

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 02.09.2014

Version 10.0

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

### 1.1 Product identifier

Catalogue No.	106652
Product name	Sodium sulfite suitable for use as excipient EMPROVE® exp Ph Eur,BP,NF,E 221
REACH Registration Number	01-2119537420-49-XXXX
CAS-No.	7757-83-7

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

Identified uses	Pharmaceutical production, Cosmetic raw material For additional information on uses please refer to the Merck Chemicals portal ( <a href="http://www.merck-chemicals.com">www.merck-chemicals.com</a> ).
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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: <a href="mailto:prodsafe@merckgroup.com">prodsafe@merckgroup.com</a>

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

This substance is not classified as dangerous according to European Union legislation.

### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

### 2.3 Other hazards

None known.

## SECTION 3. Composition/information on ingredients

### 3.1 Substance

Formula	Na <sub>2</sub> SO <sub>3</sub>	Na <sub>2</sub> O <sub>3</sub> S (Hill)
EC-No.	231-821-4	
Molar mass	126,04 g/mol	

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

Remarks	No disclosure requirement according to Regulation (EC) No. 1907/2006
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### 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.

After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

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

We have no description of any toxic symptoms.

### 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. 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 empty into 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.

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#### 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. 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)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

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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	298 mg/m <sup>3</sup>
Consumer DNEL, longterm	Systemic effects	inhalation	88 mg/m <sup>3</sup>
Consumer DNEL, longterm	Systemic effects	oral	11 mg/kg Body weight

##### Predicted No Effect Concentration (PNEC)

PNEC Fresh water	1,33 mg/l
PNEC Marine water	0,13 mg/l
PNEC Sewage treatment plant	99,9 mg/kg

#### 8.2 Exposure controls

##### 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:

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                    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)).

*Respiratory protection*

required when dusts are generated.

Recommended Filter type: Filter P 1 (acc. to DIN 3181) for solid particles of inert 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 empty into drains.

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**SECTION 9. Physical and chemical properties**

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

Form	powder
Colour	white
Odour	odourless
Odour Threshold	Not applicable
pH	8,8 - 10 at 50 g/l 20 °C
Melting point	> 500 °C (decomposition)
Boiling point/boiling range	(decomposition)
Flash point	Not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.

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Lower explosion limit	Not applicable
Upper explosion limit	Not applicable
Vapour pressure	Not applicable
Relative vapour density	No information available.
Density	2,63 g/cm <sup>3</sup> at 20 °C
Relative density	No information available.
Water solubility	220 g/l at 20 °C
Partition coefficient: n-octanol/water	log Pow: -4 (25 °C) OECD Test Guideline 107 Bioaccumulation is not expected.
Auto-ignition temperature	No information available.
Decomposition temperature	> 500 °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	ca. 1.480 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**

Violent reactions possible with:

nitrites

Exothermic reaction with:

Oxidizing agents

Generates dangerous gases or fumes in contact with:

acids

**10.4 Conditions to avoid**

Strong heating (decomposition).

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**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: 2.610 mg/kg (IUCLID)

*Acute inhalation toxicity*

LC50 Rat: > 5,5 mg/l; 4 h (IUCLID)

*Acute dermal toxicity*

This information is not available.

*Skin irritation*

Rabbit

Result: No irritation

(IUCLID)

*Eye irritation*

Rabbit

Result: No eye irritation

(IUCLID)

*Sensitisation*

This information is not available.

*Germ cell mutagenicity*

*Genotoxicity in vitro*

Ames test

Result: negative

Method: OECD Test Guideline 471

*Carcinogenicity*

This information is not available.

*Reproductive toxicity*

This information is not available.

*Teratogenicity*

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

*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**

Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

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 Leuciscus idus (Golden orfe): 315 mg/l; 96 h  
DIN 38412 T15 (External MSDS)

*Toxicity to bacteria*

EC10 Pseudomonas putida: 260 mg/l; 17 h (External MSDS)

**12.2 Persistence and degradability**

*Chemical Oxygen Demand (COD)*

125 mg/g  
(External MSDS)

**12.3 Bioaccumulative potential**

*Partition coefficient: n-octanol/water*

log Pow: -4 (25 °C)  
OECD Test Guideline 107  
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**

*Additional ecological information*

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)**

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

**Inland waterway transport (ADN)**

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

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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	96/82/EC
Legislation	Directive 96/82/EC does not apply

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

Regulation (EC) No 689/2008 concerning the export and import of dangerous chemicals 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).
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*National legislation*

Storage class	10 - 13
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**15.2 Chemical Safety Assessment**

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

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**SECTION 16. Other information**

**Training advice**

Provide adequate information, instruction and training for operators.

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

The product does not need to be labelled in accordance with EC directives or respective national laws.

**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.*