

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 17.10.2017

Version 17.3

SECTION 1. Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Catalogue No.	100987
Product name	Benzyl alcohol special grade (benzaldehyde \leq 0.05%) suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,NF
REACH Registration Number	01-2119492630-38-XXXX
CAS-No.	100-51-6

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	LS-QHC * e-mail: prodsafe@merckgroup.com

1.4 Emergency telephone number **Please contact the regional company representation in your country.**

SECTION 2. Hazards identification**2.1 Classification of the substance or mixture**

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Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4, Oral, H302

Acute toxicity, Category 4, Inhalation, H332

Eye irritation, Category 2, H319

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Warning

Hazard statements

H302 + H332 Harmful if swallowed or if inhaled.

H319 Causes serious eye irritation.

Precautionary statements

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.

Reduced labelling (\leq 125 ml)

Hazard pictograms



Signal word

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Warning

Contains: Benzyl alcohol

Index-No. 603-057-00-5

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula	C ₆ H ₅ CH ₂ OH	C ₇ H ₈ O (Hill)
Index-No.	603-057-00-5	
EC-No.	202-859-9	
Molar mass	108,14 g/mol	

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

Chemical name (Concentration)

CAS-No.	Registration number	Classification
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Benzyl alcohol (\leq 100 %)

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

100-51-6	01-2119492630-38-XXXX	Acute toxicity, Category 4, H302 Acute toxicity, Category 4, H332 Eye irritation, Category 2, H319
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For the full text of the H-Statements 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. If breathing stops: mouth-to-mouth breathing or artificial respiration.

Oxygen if necessary. Immediately call in physician.

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. Call in ophthalmologist. Remove contact lenses.

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

Drying-out effect resulting in rough and chapped skin., irritant effects, Cough, Shortness of breath, respiratory arrest, Drowsiness, inebriation, agitation, Diarrhoea, Nausea, Vomiting, Headache, Convulsions, CNS disorders, Unconsciousness

4.3 Indication of any immediate medical attention and special treatment needed

Laxative: Sodium sulfate (1 tablespoon/1/4 l water).

SECTION 5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water, Foam, Carbon dioxide (CO₂), Dry powder

Unsuitable extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Combustible.

Vapours are heavier than air and may spread along floors.

Forms explosive mixtures with air on intense heating.

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Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

Special protective equipment for firefighters

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

Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapours, aerosols. 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 with liquid-absorbent material (e.g. Chemizorb®). Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7. Handling and storage

7.1 Precautions for safe handling

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Advice on safe handling

Observe label precautions.

Work under hood. Do not inhale substance/mixture. Avoid generation of vapours/aerosols.

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. Protected from light.

Recommended storage temperature see product label.

7.3 Specific end use(s)

See exposure scenario in the Annex to this MSDS.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

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Derived No Effect Level (DNEL)

Worker DNEL, acute	Systemic effects	inhalation	450 mg/m ³
Worker DNEL, acute	Systemic effects	dermal	47 mg/kg Body weight
Worker DNEL, longterm	Systemic effects	inhalation	90 mg/m ³
Worker DNEL, longterm	Systemic effects	dermal	9,5 mg/kg Body weight
Consumer DNEL, acute	Systemic effects	oral	25 mg/kg Body weight
Consumer DNEL, acute	Systemic effects	inhalation	95,5 mg/m ³
Consumer DNEL, acute	Systemic effects	dermal	28,5 mg/kg Body weight
Consumer DNEL, longterm	Systemic effects	oral	5 mg/kg Body weight
Consumer DNEL, longterm	Systemic effects	inhalation	19,1 mg/m ³
Consumer DNEL, longterm	Systemic effects	dermal	5,7 mg/kg Body weight

Predicted No Effect Concentration (PNEC)

PNEC Fresh water	1 mg/l
PNEC Fresh water sediment	5,27 mg/kg
PNEC Marine water	0,1 mg/l
PNEC Marine sediment	0,527 mg/kg
PNEC Soil	0,456 mg/kg
PNEC Sewage treatment plant	39 mg/l
PNEC Aquatic intermittent release	2,3 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

Safety glasses

Hand protection

full contact:

Glove material:	butyl-rubber
Glove thickness:	0,7 mm
Break through time:	> 480 min

splash contact:

Glove material:	Viton (R)
Glove thickness:	0,70 mm
Break through time:	> 120 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 898 Butoject® (full contact), KCL 890 Vitoject® (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).

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Other protective equipment

protective clothing

Respiratory protection

required when vapours/aerosols are generated.

Recommended Filter type: Filter A (acc. to DIN 3181) for vapours of organic compounds

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.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colourless
Odour	characteristic
Odour Threshold	No information available.
pH	No information available.
Melting point	-15,3 °C
Boiling point/boiling range	205 °C at 1.013 hPa

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Flash point	101 °C Method: DIN 51758
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	1,3 %(V)
Upper explosion limit	13 %(V)
Vapour pressure	0,07 hPa at 20 °C
Relative vapour density	3,72
Density	1,05 g/cm ³ at 20 °C
Relative density	No information available.
Water solubility	40 g/l at 20 °C
Partition coefficient: n-octanol/water	log Pow: 1,05 (20 °C) (experimental) Bioaccumulation is not expected.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.

