

Trade name: Stesolid 5mg/Rommelag CDMO Switzerland

Substance number: 336173

Version: 2 / CH

Date revised: 04.12.2025

Replaces Version: 1 / CH

Print date: 04.12.25

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

Stesolid 5mg/Rommelag CDMO Switzerland  
Item No. 33617300

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/preparation**

Medicinal product

**1.3. Details of the supplier of the safety data sheet****Address/Manufacturer**

Hänseler AG  
Industriestrasse 35  
9100 Herisau  
Telephone no. 0041 (0)71 353 58 58  
E-mail address of sdb@haenseler.ch  
person responsible  
for this SDS

**1.4. Emergency telephone number**

Switzerland :145 / Abroad +41 (0)44 251 51 51

**SECTION 2: Hazards identification \*\*\*****2.1. Classification of the substance or mixture****Classification (Regulation (EC) No. 1272/2008)**

Classification (Regulation (EC) No. 1272/2008)  
Skin Sens. 1B H317

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008  
For explanation of abbreviations see section 16.

**2.2. Label elements****Labelling according to regulation (EC) No 1272/2008**

The product does not require a hazard warning label in accordance with Regulation (EC) No 1272/2008.

**Hazard pictograms \*\*\*****Signal word \*\*\***

Warning

**Hazard statements \*\*\***

H317 May cause an allergic skin reaction.

**Precautionary statements \*\*\***

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.

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P302+P352

IF ON SKIN: Wash with plenty of soap and water.

P333+P313

If skin irritation or rash occurs: Get medical advice/attention.

P501.3

Disposal in compliance with local and national regulations.

**Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)**

contains \*\*\*

benzyl alcohol

**Reduced labeling (<= 125 ml)****Hazard pictograms \*\*\*****Signal word \*\*\***

Warning

**Hazard statements \*\*\***

H317

May cause an allergic skin reaction.

**Precautionary statements \*\*\***

P261

Avoid breathing dust/fume/gas/mist/vapours/spray.

P272

Contaminated work clothing should not be allowed out of the workplace.

P280

Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352

IF ON SKIN: Wash with plenty of soap and water.

P333+P313

If skin irritation or rash occurs: Get medical advice/attention.

P501.3

Disposal in compliance with local and national regulations.

**2.3. Other hazards**

No special hazards have to be mentioned.

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The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

**SECTION 3: Composition/information on ingredients \*\*\*****3.2. Mixtures****Chemical characterization**

Medicinal products

**Hazardous ingredients \*\*\*****Sodium benzoate**

CAS No. 532-32-1

EINECS no. 208-534-8

Registration no. 01-2119460683-35-XXXX

Concentration &gt;= 1 &lt; 6.6 %

Classification (Regulation (EC) No. 1272/2008)

Eye Irrit. 2 H319

**benzyl alcohol**

CAS No. 100-51-6

EINECS no. 202-859-9

Registration no. 01-2119492630-38-0021

Concentration &gt;= 1 &lt; 3.3 %

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Acute Tox. 4 H302  
 Eye Irrit. 2 H319  
 Skin Sens. 1B H317

ATE oral 1'200 mg/kg  
 ATE dermal 2'000 mg/kg

**Diazepam**

CAS No. 439-14-5  
 EINECS no. 207-122-5  
 Concentration  $\geq$  0.1 < 1 %  
 Classification (Regulation (EC) No. 1272/2008)  
 Acute Tox. 3 H301  
 Aquatic Chronic 2 H411

ATE oral 249 mg/kg

**Further ingredients****water**

CAS No. 7732-18-5  
 EINECS no. 231-791-2  
 Concentration  $\geq$  25 < 50 %  
 Advice: [4]

**Propane-1,2-diol**

CAS No. 57-55-6  
 EINECS no. 200-338-0  
 Registration no. 01-2119456809-23  
 Concentration  $\geq$  25 < 50 %  
 Advice: [4]

