

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 13.01.2016

Version 10.0

## SECTION 1. Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Catalogue No.	106357
Product name	Sodium disulfite (sodium metabisulfite) suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,NF,E 223
REACH Registration Number	01-2119531326-45-XXXX
CAS-No.	7681-57-4

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

Identified uses	Pharmaceutical production, Cosmetic raw material In compliance with the conditions described in the annex to this safety data sheet.
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### 1.3 Details of the supplier of the safety data sheet

Company	Merck KGaA * 64271 Darmstadt * Germany * Phone:+49 6151 72-0
Responsible Department	EQ-RS * e-mail: prodsafe@merckgroup.com

1.4 Emergency telephone number	Please contact the regional company representation in your country.
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## SECTION 2. Hazards identification

### 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4, Oral, H302  
Serious eye damage, Category 1, H318

For the full text of the H-Statements mentioned in this Section, see Section 16.

Classification (67/548/EEC or 1999/45/EC)

Xn	Harmful	R31
Xi	Irritant	R22
		R41

For the full text of the R-phrases mentioned in this Section, see Section 16.

### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word  
Danger

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*Hazard statements*

H302 Harmful if swallowed.  
H318 Causes serious eye damage.  
EUH031 Contact with acids liberates toxic gas.

*Precautionary statements*

Prevention  
P280 Wear eye protection.  
Response  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P313 Get medical advice/ attention.

**Reduced labelling (≤125 ml)**

*Hazard pictograms*



*Signal word*  
Danger

*Hazard statements*  
H318 Causes serious eye damage.

*Precautionary statements*  
P280 Wear eye protection.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P313 Get medical advice/ attention.

*Index-No.* 016-063-00-2

**2.3 Other hazards**

None known.

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**SECTION 3. Composition/information on ingredients**

**3.1 Substance**

Formula Na2O5S2 (Hill)  
Index-No. 016-063-00-2  
EC-No. 231-673-0  
Molar mass 190,11 g/mol

**Hazardous components (REGULATION (EC) No 1272/2008)**

*Chemical Name (Concentration)*

CAS-No.	Registration number	Classification
sodium metabisulphite (<= 100 % )		

*Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.*

7681-57-4	01-2119531326-45-XXXX	Acute toxicity, Category 4, H302 Serious eye damage, Category 1, H318
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For the full text of the H-Statements mentioned in this Section, see Section 16.

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**Hazardous components (1999/45/EC)**

*Chemical Name (Concentration)*

CAS-No.	Classification
sodium metabisulphite (<= 100 % )	
7681-57-4	R31
	Xn, Harmful; R22
	Xi, Irritant; R41

For the full text of the R-phrases mentioned in this Section, see Section 16.

**3.2 Mixture**

Not applicable

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**SECTION 4. First aid measures**

**4.1 Description of first aid measures**

After inhalation: fresh air.

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/shower.

After eye contact: rinse out with plenty of water. Immediately call in ophthalmologist.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

**4.2 Most important symptoms and effects, both acute and delayed**

Irritation and corrosion

Risk of serious damage to eyes.

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

No information available.

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**SECTION 5. Firefighting measures**

**5.1 Extinguishing media**

*Suitable extinguishing media*

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

*Unsuitable extinguishing media*

For this substance/mixture no limitations of extinguishing agents are given.

**5.2 Special hazards arising from the substance or mixture**

Not combustible.

Ambient fire may liberate hazardous vapours.

Fire may cause evolution of:

Sulphur oxides

**5.3 Advice for firefighters**

*Special protective equipment for firefighters*

In the event of fire, wear self-contained breathing apparatus.

*Further information*

Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

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## SECTION 6. Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders:

Protective equipment see section 8.

### 6.2 Environmental precautions

Do not let product enter drains.

### 6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

### 6.4 Reference to other sections

Indications about waste treatment see section 13.

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## SECTION 7. Handling and storage

### 7.1 Precautions for safe handling

*Advice on safe handling*

Observe label precautions.

*Hygiene measures*

Change contaminated clothing. Preventive skin protection recommended. Wash hands after working with substance.

### 7.2 Conditions for safe storage, including any incompatibilities

*Storage conditions*

Tightly closed. Dry.

Recommended storage temperature see product label.

### 7.3 Specific end use(s)

See exposure scenario in the Annex to this MSDS.

