release 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.

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Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No specific measures identified	

2.2.11 Contributing scenario controlling environmental exposure (ERC2)

Formulation (COLIPA 16)		
ERC2	Formulation into mixture	
Assessment method	Cosmetics Europe / AISE SPERC 2.3.c.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	≤ 0.45 t/d
	Amounts used	≤ 100 t/yr
	Annual site tonnage	
Frequency and duration of use	Emission days	250 days/yr
Other given operational conditions affecting environmental exposure	Indoor use, Product applied in aqueous process solution with negligible volatilization	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Equipment cleaned with water, washing disposed of with wastewater. Worst case assumption for solvent-borne products	
	Technical conditions and measures at process level (source) to prevent release 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 Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

3. Exposure estimation and reference to its source

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3.1. Health

Long-term - systemic effects						
DNEL	Inhalation: 43.75 mg/m ³ Dermal: 12.5 mg/kg bodyweight/day					
Contributing Scenario	inhalation exposure	RCR	dermal exposure	RCR	Sum RCR	Assessment method
PROC1 (General exposures (closed systems))	0.01 mg/m ³	0	0.007 mg/kg bw/day	0.001	0.001	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC2 (General exposures (closed systems))	1 mg/m ³	0.023	0.274 mg/kg bw/day	0.022	0.045	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC3	1 mg/m ³	0.023	0.138 mg/m ³	0.011	0.034	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC4	17.5 mg/m ³	0.4	1.372 mg/kg bw/day	0.11	0.51	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC5	25 mg/m ³	0.571	2.742 mg/kg bw/day	0.219	0.79	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC8a	15 mg/m ³	0.343	2.742 mg/kg bw/day	0.219	0.562	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC8b	25 mg/m ³	0.571	2.742 mg/kg bw/day	0.219	0.79	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC9	20 mg/m ³	0.457	1.372 mg/kg bw/day	0.11	0.567	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC13	5 mg/m ³	0.114	2.742 mg/kg bw/day	0.219	0.333	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC14	35 mg/m ³	0.8	0.686 mg/kg bw/day	0.055	0.855	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC15	5 mg/m ³	0.114	0.068 mg/kg bw/day	0.005	0.119	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3

3.2. Environment

2.2.1					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.107	1	0.107	Cosmetics Europe SPERC 2.1.a.v2
Marine water	mg/l	0.011	0.1	0.11	Cosmetics Europe SPERC 2.1.a.v2
Secondary Poisoning	mg/kg bw/day	< 0.003		< 0.01	Cosmetics Europe SPERC 2.1.a.v2
Freshwater sediment	mg/kg dwt	0.548	1.1085	0.494	Cosmetics Europe SPERC 2.1.a.v2
Marine water sediment	mg/kg dwt	0.055	0.1109	0.496	Cosmetics Europe SPERC 2.1.a.v2
Sewage treatment plant	mg/l	1.056	423.5	0.002	Cosmetics Europe SPERC 2.1.a.v2
Soil	mg/kg dwt	0.04	0.33	0.121	Cosmetics Europe SPERC 2.1.a.v2

2.2.2					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.059	1	0.059	Cosmetics Europe SPERC 2.1.b.v2
Marine water	mg/l	0.006	0.1	0.06	Cosmetics Europe SPERC 2.1.b.v2

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Secondary Poisoning				< 0.01	Cosmetics Europe SPERC 2.1.b.v2
Freshwater sediment	mg/kg dwt	0.299	1.1085	0.27	Cosmetics Europe SPERC 2.1.b.v2
Marine water sediment	mg/kg dwt	0.03	0.1109	0.271	Cosmetics Europe SPERC 2.1.b.v2
Sewage treatment plant	mg/l	0.569	423.5	0.001	Cosmetics Europe SPERC 2.1.b.v2
Soil	mg/kg dwt	0.024	0.33	0.073	Cosmetics Europe SPERC 2.1.b.v2