**ethanol**

CAS No. 64-17-5  
 EINECS no. 200-578-6  
 Registration no. 01-2119457610-43-0098  
 Concentration  $\geq$  1 < 10 %  
 Advice: [3]  
 Classification (Regulation (EC) No. 1272/2008)  
 Flam. Liq. 2 H225

**benzoic acid**

CAS No. 65-85-0  
 EINECS no. 200-618-2  
 Registration no. 01-2119455536-33  
 Concentration < 1 %  
 Advice: [4]  
 Classification (Regulation (EC) No. 1272/2008)  
 Skin Irrit. 2 H315  
 Eye Dam. 1 H318  
 STOT RE 1 H372

**Note**

[3] Substance with occupational exposure limits

[4] Voluntary information

**Other information**

The product is an article within the meaning of Article 3 No. 3 of the REACH Regulation and thus not to

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be labelled according to the CLP regulation. The compilation of the Safety Data sheet is not required according to Article 31 REACH Regulation for articles and is done on a voluntary basis.

## **SECTION 4: First aid measures**

### **4.1. Description of first aid measures**

#### **General information**

If you feel unwell, seek medical advice (show the label where possible). Remove contaminated, soaked clothing immediately and dispose of safely.

#### **After inhalation**

Ensure supply of fresh air. Summon a doctor immediately.

#### **After skin contact**

Wash immediately with plenty of water for several minutes. Consult a doctor if skin irritation persists.

#### **After eye contact**

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

#### **After ingestion**

Rinse mouth thoroughly with water. Consult a physician if necessary.

## **SECTION 5: Firefighting measures**

### **5.1. Extinguishing media**

#### **Suitable extinguishing media**

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

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

In case of combustion evolution of dangerous gases possible.

### **5.3. Advice for firefighters**

#### **Special protective equipment for fire-fighting**

Use self-contained breathing apparatus.

## **SECTION 6: Accidental release measures**

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

Ensure adequate ventilation. Wear protective equipment

### **6.2. Environmental precautions**

Do not discharge into the drains/surface waters/groundwater.

### **6.3. Methods and material for containment and cleaning up**

Pick up with absorbent material (eg sand, kieselgur, acid binder, universal binder). Send in suitable containers for recovery or disposal. Clean up affected area.

## **SECTION 7: Handling and storage**

### **7.1. Precautions for safe handling**

#### **Advice on safe handling**

No special requirements.

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

#### **Storage classes**

Storage class according to TRGS 510

12

Non-combustible liquids

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Storage category (Switzerland)

10/12

Other liquid hazardous substances

**Further information on storage conditions**

Keep container tightly closed and dry in a cool, well-ventilated place.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Exposure limit values****ethanol**

List	SUVA			
Type	MAK			
Value	960	mg/m <sup>3</sup>	500	ppm(V)
Short term exposure limit	1920	mg/m <sup>3</sup>	1000	ppm(V)
Pregnancy group: S	Remarks: SSs; Formal; INRS NIOSH			

**benzyl alcohol**

List	SUVA			
Type	MAK			
Value	22	mg/m <sup>3</sup>	5	ppm(V)
Remarks: H SSs; AW; NIOSH				

**Derived No/Minimal Effect Levels (DNEL/DMEL)****benzoic acid**

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	0.1	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	3	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	62.5	mg/kg/d

Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	1.5	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	

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Concentration	0.06	mg/m <sup>3</sup>
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Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	31.25	mg/kg

Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	oral	
Mode of action	Chronic effects	
Concentration	8.3	mg/kg

**Sodium benzoate**

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	0.1	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	3	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	62.5	mg/kg/d

Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	0.06	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	1.5	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Long term	
Route of exposure	dermal	

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Mode of action	Systemic effects	
Concentration	31.25	mg/kg/d

Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Long term	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	16.6	mg/kg/d

**ethanol**

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	343	mg/kg/d

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	950	mg/m <sup>3</sup>

**benzyl alcohol**

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Acute	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	110	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	22	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Acute	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	40	mg/kg/d