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Viscosity, dynamic	6,57 mPa.s at 20 °C
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Explosive properties	Not classified as explosive.
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Oxidizing properties	none
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9.2 Other data

Ignition temperature	435 °C DIN 51794
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SECTION 10. Stability and reactivity

10.1 Reactivity

Forms explosive mixtures with air on intense heating.

A range from approx. 15 Kelvin below the flash point is to be rated as critical.

10.2 Chemical stability

Sensitivity to light

Sensitive to air.

10.3 Possibility of hazardous reactions

Risk of explosion with:

nonmetallic halides

Exothermic reaction with:

Oxidizing agents, polymerisation initiators, hydrogen bromide, Iron, sulphuric acid, Acids,

Isocyanates

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

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various plastics

10.6 Hazardous decomposition products

no information available

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

LD50 Rat: 1.620 mg/kg

(ECHA)

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

Acute inhalation toxicity

Acute toxicity estimate: 1,51 mg/l

Expert judgement

Symptoms: mucosal irritations, Cough, Shortness of breath

Acute dermal toxicity

This information is not available.

Skin irritation

Rabbit

Result: No irritation

OECD Test Guideline 404

Eye irritation

Rabbit

Result: irritating

OECD Test Guideline 405

Causes serious eye irritation.

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Sensitisation

Maximisation Test

Result: negative

Method: OECD Test Guideline 406

Germ cell mutagenicity

This information is not available.

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

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

After absorption:

Systemic effects:

Nausea, Headache, agitation, inebriation, CNS disorders, respiratory arrest, Convulsions, Drowsiness, Unconsciousness

Chronic intoxication:

Damage to:

Cardiac

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

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SECTION 12. Ecological information

12.1 Toxicity

Toxicity to fish

static test LC50 Pimephales promelas (fathead minnow): 460 mg/l; 96 h
US-EPA

Toxicity to daphnia and other aquatic invertebrates

Immobilization EC50 Daphnia magna (Water flea): 230 mg/l; 48 h
OECD Test Guideline 202

Toxicity to algae

static test ErC50 Pseudokirchneriella subcapitata (green algae): 700 mg/l; 72 h
OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

semi-static test NOEC Daphnia magna (Water flea): 51 mg/l; 21 d
OECD Test Guideline 211

12.2 Persistence and degradability

Biodegradability

92 - 96 %; 14 d; aerobic

OECD Test Guideline 301C

Readily biodegradable

95 - 97 %; 21 d; aerobic

OECD Test Guideline 301A

Readily biodegradable

Biochemical Oxygen Demand (BOD)

1.550 mg/g (5 d)

(Lit.)

Theoretical oxygen demand (ThOD)

2.515 mg/g

(IUCLID)

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Ratio BOD/ThBOD

BOD5 62 %

(Lit.)

Ratio COD/ThBOD

96 %

(Lit.)

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: 1,05 (20 °C)

(experimental)

Bioaccumulation is not expected.

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.

SECTION 13. Disposal considerations

Waste treatment methods

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

SECTION 14. Transport information

Land transport (ADR/RID)

14.1 - 14.6

Not classified as dangerous in the meaning of transport regulations.

Inland waterway transport (ADN)

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Not relevant

Air transport (IATA)

14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

Sea transport (IMDG)

14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

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
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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
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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.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Warning

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Hazard statements

H302 + H332 Harmful if swallowed or if inhaled.

H319 Causes serious eye irritation.

Precautionary statements

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.

Contains: Benzyl alcohol

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.

Regional representation

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

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)

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)

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ERC6b Industrial use of reactive processing aids

2. Contributing scenarios: Operational conditions and risk management measures

2.1 Contributing scenario controlling environmental exposure for: ERC1, SpERC ESVOC 1

Amount used

Annual amount per site	100 t
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Environment factors not influenced by risk management

Dilution Factor (River)	10
Dilution Factor (Coastal Areas)	100

Other given operational conditions affecting environmental exposure

Number of emission days per year	300
Emission or Release Factor: Air	0,01 %
Emission or Release Factor: Water	1 %
Emission or Release Factor: Soil	0,01 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant	Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent	2.000 m ³ /d
Effectiveness (of a measure)	87,4 %

2.2 Contributing scenario controlling environmental exposure for: ERC2

Amount used

Annual amount per site	1000 t
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Environment factors not influenced by risk management

Dilution Factor (River)	10
Dilution Factor (Coastal Areas)	100

Conditions and measures related to municipal sewage treatment plant

The Safety Data Sheets for catalogue items are available at www.merckgroup.com

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Type of Sewage Treatment Plant	Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent	2.000 m3/d
Effectiveness (of a measure)	87,4 %

2.3 Contributing scenario controlling environmental exposure for: ERC4, SpERC ESVOC 3

Amount used

Annual amount per site	500 t
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Environment factors not influenced by risk management