2.2.3					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.013	1	0.013	Cosmetics Europe SPERC 2.1.c.v2
Marine water	mg/l	0.001	0.1	0.01	Cosmetics Europe SPERC 2.1.c.v2
Secondary Poisoning	mg/kg bw/day	< 0.001		< 0.01	Cosmetics Europe SPERC 2.1.c.v2
Freshwater sediment	mg/kg dwt	0.067	1.1085	0.06	Cosmetics Europe SPERC 2.1.c.v2
Marine water sediment	mg/kg dwt	0.007	0.1109	0.063	Cosmetics Europe SPERC 2.1.c.v2
Sewage treatment plant	mg/l	0.114	423.5	0	Cosmetics Europe SPERC 2.1.c.v2
Soil	mg/kg dwt	0.009	0.33	0.027	Cosmetics Europe SPERC 2.1.c.v2

2.2.4					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.191	1	0.191	Cosmetics Europe SPERC 2.1.f.v2
Marine water	mg/l	0.019	0.1	0.19	Cosmetics Europe SPERC 2.1.f.v2
Secondary Poisoning				< 0.01	Cosmetics Europe SPERC 2.1.f.v2
Freshwater sediment	mg/kg dwt	0.976	1.1085	0.88	Cosmetics Europe SPERC 2.1.f.v2
Marine water sediment	mg/kg dwt	0.098	0.1109	0.884	Cosmetics Europe SPERC 2.1.f.v2
Sewage treatment plant	mg/l	1.896	423.5	0.004	Cosmetics Europe SPERC 2.1.f.v2
Soil	mg/kg dwt	0.067	0.33	0.203	Cosmetics Europe SPERC 2.1.f.v2

2.2.5					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Marine water	mg/l	0.006	0.1	0.06	Cosmetics Europe SPERC 2.1.g.v2
Secondary Poisoning				< 0.01	Cosmetics Europe SPERC 2.1.g.v2
Freshwater sediment	mg/kg dwt	0.299	1.1085	0.27	Cosmetics Europe SPERC 2.1.g.v2
Marine water sediment	mg/kg dwt	0.03	0.1109	0.271	Cosmetics Europe SPERC 2.1.g.v2
Sewage treatment plant	mg/l	0.569	423.5	0.001	Cosmetics Europe SPERC 2.1.g.v2
Soil	mg/kg dwt	0.024	0.33	0.073	Cosmetics Europe SPERC 2.1.g.v2

2.2.6					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.191	1	0.191	Cosmetics Europe SPERC 2.1.h.v2
Marine water	mg/l	0.019	0.1	0.19	Cosmetics Europe SPERC 2.1.h.v2
Secondary Poisoning				< 0.01	Cosmetics Europe SPERC 2.1.h.v2
Freshwater sediment	mg/kg dwt	0.976	1.1085	0.88	Cosmetics Europe SPERC 2.1.h.v2
Marine water sediment	mg/kg dwt	0.098	0.1109	0.884	Cosmetics Europe SPERC 2.1.h.v2
Sewage treatment plant	mg/l	1.896	423.5	0.004	Cosmetics Europe SPERC 2.1.h.v2
Soil	mg/kg dwt	0.067	0.33	0.203	Cosmetics Europe SPERC 2.1.h.v2

2.2.7					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.191	1	0.191	Cosmetics Europe SPERC 2.1.i.v2

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Marine water	mg/l	0.019	0.1	0.19	Cosmetics Europe SPERC 2.1.i.v2
Secondary Poisoning				< 0.01	Cosmetics Europe SPERC 2.1.i.v2
Freshwater sediment	mg/kg dwt	0.976	1.1085	0.88	Cosmetics Europe SPERC 2.1.i.v2
Marine water sediment	mg/kg dwt	0.098	0.1109	0.884	Cosmetics Europe SPERC 2.1.i.v2
Sewage treatment plant	mg/l	1.896	423.5	0.004	Cosmetics Europe SPERC 2.1.i.v2
Soil	mg/kg dwt	0.067	0.33	0.203	Cosmetics Europe SPERC 2.1.i.v2