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	8	mg/kg/d

Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	

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Duration of exposure	Acute	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	27	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	5.4	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Acute	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	20	mg/kg/d
Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	4	mg/kg/d
Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Acute	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	20	mg/kg/d
Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Long term	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	4	mg/kg/d
<b>Propane-1,2-diol</b>		
Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	50	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	168	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	



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Reference group	General Population	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	10	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	10	mg/m <sup>3</sup>

**Predicted No Effect Concentration (PNEC)****benzoic acid**

Type of value	PNEC	
Type	Water	
Concentration	0.011	mg/l

Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	100	mg/l
Source	Literature value	

Type of value	PNEC	
Type	Saltwater	
Concentration	0.011	mg/l

Type of value	PNEC	
Type	Freshwater sediment	
Concentration	0.149	mg/kg

Type of value	PNEC	
Type	Marine sediment	
Concentration	0.149	mg/kg

Type of value	PNEC	
Type	Water (intermittent release)	
Concentration	3.3	mg/l

Type of value	PNEC	
Type	Soil	
Concentration	0.0233	mg/kg

**Sodium benzoate**

Type of value	PNEC	
Type	Freshwater	
Concentration	0.13	mg/l

Type of value	PNEC	
Type	Freshwater sediment	
Concentration	1.76	mg/kg

Type of value	PNEC	
Type	Saltwater	
Concentration	0.013	mg/l

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Type of value	PNEC	
Type	Marine sediment	
Concentration	0.176	mg/kg

Type of value	PNEC	
Conditions	Intermittend	
Concentration	0.305	mg/l

Type of value	PNEC	
Type	Soil	
Concentration	0.276	mg/kg

Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	10	mg/l

**ethanol**

Type of value	PNEC	
Type	Freshwater	
Conditions	Long term	
Concentration	0.96	mg/l

Type of value	PNEC	
Type	Saltwater	
Concentration	0.79	mg/l

Type of value	PNEC	
Type	Freshwater sediment	
Concentration	3.6	mg/kg

Type of value	PNEC	
Type	Marine sediment	
Concentration	2.9	mg/kg

Type of value	PNEC	
Type	Freshwater	
Conditions	Intermittend	
Concentration	2.75	mg/l

Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	580	mg/l

**benzyl alcohol**

Type of value	PNEC	
Type	Freshwater	
Concentration	1	mg/l

Type of value	PNEC	
Type	Freshwater sediment	
Concentration	5.27	mg/kg

Type of value	PNEC	
Type	Saltwater	
Concentration	0.1	mg/l

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Type of value	PNEC	
Type	Marine sediment	
Concentration	0.527	mg/kg

Type of value	PNEC	
Type	Soil	
Concentration	0.456	mg/kg

Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	39	mg/l

**Propane-1,2-diol**

Type of value	PNEC	
Type	Soil	
Concentration	50	mg/kg

Type of value	PNEC	
Type	Saltwater	
Concentration	26	mg/l

Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	20000	mg/l

Type of value	PNEC	
Type	Freshwater	
Concentration	260	mg/l

Type of value	PNEC	
Type	Marine sediment	
Concentration	57.2	mg/kg

Type of value	PNEC	
Type	Freshwater sediment	
Concentration	572	mg/kg

**8.2. Exposure controls****General protective and hygiene measures**

General industrial hygiene practice. Avoid any contact with the body.

**Respiratory protection**

necessary; Provide adequate ventilation.

**Hand protection**

necessary

**Eye protection**

necessary

**Body protection**

necessary

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

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**Physical state**

liquid, clear

**Colour**

yellowish

**Boiling point or initial boiling point and boiling range**

Remarks

not determined

**Flash point**

Value

°C

Remarks

Not applicable

**pH value**

Value

6.5

to

7.2

**Vapour pressure**

Remarks

Not applicable

**9.2. Other information****Solubility in water**

Remarks

soluble

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No decomposition if stored and applied as directed.

