

Trade name: Stesolid 5mg / Maropack AG

Substance number: 336173

Version: 1 / CH

Date revised: 20.01.2020

Replaces Version: - / CH

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

### **1.1. Product identifier**

Stesolid 5mg / Maropack AG

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**

This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

### **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.

#### **Supplemental information**

EUH210

Safety data sheet available on request.

### **2.3. Other hazards**

No special hazards have to be mentioned.

## **SECTION 3: Composition/information on ingredients**

### **Hazardous ingredients**

#### **sodium benzoate**

CAS No. 532-32-1

EINECS no. 208-534-8

Concentration &gt;= 1 &lt; 10 %

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

Eye Irrit. 2 H319

#### **Benzyl alcohol**

CAS No. 100-51-6

EINECS no. 202-859-9

Concentration &gt;= 1 &lt; 10 %

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

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Acute Tox. 4 H302  
Acute Tox. 4 H332

**Diazepam**

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

**Further ingredients**

**Water**

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

**Propane-1,2-diol**

CAS No. 57-55-6  
EINECS no. 200-338-0  
Concentration >= 25 < 50 %  
Advice: [4]

**Ethanol**

CAS No. 64-17-5  
EINECS no. 200-578-6  
Concentration >= 1 < 10 %  
Advice: [4]  
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  
Lungs; Route of exposure: inhalative

**Methanol**

CAS No. 67-56-1  
EINECS no. 200-659-6  
Registration no. 01-2119433307-44-XXXX  
Concentration < 1 %  
Advice: [4]  
Classification (Regulation (EC) No. 1272/2008)  
Flam. Liq. 2 H225  
Acute Tox. 3 H301  
Acute Tox. 3 H311  
Acute Tox. 3 H331

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STOT SE 1 H370

Concentration limits (Regulation (EC) No. 1272/2008)

STOT SE 1 H370  $\geq 10$ STOT SE 2 H371  $\geq 3 < 10$ **Note**

[4] Voluntary information

**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

In case of persistent symptoms consult doctor.

**After inhalation**

Ensure supply of fresh air. In the event of symptoms take medical treatment.

**After skin contact**

In case of contact with skin wash off with warm water. 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 out mouth and give plenty of water to drink.

**Adhere to personal protective measures when giving first aid**

First aider: Pay attention to self-protection!

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

Until now no symptoms known so far.

**4.3. Indication of any immediate medical attention and special treatment needed****Hints for the physician / hazards**

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**

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

**5.3. Advice for firefighters****Special protective equipment for fire-fighting**

In case of combustion use a suitable breathing apparatus.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Wear protective equipment

**6.2. Environmental precautions**

Do not allow to enter drains or waterways.

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

Pick up with absorbent material. Clean contaminated floors and objects thoroughly, observing

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environmental regulations.

#### 6.4. Reference to other sections

Information regarding Safe handling, see Section 7. Information regarding personal protective measures, see Section 8.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

##### Advice on safe handling

Observe the usual precautions for handling chemicals.

##### Advice on protection against fire and explosion

No special measures required.

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

##### Requirements for storage rooms and vessels

Store product in closed containers.

##### Hints on storage assembly

Do not store together with foodstuffs.

##### Storage classes

Storage class according to TRGS 510      12                      Non-combustible liquids

##### Further information on storage conditions

Keep container tightly closed and dry.

### 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; Status: 2017; Remarks: SSc; OAW, FormalKT HU; INRS, NIOSH

##### Other information

Contains no substances with occupational exposure limit values.

#### 8.2. Exposure controls

##### General protective and hygiene measures

Observe the usual precautions for handling chemicals.

##### Respiratory protection

Not necessary, but do not inhale vapours. If workplace limits are exceeded, a respiratory protection approved for this particular job must be worn.

##### Hand protection

Appropriate Material                      neoprene

##### Eye protection

Safety glasses

##### Body protection

Clothing as usual in the chemical industry.

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## **SECTION 9: Physical and chemical properties**

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

**Form** liquid, clear

**Colour** yellowish

**Odour threshold**

Remarks not determined

**pH value**

Value 6.5 to 7.2

**Melting point**

Remarks not determined

**Freezing point**

Remarks not determined

**Initial boiling point and boiling range**

Remarks not determined

**Flash point**

Value °C

Remarks Not applicable

**Evaporation rate (ether = 1) :**

Remarks not determined

**Flammability (solid, gas)**

not determined

**Upper/lower flammability or explosive limits**

Remarks not determined

**Vapour pressure**

Remarks Not applicable

**Vapour density**

Remarks not determined

**Density**

Remarks not determined

**Solubility in water**

Remarks not determined

**Solubility(ies)**

Remarks not determined

**Partition coefficient: n-octanol/water**

Remarks not determined

**Ignition temperature**

Remarks not determined

**Decomposition temperature**

Remarks not determined

**Viscosity**

Remarks not determined

**Explosive properties**

evaluation not determined

**Oxidising properties**

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Remarks not determined

**9.2. Other information****Other information**

None known

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

No dangerous reactions known.