2.2.8					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.116	1	0.116	Cosmetics Europe SPERC 2.1.j.v2
Marine water	mg/l	0.012	0.1	0.12	Cosmetics Europe SPERC 2.1.j.v2
Secondary Poisoning				< 0.01	
Freshwater sediment	mg/kg dwt	0.59	1.1085	0.532	Cosmetics Europe SPERC 2.1.j.v2
Marine water sediment	mg/kg dwt	0.059	0.1109	0.532	Cosmetics Europe SPERC 2.1.j.v2
Sewage treatment plant	mg/l	1.138	423.5	0.003	Cosmetics Europe SPERC 2.1.j.v2
Soil	mg/kg dwt	0.042	0.33	0.127	Cosmetics Europe SPERC 2.1.j.v2

2.2.9					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.055	1	0.055	Cosmetics Europe / AISE SPERC 2.3.a.v2
Marine water	mg/l	0.005	0.1	0.05	Cosmetics Europe / AISE SPERC 2.3.a.v2
Secondary Poisoning				< 0.01	Cosmetics Europe / AISE SPERC 2.3.a.v2
Freshwater sediment	mg/kg dwt	0.278	1.1085	0.251	Cosmetics Europe / AISE SPERC 2.3.a.v2
Marine water sediment	mg/kg dwt	0.028	0.1109	0.252	Cosmetics Europe / AISE SPERC 2.3.a.v2
Soil	mg/kg dwt	0.022	0.33	0.067	Cosmetics Europe / AISE SPERC 2.3.a.v2

2.2.10					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.03	1	0.03	Cosmetics Europe / AISE SPERC 2.3.b.v2
Marine water	mg/l	0.003	0.1	0.03	Cosmetics Europe / AISE SPERC 2.3.b.v2
Secondary Poisoning				< 0.01	Cosmetics Europe / AISE SPERC 2.3.b.v2
Freshwater sediment	mg/kg dwt	0.154	1.1085	0.139	Cosmetics Europe / AISE SPERC 2.3.b.v2
Marine water sediment	mg/kg dwt	0.015	0.1109	0.135	Cosmetics Europe / AISE SPERC 2.3.b.v2
Sewage treatment plant	mg/l	0.284	423.5	0.001	Cosmetics Europe / AISE SPERC 2.3.b.v2
Soil	mg/kg dwt	0.015	0.33	0.045	Cosmetics Europe / AISE SPERC 2.3.b.v2

2.2.11					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method

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Freshwater	mg/l	0.007	1	0.007	Cosmetics Europe / AISE SPERC 2.3.c.v2
Marine water	mg/l	0.0007	0.1	0.007	Cosmetics Europe / AISE SPERC 2.3.c.v2
Secondary Poisoning				< 0.01	Cosmetics Europe / AISE SPERC 2.3.c.v2
Freshwater sediment	mg/kg dwt	0.038	1.1085	0.034	Cosmetics Europe / AISE SPERC 2.3.c.v2
Marine water sediment	mg/kg dwt	0.004	0.1109	0.036	Cosmetics Europe / AISE SPERC 2.3.c.v2
Sewage treatment plant	mg/l	0.057	423.5	0	Cosmetics Europe / AISE SPERC 2.3.c.v2
Soil	mg/kg dwt	0.007	0.33	0.021	Cosmetics Europe / AISE SPERC 2.3.c.v2

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the ES

4.1. Health

Guidance - Health	Risk characterization related to combined exposure: Simultaneous exposure from combined uses at one site was excluded. Thus, assessment of combined emissions from different exposure scenarios was considered not applicable. Conclusion on risk characterisation: The substance is of no immediate concern.
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4.2. Environment

Guidance - Environment	Risk characterization related to combined exposure: Simultaneous exposure from combined uses at one site was excluded. Thus, assessment of combined emissions from different exposure scenarios was considered not applicable. Conclusion on risk characterisation: The substance is of no immediate concern.
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1. Exposure scenario ES7

Use by professional worker (cosmetics)	ES Ref.: ES7 ES Type: Environment - Worker Version: 1.0	Company ES code: ES7 Date of issue: 22/10/2018
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Use descriptors	PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC13, PROC14, PROC15 ERC8a
Processes, tasks, activities covered	Widespread use by professional workers Professional use
Assessment method	Cosmetics Europe SPERC 8a.1.a.v2 Cosmetics Europe SPERC 8a.1.b.v2 Cosmetics Europe SPERC 8a.1.c.v2 ECETOC TRA worker v3