Dilution Factor (River)	10
Dilution Factor (Coastal Areas)	100

Other given operational conditions affecting environmental exposure

Number of emission days per year	300
Emission or Release Factor: Air	0,001 %
Emission or Release Factor: Water	0,001 %
Emission or Release Factor: Soil	0 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant	Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent	2.000 m3/d
Effectiveness (of a measure)	87,4 %

2.4 Contributing scenario controlling environmental exposure for: ERC6a

Amount used

Annual amount per site	100 t
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Environment factors not influenced by risk management

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Dilution Factor (River)	10
Dilution Factor (Coastal Areas)	100

Other given operational conditions affecting environmental exposure

Number of emission days per year	20
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Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant	Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent	2.000 m ³ /d
Effectiveness (of a measure)	87,4 %

2.5 Contributing scenario controlling environmental exposure for: ERC6b, SpERC ESVOC 8

Amount used

Annual amount per site	200 t
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Environment factors not influenced by risk management

Dilution Factor (River)	10
Dilution Factor (Coastal Areas)	100

Other given operational conditions affecting environmental exposure

Number of emission days per year	20
Emission or Release Factor: Air	30 %
Emission or Release Factor: Water	0,01 %
Emission or Release Factor: Soil	0 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant	Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent	2.000 m ³ /d
Effectiveness (of a measure)	87,4 %

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2.6 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC4, 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)	Low volatile liquid
Process Temperature	< 69 °C

Frequency and duration of use

Frequency of use	8 hours/day
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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

Use suitable eye protection.

2.7 Contributing scenario controlling worker exposure for: PROC5, PROC8a, PROC8b

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)	Low volatile liquid
Process Temperature	< 69 °C

Frequency and duration of use

Frequency of use	8 hours/day
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Other operational conditions affecting workers exposure

Outdoor / Indoor Indoor without local exhaust ventilation (LEV)

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

Use suitable eye protection. Wear suitable gloves tested to EN374.

3. Exposure estimation and reference to its source

Environment

CS	Use descriptor	Msafe	Compartment	RCR	Exposure Assessment Method
2.1	ERC1		All compartments	< 1	EUSES
2.2	ERC2		All compartments	< 1	EUSES
2.3	ERC4		All compartments	< 1	EUSES
2.4	ERC6a		All compartments	< 1	EUSES
2.5	ERC6b		All compartments	< 1	EUSES

Workers

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.6	PROC1		< 1	ECETOC TRA
2.6	PROC2		< 1	ECETOC TRA
2.6	PROC3		< 1	ECETOC TRA
2.6	PROC4		< 1	ECETOC TRA
2.6	PROC9		< 1	ECETOC TRA
2.6	PROC14		< 1	ECETOC TRA
2.6	PROC15		< 1	ECETOC TRA
2.7	PROC5		< 1	ECETOC TRA, modified
2.7	PROC8a		< 1	ECETOC TRA, modified
2.7	PROC8b		< 1	ECETOC TRA, modified

The default parameters and -efficiencies of the applied exposure assessment model were used for

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Product name	Benzyl alcohol special grade (benzaldehyde \leq 0.05%) suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,NF

the calculation (unless stated differently).

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

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).

For scaling of worker exposure assessments performed with ECETOC TRA, please consult the Merck tool SciDeEx® at www.merckmillipore.com/scideex.

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EXPOSURE SCENARIO 2 (Professional use)

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

2. Contributing scenarios: Operational conditions and risk management measures

2.1 Contributing scenario controlling environmental exposure for: ERC8a, ERC8d

Amount used

Annual amount per site 1000 t

Environment factors not influenced by risk management

Dilution Factor (River) 10

Dilution Factor (Coastal Areas) 100

Other given operational conditions affecting environmental exposure

Number of emission days per year 365

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant Municipal sewage treatment plant

Flow rate of sewage treatment plant effluent 2.000 m³/d

Effectiveness (of a measure) 87,4 %

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3. Exposure estimation and reference to its source

Environment

CS	Use descriptor	Msafe	Compartment	RCR	Exposure Assessment Method
2.1	ERC8a, ERC8d		All compartments	< 1	EUSES

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.

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)

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

2. Contributing scenarios: Operational conditions and risk management measures

2.1 Contributing scenario controlling environmental exposure for: ERC8a, ERC8d: Wide dispersive indoor use of processing aids in open systems, Wide dispersive outdoor use of processing aids in open systems

Amount used

Annual amount per site 1000 t

Environment factors not influenced by risk management

Dilution Factor (River) 10

Dilution Factor (Coastal Areas) 100

Other given operational conditions affecting environmental exposure

Number of emission days per year 365

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant Municipal sewage treatment plant

Flow rate of sewage treatment plant effluent 2.000 m³/d

Effectiveness (of a measure) 87,4 %

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Catalogue No. 100987
Product name Benzyl alcohol special grade (benzaldehyde \leq 0.05%) suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,NF

3. Exposure estimation and reference to its source

Environment

CS	Use descriptor	Msafe	Compartment	RCR	Exposure Assessment Method
2.1	ERC8a, ERC8d		All compartments	< 1	EUSES

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.

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).