**10.2. Chemical stability**

No decomposition if stored and applied as directed.

**10.3. Possibility of hazardous reactions**

No decomposition if stored and applied as directed.

**10.4. Conditions to avoid**

No decomposition if stored and applied as directed.

**10.5. Incompatible materials**

No decomposition if stored and applied as directed.

**10.6. Hazardous decomposition products**

None known

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute oral toxicity**

ATE

&gt; 10'000

mg/kg

Method

calculated value according to GHS (e.g see UN GHS)

Remarks

Based on available data, the classification criteria are not met.

**Acute oral toxicity (Components)****Diazepam**

Species

rat

LD50

249

mg/kg

Source

drugs in Japan 1995

**benzoic acid**

Species

mouse

LD50

2250

mg/kg

Method

OECD 401

**Sodium benzoate**

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Species rat  
LD50 > 2000 mg/kg

**ethanol**

Species rat  
LD50 7060 mg/kg

Source Toxicology and Applied Pharmacology. Vol. 16, Pg. 718, 1970.

**ethanol**

Species rat  
LD50 10470 mg/kg

**benzyl alcohol**

Species rat  
LD50 1200 mg/kg

**Propane-1,2-diol**

Species rat  
LD50 22000 mg/kg  
Method OECD 401

**Acute dermal toxicity**

ATE > 10'000 mg/kg  
Method calculated value according to GHS (e.g see UN GHS)  
Remarks Based on available data, the classification criteria are not met.

**Acute dermal toxicity (Components)****Diazepam**

Species mouse  
LD50 800 mg/kg

**benzoic acid**

Species rabbit  
LD50 > 2000 mg/kg

**Sodium benzoate**

Species rat  
LD50 > 2000 mg/kg

**ethanol**

Species rabbit  
LD50 15800 mg/kg

**ethanol**

NOAEL 8232 mg/kg

**benzyl alcohol**

Species rabbit  
LD50 2000 mg/kg  
Source Raw Material Data Handbook, Vol. 1: Organic Solvents, 1974. Vol. 1, Pg. 6, 1974.

**benzyl alcohol**

LD50 2500 mg/kg

**Propane-1,2-diol**

Species rabbit  
LD50 > 2000 mg/kg  
Duration of exposure 24 h  
Method OECD 402

**Acute inhalational toxicity**

Remarks Based on available data, the classification criteria are not met.

**Acute inhalative toxicity (Components)****benzoic acid**

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Species	rat		
LD50	>	12.2	mg/l
Duration of exposure		4	h
Method	Value taken from the literature		

**Sodium benzoate**

Species	rat		
LC50		12.2	mg/l
Administration/Form	Dust/Mist		

**ethanol**

Species	rat		
LC50		30000	mg/m <sup>3</sup>
Duration of exposure		4	h
Administration/Form	Vapors		

**benzyl alcohol**

Species	rat		
LC50	>	5.4	mg/l
Administration/Form	Dust/Mist		

**Propane-1,2-diol**

Species	rabbit		
LC50		317042	mg/m <sup>3</sup>
Duration of exposure		2	h
Method	OECD 403		

**Skin corrosion/irritation**

Remarks	Based on available data, the classification criteria are not met.
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**Skin corrosion/irritation (Components)****benzoic acid**

Species	guinea pig
evaluation	irritant
Source	Literature value

**Sodium benzoate**

Species	rabbit
evaluation	non-irritant
Method	OECD 404

**Diazepam**

evaluation	slightly irritant
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**ethanol**

evaluation	non-irritant
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**benzyl alcohol**

Species	rabbit
evaluation	slightly irritant
Method	OECD 404

**Propane-1,2-diol**

evaluation	irritant effect possible
Method	OECD 404

**Serious eye damage/irritation**

Remarks	Based on available data, the classification criteria are not met.
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**Serious eye damage/irritation (Components)****benzoic acid**

Species	rabbit
evaluation	strongly irritant
Source	Literature value

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**Sodium benzoate**

Species rabbit  
 evaluation strongly irritant  
 Method OECD 405

**Diazepam**

evaluation slightly irritant

**ethanol**

evaluation irritant

**benzyl alcohol**

Species rabbit  
 Duration of exposure 24 h  
 evaluation irritant - risk of serious damage to eyes  
 Method OECD 405

**Propane-1,2-diol**

evaluation irritant effect possible  
 Method OECD 405

**Sensitization**

evaluation May cause sensitization by skin contact.  
 Remarks The classification criteria are met.