2. Operational conditions and risk management measures

2.2.1 Contributing scenario controlling environmental exposure (ERC8a)

Use by professional worker (COLIPA 17)		
ERC8a	Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)	
Assessment method	Cosmetics Europe SPERC 8a.1.a.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	≤ 0.00055 t/d
Other given operational conditions affecting environmental exposure	Indoor use, Product applied in aqueous process solution with negligible volatilization	
Risk Management Measures		
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No specific measures identified	

2.2.2 Contributing scenario controlling environmental exposure (ERC8a)

Use by professional worker (COLIPA 18)		
ERC8a	Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	

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Operational conditions		
Amounts used	Reference previous Contributing Scenario	
Other given operational conditions affecting environmental exposure	Spray application with complete evaporation of volatiles	
	Other given operational conditions affecting environmental exposure Indoor use	
Risk Management Measures		
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	100 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

2.2.3 Contributing scenario controlling environmental exposure (ERC8a)

Use by professional worker (COLIPA 19)		
ERC8a	Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)	
Assessment method	Cosmetics Europe SPERC 8a.1.c.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Reference previous Contributing Scenario	
Other given operational conditions affecting environmental exposure	Indoor use	
	Other given operational conditions affecting environmental exposure Spraying of involatile solids, which finally are disposed off via wastewater.	
Risk Management Measures		
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

2.1.1 Contributing scenario controlling worker exposure (PROC1)

Worker contributing scenario (PROC 1)		
PROC1	Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions	

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Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Exposure duration	< 8 h/day
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,one hand,face	240 cm ²
Other given operational conditions affecting workers exposure	Indoor,Assumes activities are at room temperature,Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Handle substance within a closed system	
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes an effective Occupational Health and Safety management System.	
Conditions and measures related to personal protection, hygiene and health evaluation	Wear safety glasses with side shields.	
	Conditions and measures related to personal protection, hygiene and health evaluation Wear suitable gloves tested to EN374	80 % Effectiveness Dermal

2.1.2 Contributing scenario controlling worker exposure (PROC2)

Worker contributing scenario (PROC 2)		
PROC2	Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Reference previous Contributing Scenario	
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands,face	480 cm ²
Other given operational conditions affecting workers exposure	Reference previous Contributing Scenario	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Use in closed, continuous process with occasional controlled exposure	
Organisational measures to prevent /limit releases, dispersion and exposure	Reference previous Contributing Scenario	
Conditions and measures related to personal protection, hygiene and health evaluation	Reference previous Contributing Scenario	

2.1.3 Contributing scenario controlling worker exposure (PROC3)

Worker contributing scenario (PROC 3)		
PROC3	Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Reference previous Contributing Scenario	
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,one hand,face	240 cm ²
Other given operational conditions affecting workers exposure	Reference previous Contributing Scenario	

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Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Use in closed batch process (synthesis or formulation). With occasional controlled exposure	
Organisational measures to prevent /limit releases, dispersion and exposure	Reference previous Contributing Scenario	
Conditions and measures related to personal protection, hygiene and health evaluation	Reference previous Contributing Scenario	

2.1.4 Contributing scenario controlling worker exposure (PROC4)

Worker contributing scenario (PROC 4)		
PROC4	Chemical production where opportunity for exposure arises	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Reference previous Contributing Scenario	
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands,face	480 cm ²
Other given operational conditions affecting workers exposure	Assumes activities are at room temperature,Indoor	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour)	
	Technical conditions and measures at process level (source) to prevent release Semi-closed system. With occasional controlled exposure	
Organisational measures to prevent /limit releases, dispersion and exposure	Reference previous Contributing Scenario	
Conditions and measures related to personal protection, hygiene and health evaluation	Reference previous Contributing Scenario	

