

Trade name: Trometamolium

Substance number: 068380

Version: 3 / CH

Date revised: 11.11.2025

Replaces Version: 2 / CH

Print date: 11.11.25

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

Trometamolium

Item No. 06838000

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

Manufacture of pharmaceutical products

**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 Irrit. 2 H315

Eye Irrit. 2 H319

STOT SE 3 H335

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

Warning

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

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

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

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P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P312 Call a POISON CENTRE or doctor if you feel unwell.  
 P501.3 Disposal in compliance with local and national regulations.

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

contains \*\*\* trometamol

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

Warning

**2.3. Other hazards**

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The Substance does not meet PBT-criteria. This substance does not meet the vPvB-criteria. This substance does not have endocrine disrupting properties with respect to humans. This substance does not have endocrine disrupting properties with respect to non-target organisms.

**SECTION 3: Composition/information on ingredients \*\*\*****Hazardous ingredients \*\*\*****trometamol**

CAS No.	77-86-1	
EINECS no.	201-064-4	
Concentration	>= 50	%
Classification (Regulation (EC) No. 1272/2008)		
	Skin Irrit. 2	H315
	Eye Irrit. 2	H319
	STOT SE 3	H335

**SECTION 4: First aid measures****4.1. Description of first aid measures****After inhalation**

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

**After skin contact**

Wash off immediately with soap and water and rinse well. Remove contaminated, soaked clothing immediately and dispose of safely. Consult a doctor if skin irritation persists.

**After eye contact**

Separate eyelids, wash the eyes thoroughly with water (15 min.). By continuous complaints consult a physician.

**After ingestion**

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By continuous complaints consult a physician. Do not induce vomiting. Never give anything by mouth to an unconscious person. Let plenty of water be drunk in small gulps.

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

Causes very strong irritations of the eyes, skin and mucous membranes. Cyanosis, Excitement, Nausea, Vomiting, Convulsions, Muscular atrophy, amentia, coma

### **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

##### **Suitable extinguishing media**

Water, Carbon dioxide, Foam, Dry powder, Extinguishing measures to suit surroundings

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

In the event of fire the following can be released: Nitrogen oxides (NO<sub>x</sub>); 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. Use personal protective clothing.

##### **Other information**

Suppress vapours with water spray jet. Collect contaminated fire-fighting water separately, must not be discharged into the drains.

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

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

Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not inhale dust. Ensure adequate ventilation.

#### 6.2. Environmental precautions

Do not allow to enter drains or waterways.

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

To pick up dry. Dispose of absorbed material in accordance with the regulations. Clean up affected area. Avoid raising dust.

#### 6.4. Reference to other sections

Information regarding waste disposal, see Section 13.

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

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

##### **Recommended storage temperature**

Value	15	-	25	°C
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##### **Requirements for storage rooms and vessels**

Keep container tightly closed and dry.

##### **Storage classes \*\*\***

Storage class according to TRGS 510	11	Combustible solids
Storage category (Switzerland)	11/13	Other solid hazardous substances with classification/labelling hazardous

### **SECTION 8: Exposure controls/personal protection \*\*\***

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**8.1. Control parameters****Exposure limit values****trometamol**

List	SUVA	
Type	MAK	
Value	0,1	mg/m <sup>3</sup>
Short term exposure limit	0,2	mg/m <sup>3</sup>
Maximum limit value: 4x15 Pregnancy group: C; Status: 2005		

**8.2. Exposure controls****Exposure controls**

See Section 7. No measures exceeding the ones mentioned necessary.

**General protective and hygiene measures**

Remove contaminated, soaked clothing immediately and dispose of safely. Preventative skin protection. Wash hands before breaks and after work. Keep away from food-stuffs, beverages and feed-stocks.

**Respiratory protection**

Dust mask

**Hand protection \*\*\***

The glove material must be sufficient impermeable and resistant to the substance. Check the tightness before wear. Gloves should be well cleaned before being removed, then stored in a well ventilated location.

Hand protection must comply with EN 374.

**Eye protection**

Tightly fitting safety glasses

**Body protection**

Protective clothing

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

<b>Physical state</b>	solid	
<b>Colour</b>	colourless	
<b>Odour</b>	odourless	
<b>Physical state</b>	crystals	
<b>Melting point</b>		
Value	169	°C
<b>Boiling point or initial boiling point and boiling range</b>		
Value	288	°C
<b>Flammability</b>		
evaluation	Not ignitable	
<b>Upper and lower explosive limits</b>		
Remarks	not determined	
<b>Flash point</b>		
Remarks	Not applicable	
<b>Auto-ignition temperature</b>		
Remarks	not determined	
<b>Viscosity</b>		
dynamic		

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Remarks Not applicable

**Partition coefficient n-octanol/water (log value)**

Remarks not determined

**Vapour pressure**

Remarks Not applicable

**Density and/or relative density \*\*\***

Value	1.32		g/cm <sup>3</sup>
Temperature	20	°C	

**9.2. Other information****Evaporation rate (ether = 1) :**

Remarks Not applicable

**Solubility in water**

Value	684		g/l
Temperature	20	°C	

**Explosive properties**

evaluation Not applicable

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

No dangerous reactions known.

**10.3. Possibility of hazardous reactions**

No hazardous reactions known.

**10.4. Conditions to avoid**

Protect from extreme heat and cold.

**10.5. Incompatible materials**

Bases, Reactions with oxidising agents.

**10.6. Hazardous decomposition products**

Corrosive gases/vapours

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

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

**Acute oral toxicity (Components)****trometamol**

Species	rat		
LD50	5000		mg/kg

**Acute dermal toxicity**

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

**Acute inhalational toxicity**

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

**Skin corrosion/irritation**

evaluation	irritant
Remarks	The classification criteria are met.

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**Skin corrosion/irritation (Components)**

trometamol  
evaluation                      irritant

**Serious eye damage/irritation**

evaluation                      irritant  
Remarks                      The classification criteria are met.

**Serious eye damage/irritation (Components)**

trometamol  
evaluation                      irritant - risk of serious damage to eyes

**Sensitization**

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

**Mutagenicity**

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

**Reproductive toxicity**

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

**Carcinogenicity**

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

**Specific Target Organ Toxicity (STOT)**

**Single exposure**  
Remarks                      The classification criteria are met.  
evaluation                      May cause respiratory irritation.

**Repeated exposure**  
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**

This substance does not have endocrine disrupting properties with respect to humans.

**Other information**

Observe the usual precautions for handling chemicals.

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

No data available

**12.2. Persistence and degradability****Biodegradability (Components)**

trometamol  
evaluation                      Readily biodegradable

**Ready degradability (Components)**

trometamol

**12.3. Bioaccumulative potential****Partition coefficient n-octanol/water (log value)**

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Remarks not determined

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

The Substance does not meet PBT-criteria.

This substance does not meet the vPvB-criteria.

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

This substance does not have endocrine disrupting properties with respect to non-target organisms.

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

Do not allow it to reach soil, ground water, water bodies or sewage system.

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

EWC waste code

No not dispose with rubbish.

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

WGK 3

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 Irrit. 2

H315

Calculation method

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Eye Irrit. 2  
STOT SE 3H319  
H335Calculation method  
Calculation method**Hazard statements listed in Chapter 2/3**

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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

Eye Irrit. 2	Eye irritation, Category 2
Skin Irrit. 2	Skin irritation, Category 2
STOT SE 3	Specific target organ toxicity - single exposure, Category 3

**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.