**Sensitization (Components)****benzoic acid**

Species guinea pig  
 Remarks No sensitization effect known.  
 Source Literature value

**Sodium benzoate**

Species mouse  
 evaluation non-sensitizing  
 Method OECD 429

**ethanol**

evaluation non-sensitizing

**benzyl alcohol**

Route of exposure dermal  
 Species mouse  
 evaluation sensitizing

**Propane-1,2-diol**

Remarks Based on available data, the classification criteria are not met.

**Subacute, subchronic, chronic toxicity (Components)****Propane-1,2-diol**

Remarks No data available.

**Mutagenicity**

Remarks Based on available data, the classification criteria are not met.

**Mutagenicity (Components)****benzoic acid**

evaluation No mutagenicity in the Ames-test.

**Sodium benzoate**

Species Salmonella typhimurium  
 evaluation No mutagenicity in the Ames-test.

**Sodium benzoate**

Species Escherichia coli  
 evaluation No mutagenicity in the Ames-test.

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**Sodium benzoate**

Species hamster  
 evaluation Information on genotoxicity in vitro available.  
 Method OECD 473

**Sodium benzoate**

Species Human  
 evaluation Information on genotoxicity in vitro available.  
 Method OECD 479

**Sodium benzoate**

Species Human  
 evaluation Information on genotoxicity in vitro available.  
 Method OECD 487

**Sodium benzoate**

Species rat  
 evaluation No experimental information on genotoxicity in vitro available.  
 Method OECD 475

**ethanol**

evaluation No mutagenicity in the Ames-test.

**benzyl alcohol**

evaluation No experimental indications on genotoxicity in vivo found.

**Propane-1,2-diol**

Remarks Based on available data, the classification criteria are not met.

**Reproductive toxicity**

Remarks Based on available data, the classification criteria are not met.

**Reproduction toxicity (Components)****benzoic acid**

Remarks Indications of toxic effects are available from reproduction studies in animals.

**Sodium benzoate**

evaluation Based on available data, the classification criteria are not met.

**benzyl alcohol**

evaluation No negative effects

**Propane-1,2-diol**

Remarks Based on available data, the classification criteria are not met.

**Carcinogenicity**

Remarks Based on available data, the classification criteria are not met.

**Carcinogenicity (Components)****benzoic acid**

evaluation No indications of carcinogenic effects are available from long-term trials.  
 Source Literature value

**Sodium benzoate**

Species rat  
 Dose >= 20000 ppm(m)  
 evaluation Based on available data, the classification criteria are not met.

**benzyl alcohol**

evaluation No negative effects

**Propane-1,2-diol**

Remarks No data available.

**Specific Target Organ Toxicity (STOT)**

Single exposure



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Remarks Based on available data, the classification criteria are not met.

**Repeated exposure**

Remarks Based on available data, the classification criteria are not met.

**Specific Target Organ Toxicity (STOT) (Components)****benzoic acid**

Reference substance benzoic acid  
 evaluation May cause damage to organs.  
 Route of exposure inhalative  
 Organs: Lungs  
 Source Literature value

**Sodium benzoate**

Remarks Based on available data, the classification criteria are not met.

**Propane-1,2-diol**

Remarks Based on available data, the classification criteria are not met.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**11.2. Information on other hazards****Endocrine disrupting properties with respect to humans**

The product does not contain a substance that has endocrine disrupting properties with respect to humans.

**Other information**

By appropriate use of the product no health damage is known.  
 Product specific toxicological data are not known.