2.1.5 Contributing scenario controlling worker exposure (PROC5)

Worker contributing scenario (PROC 5)		
PROC5	Mixing or blending in batch processes	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Reference previous Contributing Scenario	
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands,face	480 cm ²
Other given operational conditions affecting workers exposure	Assumes activities are at room temperature,Indoor	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Provide a good standard of controlled ventilation (5 to 10 air changes per hour)	
	Technical conditions and measures at process level (source) to prevent release Containment	No
	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No

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Organisational measures to prevent /limit releases, dispersion and exposure	Reference previous Contributing Scenario	
Conditions and measures related to personal protection, hygiene and health evaluation	Reference previous Contributing Scenario	

2.1.6 Contributing scenario controlling worker exposure (PROC8a)

Worker contributing scenario (PROC 8a)		
PROC8a	Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Reference previous Contributing Scenario	
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands	960 cm ²
Other given operational conditions affecting workers exposure	Reference previous Contributing Scenario	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Reference previous Contributing Scenario	
Organisational measures to prevent /limit releases, dispersion and exposure	Reference previous Contributing Scenario	
Conditions and measures related to personal protection, hygiene and health evaluation	Reference previous Contributing Scenario	

2.1.7 Contributing scenario controlling worker exposure (PROC8b)

Worker contributing scenario (PROC 8b)		
PROC8b	Transfer of substance or mixture (charging and discharging) at dedicated facilities	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Reference previous Contributing Scenario	
Human factors not influenced by risk management	Reference previous Contributing Scenario	
Other given operational conditions affecting workers exposure	Reference previous Contributing Scenario	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Provide a good standard of controlled ventilation (5 to 10 air changes per hour) Technical conditions and measures at process level (source) to prevent release Semi-closed system. With occasional controlled exposure. Provide a good standard of controlled ventilation (5 to 10 air changes per hour)	
Organisational measures to prevent /limit releases, dispersion and exposure	Reference previous Contributing Scenario	
Conditions and measures related to personal protection, hygiene and health evaluation	Reference previous Contributing Scenario	

2.1.8 Contributing scenario controlling worker exposure (PROC9)

Worker contributing scenario (PROC 9)		
PROC9	Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	
Product characteristics		
Dustiness	Solid, high dustiness	

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Operational conditions		
Frequency and duration of use	Reference previous Contributing Scenario	
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,Both hands,face	480 cm ²
Other given operational conditions affecting workers exposure	Assumes activities are at room temperature,Indoor	
	Other given operational conditions affecting workers exposure Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Semi-closed system. With occasional controlled exposure	
Organisational measures to prevent /limit releases, dispersion and exposure	Reference previous Contributing Scenario	
Conditions and measures related to personal protection, hygiene and health evaluation	Reference previous Contributing Scenario	

2.1.9 Contributing scenario controlling worker exposure (PROC13)

Worker contributing scenario (PROC 13)		
PROC13	Treatment of articles by dipping and pouring	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Reference previous Contributing Scenario	
Human factors not influenced by risk management	Reference previous Contributing Scenario	
Other given operational conditions affecting workers exposure	Assumes activities are at room temperature,Indoor	
	Other given operational conditions affecting workers exposure Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Containment	No
	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No
Organisational measures to prevent /limit releases, dispersion and exposure	Reference previous Contributing Scenario	
Conditions and measures related to personal protection, hygiene and health evaluation	Reference previous Contributing Scenario	

2.1.10 Contributing scenario controlling worker exposure

Worker contributing scenario (PROC 14)		
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Reference previous Contributing Scenario	
Human factors not influenced by risk management	Reference previous Contributing Scenario	
Other given operational conditions affecting workers exposure	Assumes activities are at room temperature,Indoor	
Risk Management Measures		

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Technical conditions and measures at process level (source) to prevent release	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour)	
	Technical conditions and measures at process level (source) to prevent release Containment	No
	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No
Organisational measures to prevent /limit releases, dispersion and exposure	Reference previous Contributing Scenario	
Conditions and measures related to personal protection, hygiene and health evaluation	Reference previous Contributing Scenario	