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## SECTION 8. Exposure controls/personal protection

### 8.1 Control parameters

#### Derived No Effect Level (DNEL)

Worker DNEL, longterm	Systemic effects	inhalation	10 mg/m <sup>3</sup>
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#### Predicted No Effect Concentration (PNEC)

PNEC Fresh water	1 mg/l
PNEC Marine water	0,1 mg/l
PNEC Sewage treatment plant	75,4 mg/l

### 8.2 Exposure controls

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**Engineering measures**

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

**Individual protection measures**

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

*Eye/face protection*

Tightly fitting safety goggles

*Hand protection*

full contact:

Glove material:	Nitrile rubber
Glove thickness:	0,11 mm
Break through time:	> 480 min

splash contact:

Glove material:	Nitrile rubber
Glove thickness:	0,11 mm
Break through time:	> 480 min

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 741 Dermatril® L (full contact), KCL 741 Dermatril® L (splash contact).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

This recommendation applies only to the product stated in the safety data sheet(>,<)> supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: [www.kcl.de](http://www.kcl.de)).

*Other protective equipment*

protective clothing

*Respiratory protection*

required when dusts are generated.

Recommended Filter type: Filter P 2 (acc. to DIN 3181) for solid and liquid particles of harmful substances

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

**Environmental exposure controls**

Do not let product enter drains.

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**SECTION 9. Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

Form	powder
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Colour	colourless
Odour	slight
Odour Threshold	No information available.
pH	3,5 - 5 at 50 g/l 20 °C
Melting point	ca. 150 °C (decomposition)
Boiling point/boiling range	Not applicable
Flash point	Not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	The product is not flammable.
Lower explosion limit	Not applicable
Upper explosion limit	Not applicable
Vapour pressure	No information available.
Relative vapour density	No information available.
Density	2,36 g/cm <sup>3</sup> at 20 °C
Relative density	No information available.
Water solubility	ca.650 g/l at 20 °C
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	> 150 °C
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

## 9.2 Other data

Ignition temperature	Not applicable
Bulk density	1.000 - 1.200 kg/m <sup>3</sup>

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**SECTION 10. Stability and reactivity**

**10.1 Reactivity**

See section 10.3

**10.2 Chemical stability**

The product is chemically stable under standard ambient conditions (room temperature) .

**10.3 Possibility of hazardous reactions**

Generates dangerous gases or fumes in contact with:

acids

Exothermic reaction with:

Oxidizing agents, nitrites, nitrates, Sulphides

**10.4 Conditions to avoid**

Strong heating (decomposition).

**10.5 Incompatible materials**

no information available

**10.6 Hazardous decomposition products**

in the event of fire: See section 5.

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**SECTION 11. Toxicological information**

**11.1 Information on toxicological effects**

*Acute oral toxicity*

LD50 Rat: 1.540 mg/kg

OECD Test Guideline 401

Symptoms: Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

absorption

*Acute inhalation toxicity*

Symptoms: Possible damages:, mucosal irritations

*Acute dermal toxicity*

LD50 Rat: > 2.000 mg/kg

(RTECS)

*Skin irritation*

Rabbit

Result: No irritation

OECD Test Guideline 404

*Eye irritation*

Rabbit

Result: Eye irritation

OECD Test Guideline 405

Causes serious eye damage.

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*Sensitisation*

Sensitisation test: Guinea pig

Result: negative

(External MSDS)

*Germ cell mutagenicity*

*Genotoxicity in vitro*

Ames test

Result: negative

Method: OECD Test Guideline 471

Mutagenicity (mammal cell test): micronucleus.

Result: negative

(IUCLID)

*Carcinogenicity*

Did not show carcinogenic effects in animal experiments. (IUCLID)

*Reproductive toxicity*

No impairment of reproductive performance in animal experiments. (IUCLID)

*Teratogenicity*

Did not show teratogenic effects in animal experiments. (External MSDS)

*Specific target organ toxicity - single exposure*

This information is not available.

*Specific target organ toxicity - repeated exposure*

This information is not available.

*Aspiration hazard*

This information is not available.

## 11.2 Further information

Handle in accordance with good industrial hygiene and safety practice.