**SECTION 12: Ecological information****12.1. Toxicity****Fish toxicity (Components)****Diazepam**

Species rainbow trout (*Oncorhynchus mykiss*)  
 LC50 84 mg/l  
 Duration of exposure 96 h

**benzoic acid**

Species Bluegill (*Lepomis macrochirus*)  
 LC50 44.6 mg/l  
 Duration of exposure 96 h  
 Source Literature value

**benzoic acid**

Species rainbow trout (*Oncorhynchus mykiss*)  
 NOEC > 120 mg/l  
 Duration of exposure 28 d  
 Source Literature value

**Sodium benzoate**

Species Fathead minnow (*Pimephales promelas*)  
 LC50 484 mg/l  
 Duration of exposure 96 h

**Sodium benzoate**

Species zebra fish (*Brachydanio rerio*)  
 NOEC 10 mg/l  
 Duration of exposure 144 h

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**ethanol**

Species	golden orfe ( <i>Leuciscus idus</i> )	
LC50	8140	mg/l
Duration of exposure	96	h

**benzyl alcohol**

Species	Fathead minnow ( <i>Pimephales promelas</i> )	
LC50	460	mg/l
Duration of exposure	96	h
Method	OECD 203	

**benzyl alcohol**

Species	Bluegill ( <i>Lepomis macrochirus</i> )	
LC50	10	mg/l
Duration of exposure	96	h

**Propane-1,2-diol**

Species	rainbow trout ( <i>Oncorhynchus mykiss</i> )	
LC50	40613	mg/l
Duration of exposure	96	h

**Daphnia toxicity (Components)****Diazepam**

Species	Daphnia magna	
EC50	4.3	mg/l
Duration of exposure	24	h

**benzoic acid**

Species	Daphnia magna	
EC50	> 100	
Duration of exposure	48	h
Source	Literature value	

**benzoic acid**

Species	Daphnia magna	
NOEC	>= 25	mg/l
Duration of exposure	21	d
Method	OECD 211	
Source	Literature value	

**Sodium benzoate**

Species	Daphnia magna	
EC50	> 100	mg/l
Duration of exposure	96	h
Method	OECD 202	

**ethanol**

Species	Daphnia magna	
EC50	9000	to 14000 mg/l
Duration of exposure	48	h

**benzyl alcohol**

Species	Daphnia magna	
EC50	230	mg/l
Duration of exposure	48	h
Method	OECD 202	

**benzyl alcohol**

Species	Daphnia magna	
NOEC	51	mg/l
Duration of exposure	21	d

**Propane-1,2-diol**

Species	Ceriodaphnia dubia
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LC50	18340	mg/l
Duration of exposure	48 h	
Method	static test	
Source	EPA 600/489/001	

**Propane-1,2-diol**

Species	Ceriodaphnia dubia	
NOEC	13020	mg/l
Duration of exposure	7 d	
Method	US-EPA	

**Algae toxicity (Components)****Diazepam**

Species	Scenedesmus subspicatus	
ErC50	3.11	mg/l
Duration of exposure	72 h	

**benzoic acid**

Species	Raphidocelis subcapitata	
EC50	> 33.1	
Duration of exposure	72 h	
Method	OECD 201	
Source	Literature value	

**Sodium benzoate**

Species	Pseudokirchneriella subcapitata	
EC50	> 30.5	mg/l
Duration of exposure	72 h	

**Sodium benzoate**

Species	Pseudokirchneriella subcapitata	
NOEC	0.09	mg/l
Duration of exposure	72 h	

**Sodium benzoate**

Species	Desmodesmus subspicatus	
EC10	6.5	mg/l
Duration of exposure	72 h	
Method	OECD 201	

**benzyl alcohol**

Species	Algae	
IC50	770	mg/l
Duration of exposure	72 h	

**benzyl alcohol**

Species	Raphidocelis subcapitata	
NOEC	310	mg/l
Duration of exposure	72 h	
Method	OECD 201	