2.1.11 Contributing scenario controlling worker exposure (PROC15)

Worker contributing scenario (PROC 15)		
PROC15	Use as laboratory reagent	
Product characteristics		
Dustiness	Solid, high dustiness	
Operational conditions		
Frequency and duration of use	Reference previous Contributing Scenario	
Human factors not influenced by risk management	Area of skin contact with the substance under conditions of use: ,one hand,face	240 cm ²
Other given operational conditions affecting workers exposure	Assumes activities are at room temperature,Indoor	
	Other given operational conditions affecting workers exposure Provide a basic standard of general ventilation (1 to 3 air changes per hour).	
Risk Management Measures		
Technical conditions and measures at process level (source) to prevent release	Containment	No
	Technical conditions and measures at process level (source) to prevent release Local exhaust ventilation	No
Organisational measures to prevent /limit releases, dispersion and exposure	Reference previous Contributing Scenario	
Conditions and measures related to personal protection, hygiene and health evaluation	Reference previous Contributing Scenario	

3. Exposure estimation and reference to its source

3.1. Health

Long-term - systemic effects						
DNEL	Inhalation: 43.75 mg/m ³ Dermal: 12.5 mg/kg bodyweight/day					
Contributing Scenario	inhalation exposure	RCR	dermal exposure	RCR	Sum RCR	Assessment method
PROC1	0.1 mg/m ³	0.002	0.007 mg/kg bw/day	0.001	0.003	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC2	5 mg/m ³	0.114	0.274 mg/kg bw/day	0.022	0.136	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC3	5 mg/m ³	0.114	0.138 mg/kg bw/day	0.011	0.125	Inhalation: ECETOC TRA worker v3

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						Dermal: ECETOC TRA worker v3
PROC4	35 mg/m ³	0.8	1.372 mg/kg bw/day	0.11	0.91	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC5	15 mg/m ³	0.343	2.742 mg/kg bw/day	0.219	0.562	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC8a	15 mg/m ³	0.343	2.742 mg/kg bw/day	0.219	0.562	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC8b	15 mg/m ³	0.343	2.742 mg/kg bw/day	0.219	0.562	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC9	20 mg/m ³	0.457	1.372 mg/kg bw/day	0.11	0.567	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC13	5 mg/m ³	0.114	2.742 mg/kg bw/day	0.219	0.333	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
	35 mg/m ³	0.8	0.686 mg/kg bw/day	0.055	0.855	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3
PROC15	5 mg/m ³	0.114	0.068 mg/kg bw/day	0.005	0.119	Inhalation: ECETOC TRA worker v3 Dermal: ECETOC TRA worker v3

3.2. Environment

2.2.1						
Environmental exposure	Unit	Exposure estimation	PNEC	RCR		Assessment method
Freshwater	mg/l	0.005	1	0.005		Cosmetics Europe SPERC 8a.1.a.v2
Marine water	mg/l	0.0005	0.1	0.005		Cosmetics Europe SPERC 8a.1.a.v2
Secondary Poisoning				< 0.01		Cosmetics Europe SPERC 8a.1.a.v2
Freshwater sediment	mg/kg dwt	0.027	1.1085	0.024		Cosmetics Europe SPERC 8a.1.a.v2
Marine water sediment	mg/kg dwt	0.003	0.1109	0.027		Cosmetics Europe SPERC 8a.1.a.v2
Sewage treatment plant	mg/l	0.035	423.5	0		Cosmetics Europe SPERC 8a.1.a.v2
Soil	mg/kg dwt	0.006	0.33	0.018		Cosmetics Europe SPERC 8a.1.a.v2

2.2.2						
Environmental exposure	Unit	Exposure estimation	PNEC	RCR		Assessment method
Freshwater	mg/l	0.012	1	0.012		Cosmetics Europe SPERC 8a.1.b.v2
Marine water	mg/l	0.00017	0.1	0.002		
Secondary Poisoning				< 0.01		Cosmetics Europe SPERC 8a.1.b.v2
Freshwater sediment	mg/kg dwt	0.009	1.1085	0.008		Cosmetics Europe SPERC 8a.1.b.v2
Marine water sediment	mg/kg dwt	0.0008951	0.1109	0.008		Cosmetics Europe SPERC 8a.1.b.v2
Sewage treatment plant	mg/l	0	423.5	0		Cosmetics Europe SPERC 8a.1.b.v2
Soil	mg/kg dwt	0.005	0.33	0.015		Cosmetics Europe SPERC 8a.1.b.v2