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## SECTION 12. Ecological information

### 12.1 Toxicity

*Toxicity to fish*

LC50 Oncorhynchus mykiss (rainbow trout): 150 - 220 mg/l; 96 h

DIN 38412 part 15

*Toxicity to daphnia and other aquatic invertebrates*

EC50 Daphnia magna (Water flea): 89 mg/l; 48 h

OECD Test Guideline 202

*Toxicity to algae*

IC50 Desmodesmus subspicatus (green algae): 48 mg/l; 72 h

OECD Test Guideline 201

*Toxicity to bacteria*

EC50 Pseudomonas putida: 56 mg/l; 17 h

(IUCLID)

### 12.2 Persistence and degradability

*Biodegradability*

The methods for determining the biological degradability are not applicable to inorganic substances.



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*Chemical Oxygen Demand (COD)*  
165 mg/g

(calculated) (External MSDS)

**12.3 Bioaccumulative potential**

No information available.

**12.4 Mobility in soil**

No information available.

**12.5 Results of PBT and vPvB assessment**

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

**12.6 Other adverse effects**

Discharge into the environment must be avoided.

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**SECTION 13. Disposal considerations**

*Waste treatment methods*

See [www.retrologistik.com](http://www.retrologistik.com) for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

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**SECTION 14. Transport information**

**Land transport (ADR/RID)**

<b>14.1 - 14.6</b>	Not classified as dangerous in the meaning of transport regulations.
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**Inland waterway transport (ADN)**

Not relevant

**Air transport (IATA)**

<b>14.1 - 14.6</b>	Not classified as dangerous in the meaning of transport regulations.
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**Sea transport (IMDG)**

<b>14.1 - 14.6</b>	Not classified as dangerous in the meaning of transport regulations.
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**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not relevant

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**SECTION 15. Regulatory information**

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

*EU regulations*

Major Accident Hazard	SEVESO III
Legislation	Not applicable

Occupational restrictions	Take note of Dir 94/33/EC on the protection of young people at work. Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.
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Regulation (EC) No 1005/2009 on substances that deplete the ozone layer not regulated

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC not regulated

Substances of very high concern (SVHC) This product does not contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH), Article 57 above the respective regulatory concentration limit of  $\geq 0.1$  % (w/w).

*National legislation*

|| Storage class 10 - 13

**15.2 Chemical Safety Assessment**

For this product a chemical safety assessment was not carried out.

**SECTION 16. Other information**

**Full text of H-Statements referred to under sections 2 and 3.**

H302	Harmful if swallowed.
H318	Causes serious eye damage.

**Full text of R-phrases referred to under sections 2 and 3**

R22	Harmful if swallowed.
R31	Contact with acids liberates toxic gas.
R41	Risk of serious damage to eyes.

**Training advice**

Provide adequate information, instruction and training for operators.

**Labelling**

*Hazard pictograms*



*Signal word*

Danger

*Hazard statements*

H302 Harmful if swallowed.  
H318 Causes serious eye damage.  
EUH031 Contact with acids liberates toxic gas.

*Precautionary statements*

Prevention  
P280 Wear eye protection.

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Response

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P313 Get medical advice/ attention.

Labelling (67/548/EEC or 1999/45/EC)

Symbol(s)  Xn Harmful

R-phrases 22-31-41 Harmful if swallowed. Contact with acids liberates toxic gas.  
Risk of serious damage to eyes.

S-phrases 26-39-46 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear eye/face protection. If swallowed, seek medical advice immediately and show this container or label.

EC-No. 231-673-0 EC Label

Reduced labelling (≤125 ml)

Symbol(s)  Xn Harmful

R-phrases 22-41 Harmful if swallowed. Risk of serious damage to eyes.

S-phrases 26-39 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear eye/face protection.

Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at [www.wikipedia.org](http://www.wikipedia.org).

Regional representation

This information is given on the authorised Safety Data Sheet for your country.

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*The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.*

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**EXPOSURE SCENARIO 1 (Industrial use)**

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**1. Industrial use (Pharmaceutical production, Cosmetic raw material)**

**Sectors of end-use**

*SU 3* Industrial uses: Uses of substances as such or in preparations at industrial sites  
*SU 10* Formulation [mixing] of preparations and/ or re-packaging (excluding alloys)

**Chemical product category**

*PC19* Intermediate  
*PC39* Cosmetics, personal care products

**Process categories**

*PROC1* Use in closed process, no likelihood of exposure  
*PROC2* Use in closed, continuous process with occasional controlled exposure  
*PROC3* Use in closed batch process (synthesis or formulation)  
*PROC4* Use in batch and other process (synthesis) where opportunity for exposure arises  
*PROC5* Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact)  
*PROC8a* Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities  
*PROC8b* Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities  
*PROC9* Transfer of substance or preparation into small containers (dedicated filling line, including weighing)  
*PROC14* Production of preparations or articles by tableting, compression, extrusion, pelletisation  
*PROC15* Use as laboratory reagent