**Propane-1,2-diol**

Species	Raphidocelis subcapitata	
EC50	19000	mg/l
Duration of exposure	96 h	
Method	OECD 201	

**Bacteria toxicity (Components)****Diazepam**

Species	activated sludge	
NOEC	> 100	mg/l

**benzyl alcohol**

EC50	390	mg/l
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Duration of exposure 24 h

**benzyl alcohol**Species activated sludge  
IC50 2100 mg/l

Duration of exposure 49 h

**Propane-1,2-diol**Species Pseudomonas putida  
NOEC > 20000 mg/l

Duration of exposure 18 h

**12.2. Persistence and degradability****Physico-chemical eliminability (Components)****Propane-1,2-diol**

Remarks No data available.

**Biodegradability (Components)****benzoic acid**evaluation Readily biodegradable  
Source OECD**Sodium benzoate**

Value 85 to 84 %

Duration of test 28 d

evaluation Readily biodegradable

Method OECD 301 B

**Sodium benzoate**

Value 50 to 97 %

Duration of test 60 Days

evaluation Readily biodegradable

Remarks anaerob

**ethanol**

Value 94 %

evaluation Readily biodegradable

**benzyl alcohol**

Value 92 to 96 %

Duration of test 14 d

evaluation Readily biodegradable

Method OECD 301C

**benzyl alcohol**

Value 95 to 97 %

Duration of test 21 d

evaluation Readily biodegradable

Method OECD 301 A

**Propane-1,2-diol**

Remarks The product is biodegradable.

**Ready degradability (Components)****benzyl alcohol****Propane-1,2-diol**

Remarks No data available.

**Chemical oxygen demand (COD) (Components)****ethanol**

Value 0.93 to 1.67 mg/g

**12.3. Bioaccumulative potential**

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**Octanol/water partition coefficient (log Pow) (Components)****Sodium benzoate**

log Pow -2.27

**ethanol**

log Pow -0.31

**Bioconcentration factor (BCF) (Components)****ethanol**

BCF 0.66

**benzyl alcohol**

log BCF 1.05

Temperature 20 °C

**12.5. Results of PBT and vPvB assessment****Results of PBT and vPvB assessment**

The product contains no PBT substances

The product contains no vPvB substances.

**Results of PBT and vPvB assessment (Ingredients)****ethanol**

The Substance doesn't meets PBT/vPvB-criteria

**12.6 Endocrine disrupting properties****Endocrine disrupting properties with respect to the environment**

The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

**12.7. Other adverse effects****General information / ecology**

Ecological injuries are not known or expected under normal use. For this subsection there is no ecotoxicological data available on the product as such.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal recommendations for the product**

Disposal in compliance with local and national regulations.

**Disposal recommendations for packaging**

Dispose of as unused product.

**SECTION 14: Transport information \*\*\***

	Land transport ADR/RID ***	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number or ID number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.
14.5. Environmental hazards	-		

**SECTION 15: Regulatory information \*\*\***

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**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Water Hazard Class (Germany) \*\*\***

Water Hazard Class (Germany) WGK 1

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

**Other information \*\*\***

The product does not contain substances according to Candidate List for inclusion in Annex XIV of Regulation (EC) No. 1907/2006 (REACH) with a content of  $\geq 0.1\%$  w/w.

**SECTION 16: Other information****Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:**

Classification (Regulation (EC) No. 1272/2008)

Skin Sens. 1B

H317

Calculation method

**Hazard statements listed in Chapter 2/3**

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.

**CLP categories listed in Chapter 2/3**

Acute Tox. 3	Acute toxicity, Category 3
Acute Tox. 4	Acute toxicity, Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic, Category 2
Eye Irrit. 2	Eye irritation, Category 2
Skin Sens. 1B	Skin sensitization, Category 1B

**Supplemental information**

Relevant changes compared with the previous version of the safety data sheet are marked with: \*\*\*  
This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.