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2.2.3					
Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.005	1	0.005	Cosmetics Europe SPERC 8a.1.c.v2
Marine water	mg/l	0.0005	0.1	0.005	Cosmetics Europe SPERC 8a.1.c.v2
Secondary Poisoning				< 0.01	Cosmetics Europe SPERC 8a.1.c.v2
Freshwater sediment	mg/kg dwt	0.027	1.1085	0.024	Cosmetics Europe SPERC 8a.1.c.v2
Marine water sediment	mg/kg dwt	0.003	0.1109	0.027	Cosmetics Europe SPERC 8a.1.c.v2
Soil	mg/kg dwt	0.006	0.33	0.018	Cosmetics Europe SPERC 8a.1.c.v2

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the ES

4.1. Health

Guidance - Health	Risk characterization related to combined exposure: Simultaneous exposure from combined uses at one site was excluded. Thus, assessment of combined emissions from different exposure scenarios was considered not applicable. Conclusion on risk characterisation: The substance is of no immediate concern.
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4.2. Environment

Guidance - Environment	Risk characterization related to combined exposure: Simultaneous exposure from combined uses at one site was excluded. Thus, assessment of combined emissions from different exposure scenarios was considered not applicable. Conclusion on risk characterisation: The substance is of no immediate concern.
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1. Exposure scenario ES8

Use by consumers (cosmetics)	ES Ref.: ES8 ES Type: Consumer Version: 1.0	Company ES code: ES8 Date of issue: 23/10/2018
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Use descriptors	PC39 ERC8a
Processes, tasks, activities covered	Consumer use
Assessment method	Cosmetics Europe SPERC 8a.1.a.v2 Cosmetics Europe SPERC 8a.1.b.v2 Cosmetics Europe SPERC 8a.1.c.v2

2. Operational conditions and risk management measures

2.2.1 Contributing scenario controlling environmental exposure (ERC8a)

Use by consumers (COLIPA 17)		
ERC8a	Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)	
Assessment method	Cosmetics Europe SPERC 8a.1.a.v2 Cosmetics Europe SPERC 8a.1.b.v2 Cosmetics Europe SPERC 8a.1.c.v2	
Product characteristics		
Physical form of product	Solid	
Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Daily amount per site	≤ 0.00055 t/d
Other given operational conditions affecting environmental exposure	Product applied in aqueous process solution with negligible volatilization	
	Other given operational conditions affecting environmental exposure Indoor use	
Risk Management Measures		
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

2.2.2 Contributing scenario controlling environmental exposure (ERC8a)

Use by consumers (COLIPA 18)		
ERC8a	Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)	
Assessment method	Cosmetics Europe SPERC 8a.1.b.v2	
Product characteristics		
Physical form of product	Solid	

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Concentration of substance in product	≈ 100 %	
Vapour pressure	0.00045 Pa	
Operational conditions		
Amounts used	Reference previous Contributing Scenario	
Other given operational conditions affecting environmental exposure	Indoor use	
	Other given operational conditions affecting environmental exposure Spray application with complete evaporation of volatiles	
Risk Management Measures		
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	100 % Effectiveness Water:
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

2.2.3 Contributing scenario controlling environmental exposure (ERC8a)

Use by consumers (COLIPA 19)		
ERC8a	Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)	
Assessment method	Cosmetics Europe SPERC 8a.1.c.v2	
Product characteristics		
No additional information		
Operational conditions		
Amounts used	Reference previous Contributing Scenario	
Other given operational conditions affecting environmental exposure	Spraying of involatile solids, which finally are disposed off via wastewater.	
	Other given operational conditions affecting environmental exposure Indoor use	
Risk Management Measures		
Conditions and measures related to sewage treatment plant	Municipal Sewage Treatment Plant	87.36 %
	Conditions and measures related to sewage treatment plant Assumed effluent discharge flow from site	8 m ³ /d
	Conditions and measures related to sewage treatment plant Controlled application of sewage sludge to agricultural soil	Yes
Conditions and measures related to external treatment of waste for disposal	No other specific measures identified	