**10.2. Chemical stability**

No decomposition if stored and applied as directed.

**10.3. Possibility of hazardous reactions**

No hazardous reactions known.

**10.4. Conditions to avoid**

No hazardous reactions known.

**10.5. Incompatible materials**

None known

**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute oral toxicity**

ATE	>	10'000	mg/kg
Method		calculated value (Regulation (EC) No. 1272/2008)	

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

Species	rat		
LD50		249	mg/kg
Source	drugs in Japan 1995		

**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		1230	mg/kg
Source	Food and Cosmetics Toxicology. Vol. 2, Pg. 327, 1964.		

**Propane-1,2-diol**

Species	rat		
LD50		20000	mg/kg

**Propane-1,2-diol**

Species	rat		
LD50		6660	mg/kg
Remarks	intraperitoneal		

**Propane-1,2-diol**

Species	mouse		
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LD50	9718	mg/kg
Remarks	intraperitoneal	

**Acute dermal toxicity**

ATE	> 10'000	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)	

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

Species	mouse	
LD50	800	mg/kg

**Ethanol**

Species	rabbit	
LD50	15800	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.	

**Propane-1,2-diol**

Species	rabbit	
	20800	mg/kg

**Acute inhalational toxicity**

ATE	> 100	mg/l
Administration/Form	Vapors	
Method	calculated value (Regulation (EC) No. 1272/2008)	
ATE	> 20	mg/l
Administration/Form	Dust/Mist	
Method	calculated value (Regulation (EC) No. 1272/2008)	

**Acute inhalative toxicity (Components)****Ethanol**

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

**Skin corrosion/irritation**

Remarks	not determined
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**Serious eye damage/irritation**

Remarks	not determined
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**Sensitization**

Remarks	not determined
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**Sensitization (Components)****Benzyl alcohol**

Species	guinea pig
evaluation	non-sensitizing

**Subacute, subchronic, chronic toxicity**

Remarks	not determined
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**Mutagenicity**

Remarks	not determined
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**Mutagenicity (Components)****Benzyl alcohol**

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evaluation No experimental indications on genotoxicity in vivo found.

**Reproductive toxicity**

Remarks not determined

**Carcinogenicity**

Remarks not determined

**Other information**

No toxicological data are available.

**SECTION 12: Ecological information****12.1. Toxicity****General information**

not determined

**Fish toxicity (Components)****Diazepam**

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

**Benzyl alcohol**

LC50 460 mg/l  
 Duration of exposure 96 h

**Propane-1,2-diol**

Species Fathead minnow (*Pimephales promelas*)  
 NOEC 52930 mg/l  
 Duration of exposure 96 h

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

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

**Propane-1,2-diol**

Species Daphnia  
 NOEC 13020 mg/l

**Propane-1,2-diol**

Species Daphnia magna  
 EC50 > 10000 mg/l  
 Duration of exposure 48 h

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

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

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

Species activated sludge  
 NOEC > 100 mg/l

**12.2. Persistence and degradability****General information**

not determined



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

Value 0.93 to 1.67 mg/g

**12.3. Bioaccumulative potential****General information**

not determined

**Partition coefficient: n-octanol/water**

Remarks not determined

**12.4. Mobility in soil****General information**

not determined

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

not determined

**12.6. Other adverse effects****General information**

not determined

**General information / ecology**

Do not discharge product unmonitored into the environment.

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

Disposal in compliance with local and national regulations.

Allocation of a waste code number, according to the European Waste Catalogue (EWC), should be carried out in agreement with the regional waste disposal company.

**Disposal recommendations for packaging**

Packaging that cannot be cleaned should be disposed off as product waste.

**SECTION 14: Transport information**

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	Non-dangerous goods	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Water Hazard Class (Germany)**

Water Hazard Class (Germany) WGK 3

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Remarks

Derivation of WGK according to Annex 1 No. 5.2 AwSV

**15.2. Chemical safety assessment**

For this preparation a chemical safety assessment has not been carried out.

**SECTION 16: Other information****Hazard statements listed in Chapter 3**

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H411	Toxic to aquatic life with long lasting effects.

**CLP categories listed in Chapter 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

**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.