

Tetracaine hydrochloride

Safety Data Sheet

263311

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 2.0

Date of issue: 06/10/2014 Revision date: 03/04/2017

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

1.1. Product identifier

Product form : Substance
 Substance name : Tetracaine hydrochloride
 EC-No. : 205-248-5
 CAS-No. : 136-47-0
 Product code : 263311

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : Industrial
 For professional use only

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 - The Netherlands
 T +31(0)23-5319093
farma@duchefa.nl - 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)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute toxicity (oral), Category 3 H301
 Acute toxicity (dermal), Category 3 H311
 Acute toxicity (inhalation:gas) Category 3 H331
 Skin corrosion/irritation, Category 2 H315
 Serious eye damage/eye irritation, Category 2 H319
 Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation H335

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Full text of hazard classes and 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]

Hazard pictograms (CLP) :



GHS06

GHS07

Signal word (CLP) :

Danger

Hazard statements (CLP) :

H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled
 H315 - Causes skin irritation
 H319 - Causes serious eye irritation
 H335 - May cause respiratory irritation

Precautionary statements (CLP) :

P280 - Wear protective gloves, protective clothing, eye protection
 P309+P311 - IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician
 P302+P352 - IF ON SKIN: Wash with plenty of soap and water
 P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes
 P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing

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]
Tetracaine hydrochloride	(CAS-No.) 136-47-0 (EC-No.) 205-248-5	100	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:gas), H331 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 general :

Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

- First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- First-aid measures after skin contact : Remove/Take off immediately all contaminated clothing. Wash with plenty of soap and water. Wash contaminated clothing before reuse. Get medical advice/attention.
- First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Ensure adequate flushing of eyes by separating eyelids with the fingers. Get medical advice/attention.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

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

- Symptoms/effects after inhalation : Toxic if inhaled. Danger of serious damage to health by prolonged exposure through inhalation. May cause respiratory irritation.
- Symptoms/effects after skin contact : Repeated exposure to this material can result in absorption through skin causing significant health hazard. Toxic in contact with skin. Causes skin irritation.
- Symptoms/effects after eye contact : Causes serious eye irritation.
- Symptoms/effects after ingestion : Toxic if swallowed. Swallowing a small quantity of this material will result in serious health hazard.

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

No additional information available

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray. Carbon dioxide. Dry powder. For large fire: Foam. Water.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. 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 : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

Reference to other sections (8, 13).

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Take precautionary measures against static discharges.

Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store in a dry place. Keep only in the original container in a cool, well-ventilated place.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 15 - 25 °C

Storage area : TRGS 514 "Storage of toxic and very toxic substances ..." observe.

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Facilities: shower, eye shower.

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

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

Eye protection:

Chemical goggles or safety glasses

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

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Approved dust respirator. Dustmask with filtertype P3

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Molecular mass	: 300.8 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: 4.5 - 5.5
pH solution	: 10 g/l 20 °
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 147 - 150 °C
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)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 500 kg/m ³
Solubility	: Water: 150 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

Not established.

10.3. Possibility of hazardous reactions

Not established.

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10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Toxic if swallowed. Dermal: Toxic in contact with skin. Inhalation:gas: Toxic if inhaled.

Additional information	LD50 Mou = 70mg/kg
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Skin corrosion/irritation : Causes skin irritation.
pH: 4.5 - 5.5

Serious eye damage/irritation : Causes serious eye irritation.
pH: 4.5 - 5.5

Respiratory or skin sensitisation : Not classified

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

Potential adverse human health effects and symptoms : Toxic if swallowed. Toxic in contact with skin. Toxic if inhaled.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Tetracaine hydrochloride (136-47-0)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Tetracaine hydrochloride (136-47-0)	
BCF fish 1	<
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

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12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials : Avoid release to the environment. Hazardous waste due to toxicity.

SECTION 14: Transport information

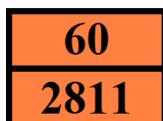
In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
6.1	6.1
	Not applicable
14.4. Packing group	
III	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

- Overland transport

Classification code (ADR) : T2
Special provisions (ADR) : 274, 614
Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1
Vehicle for tank carriage : AT
Transport category (ADR) : 2
Hazard identification number (Kemler No.) : 60
Orange plates :



Tunnel restriction code (ADR) : E
EAC code : 2X

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- 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

Tetracaine hydrochloride is not on the REACH Candidate List

Tetracaine hydrochloride 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:

1.4	Emergency telephone	Modified	Added additional information
2	R-phrases	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Skin and body protection	Modified	Added additional information (type of clothing related to concentration levels)

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.

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Other information

: REACH Disclaimer:

This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
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
H301	Toxic if swallowed
H311	Toxic in contact with skin
H315	Causes skin irritation
H319	Causes serious eye irritation
H331	Toxic if inhaled
H335	May cause respiratory irritation

SDS EU (REACH Annex II) Version 2017

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