2.1 Contributing scenario consumer end-use (PC39)

Consumer contributing scenario (PC 39)		
PC39	Cosmetics, personal care products	
Product characteristics		
No additional information		

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Operational conditions		
Other given operational conditions affecting consumers exposure	In accordance to the Article 14 (5b) of the REACH Regulation (EC) No 1907/2006, exposure estimation and risk characterisation for human health does not need to be performed for end uses in cosmetic products within the scope of Directive 76/768/EEC	
Risk Management Measures		
No additional information		

3. Exposure estimation and reference to its source

3.1. Health

In accordance to the Article 14 (5b) of the REACH Regulation (EC) No 1907/2006, exposure estimation and risk characterisation for human health does not need to be performed for end uses in cosmetic products within the scope of Directive 76/768/EEC

3.2. Environment

2.2.1	Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.005	1	0.005	Cosmetics Europe SPERC 8a.1.a.v2	
Marine water	mg/l	0.0005	0.1	0.005	Cosmetics Europe SPERC 8a.1.a.v2	
Secondary Poisoning				< 0.01	Cosmetics Europe SPERC 8a.1.a.v2	
Freshwater sediment	mg/kg dwt	0.027	1.1085	0.024	Cosmetics Europe SPERC 8a.1.a.v2	
Marine water sediment	mg/kg dwt	0.003	0.1109	0.027	Cosmetics Europe SPERC 8a.1.a.v2	
Sewage treatment plant	mg/l	0.035	423.5	0	Cosmetics Europe SPERC 8a.1.a.v2	
Soil	mg/kg dwt	0.006	0.33	0.018	Cosmetics Europe SPERC 8a.1.a.v2	

2.2.2	Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method
Freshwater	mg/l	0.002	1	0.002	Cosmetics Europe SPERC 2.1.b.v2	
Marine water	mg/l	0.0001755	0.1	0.002	Cosmetics Europe SPERC 2.1.b.v2	
Secondary Poisoning				< 0.01	Cosmetics Europe SPERC 2.1.b.v2	
Freshwater sediment	mg/kg dwt	0.009	1.1085	0.008	Cosmetics Europe SPERC 2.1.b.v2	
Marine water sediment	mg/kg dwt	0.0008951	0.1109	0.008	Cosmetics Europe SPERC 2.1.b.v2	
Sewage treatment plant	mg/l	0	423.5	0	Cosmetics Europe SPERC 2.1.b.v2	
Soil	mg/kg dwt	0.005	0.33	0.015	Cosmetics Europe SPERC 2.1.b.v2	

2.2.3	Environmental exposure	Unit	Exposure estimation	PNEC	RCR	Assessment method

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Freshwater	mg/l	0.005	1	0.005	Cosmetics Europe SPERC 8a.1.c.v2
Marine water	mg/l	0.000523	0.1	0.005	Cosmetics Europe SPERC 8a.1.c.v2
Secondary Poisoning				< 0.01	Cosmetics Europe SPERC 8a.1.c.v2
Freshwater sediment	mg/kg dwt	0.027	1.1085	0.024	Cosmetics Europe SPERC 8a.1.c.v2
Marine water sediment	mg/kg dwt	0.003	0.1109	0.027	Cosmetics Europe SPERC 8a.1.c.v2
Sewage treatment plant	mg/l	0.035	423.5	0	Cosmetics Europe SPERC 8a.1.c.v2
Soil	mg/kg dwt	0.006	0.33	0.018	Cosmetics Europe SPERC 8a.1.c.v2

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the ES

4.1. Health

Guidance - Health	Conclusion on risk characterisation: The substance is of no immediate concern.
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4.2. Environment

Guidance - Environment	Risk characterization related to combined exposure: Simultaneous exposure from combined uses at one site was excluded. Thus, assessment of combined emissions from different exposure scenarios was considered not applicable. Conclusion on risk characterisation: The substance is of no immediate concern.
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