

# Trometamol

## Safety Data Sheet

**453919**

Version: 3.0

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830  
Date of issue: 19/07/2012      Revision date 31/01/2020  
Supersedes 01/03/2017

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

#### 1.1. Product identifier

Product form : Substance  
Substance name : Trometamol  
EC-No. : 201-064-4  
CAS-No. : 77-86-1  
Product code : 453919  
Formula : C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub>  
Synonyms : TRIS  
Product group : Raw material

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

##### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry  
Use of the substance/mixture : Excipient

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Duchefa Farma BV  
A. Hofmanweg 71  
2031BH Haarlem - Nederland  
T +31(0)23-5319093  
[farma@duchefa.nl](mailto:farma@duchefa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

#### 1.4. Emergency telephone number

Emergency number : Supplier contact information:  
+31(0)23-5319093 (M-F 09:00-17:00)  
+31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 2 H315  
Serious eye damage/eye irritation, Category 2 H319

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Specific target organ toxicity — Single exposure, Category 3, H335  
Respiratory tract irritation

Full text of H statements : see section 16

### Adverse physicochemical, human health and environmental effects

No additional information available

## 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display  
classification(s) to display

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H315 - Causes skin irritation.  
H319 - Causes serious eye irritation.  
H335 - May cause respiratory irritation.

Precautionary statements (CLP) : P280 - Wear eye protection, face protection, protective clothing,  
protective gloves.  
P305+P351 - IF IN EYES: Rinse cautiously with water for several  
minutes.  
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

## 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Trometamol	(CAS-No.) 77-86-1 (EC-No.) 201-064-4	99 - 100.5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of H-statements: see section 16

## 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: Remove victim to fresh air Seek medical advice.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water Seek medical advice.
First-aid measures after ingestion	: Rinse mouth. If you feel unwell, seek medical advice.

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

Symptoms/effects : Irritation to eyes, skin and respiratory tract.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : All extinguishing agents can be used.

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

Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides.

Explosion hazard : Product is not explosive.

#### 5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

### SECTION 6: Accidental release measures

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

##### 6.1.1. For non-emergency personnel

Emergency procedures : Ensure adequate air ventilation. Avoid raising dust.

##### 6.1.2. For emergency responders

Protective equipment : Wear proper protective equipment. [In case of inadequate ventilation] wear respiratory protection.

#### 6.2. Environmental precautions

Prevent product from entering drains.

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

Methods for cleaning up : Sweep up dry powder and dispose properly.

#### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

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

Storage conditions : Store in dry, well-ventilated area  
Keep container tightly closed.

Incompatible products : Strong bases. Strong oxidizing agent.

Storage temperature : 15 - 25 °C

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

#### Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

#### Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

#### Skin and body protection:

Wear suitable protective clothing.

#### Respiratory protection:

Dustmask with filtertype P2

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 121.1 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: 10.4 (1% solution)

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Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.353 g/cm <sup>3</sup>
Solubility	: Soluble in : Water Alcohol. Water: 550 g/l
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None under normal conditions.

### 10.4. Conditions to avoid

High temperature

Moisture.

### 10.5. Incompatible materials

Strong oxidizers.

### 10.6. Hazardous decomposition products

Carbon dioxide

Carbon monoxide

Nitrogen oxides.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Trometamol (77-86-1)	
LD50 oral rat	5900 mg/kg

Skin corrosion/irritation : Causes skin irritation.  
pH: 10.4 (1% solution)

Serious eye damage/irritation : Causes serious eye irritation.  
pH: 10.4 (1% solution)

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and degradability

Trometamol (77-86-1)	
Persistence and degradability	Biodegradable.

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
<b>14.1. UN number</b>	
Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>	
Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>	
Not applicable	Not applicable
Not applicable	Not applicable
<b>14.4. Packing group</b>	
Not applicable	Not applicable
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

#### 14.6. Special precautions for user

##### . Overland transport

No data available

##### - Air transport

No data available

#### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Trometamol is not on the REACH Candidate List

Trometamol is not on the REACH Annex XIV List

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

Indication of changes:

		Modified	Change of logo
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### Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

### Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

### SDS EU (REACH Annex II) duchefa nieuwe logo

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*