**Environmental Release Categories**

*ERC1* Manufacture of substances  
*ERC2* Formulation of preparations  
*ERC4* Industrial use of processing aids in processes and products, not becoming part of articles  
*ERC6a* Industrial use resulting in manufacture of another substance (use of intermediates)  
*ERC6b* Industrial use of reactive processing aids

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**2. Contributing scenarios: Operational conditions and risk management measures**

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**2.1 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15**

**Product characteristics**

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 100 %.
Physical Form (at time of use)	Solid, medium dustiness

**Frequency and duration of use**

Frequency of use	8 hours/day
Frequency of use	5 days/week

**Other operational conditions affecting workers exposure**

Outdoor / Indoor	Indoor without local exhaust ventilation (LEV)
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**Organisational measures to prevent /limit releases, dispersion and exposure**

Covers daily exposures up to 8 hours.

**Conditions and measures related to personal protection, hygiene and health evaluation**

Wear protective gloves/ eye protection/ face protection.

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**3. Exposure estimation and reference to its source**

**Environment**

A chemical safety assessment was performed according REACH Article 14(3), Annex I, sections 3 (Environmental Hazard Assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

**Workers**

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.1	PROC1	longterm, inhalative, systemic	0,001	MEASE
2.1	PROC2	longterm, inhalative, systemic	0,05	MEASE
2.1	PROC3	longterm, inhalative, systemic	0,1	MEASE
2.1	PROC4	longterm, inhalative, systemic	0,5	MEASE
2.1	PROC5	longterm, inhalative, systemic	0,5	MEASE
2.1	PROC8a	longterm, inhalative, systemic	0,5	MEASE
2.1	PROC8b	longterm, inhalative, systemic	0,5	MEASE
2.1	PROC9	longterm, inhalative, systemic	0,5	MEASE
2.1	PROC14	longterm, inhalative, systemic	0,1	MEASE
2.1	PROC15	longterm, inhalative, systemic	0,05	MEASE

The default parameters and -efficiencies of the applied exposure assessment model were used for the calculation (unless stated differently).

For (other) acute effects risk management measures are based on qualitative risk characterisation.

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**4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario**

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC Guidance Specific Environmental Release Categories (SPERCs).

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## EXPOSURE SCENARIO 2 (Professional use)

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### 1. Professional use (Pharmaceutical production, Cosmetic raw material)

#### Sectors of end-use

*SU 22* Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

#### Chemical product category

*PC39* Cosmetics, personal care products

#### Environmental Release Categories

*ERC8a* Wide dispersive indoor use of processing aids in open systems

*ERC8d* Wide dispersive outdoor use of processing aids in open systems

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### 2. Contributing scenarios: Operational conditions and risk management measures

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### 3. Exposure estimation and reference to its source

#### Environment

A chemical safety assessment was performed according REACH Article 14(3), Annex I, sections 3 (Environmental Hazard Assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

In accordance with REACH Article 14(5b), exposure estimations and risk characterizations for human health do not need to be performed for uses of substances in cosmetic products which are under the scope of Directive 76/768/EEC.

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### 4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC Guidance Specific Environmental Release Categories (SPERCs).

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## EXPOSURE SCENARIO 3 (Consumer use)

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### 1. Consumer use (Pharmaceutical production, Cosmetic raw material)

#### Sectors of end-use

*SU 21* Consumer uses: Private households (= general public = consumers)

#### Chemical product category

*PC39* Cosmetics, personal care products

#### Environmental Release Categories

*ERC8a* Wide dispersive indoor use of processing aids in open systems

*ERC8d* Wide dispersive outdoor use of processing aids in open systems

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### 2. Contributing scenarios: Operational conditions and risk management measures

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### 3. Exposure estimation and reference to its source

#### Environment

A chemical safety assessment was performed according REACH Article 14(3), Annex I, sections 3 (Environmental Hazard Assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

In accordance with REACH Article 14(5b), exposure estimations and risk characterizations for human health do not need to be performed for uses of substances in cosmetic products which are under the scope of Directive 76/768/EEC.

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### 4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC Guidance Specific Environmental Release Categories (SPERCs).