

SAFETY DATA SHEET

Tricaine Pharmaq

The safety data sheet is in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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

Date issued 15.09.2016

Revision date 09.11.2016

1.1. Product identifier

Product name Tricaine Pharmaq

No requirement for SDS There is no requirement according to the REACH Regulation (EC) No. 1907/2006, Article 31.

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

Product group Veterinary medicinal products

Use of the substance/preparation Powder for solution bath for the treatment of fish. Anesthetic.

1.3. Details of the supplier of the safety data sheet

Distributor

Company name Pharmaq AS

Office address Industrivegen 50

Postal address Skogmo Industriområde

Postcode 7863

City Overhalla

Country Norge

Tel 74280800

Fax 74280801

E-mail customer.service@pharmaq.no

Website <http://www.pharmaq.no>

1.4. Emergency telephone number

Emergency telephone Emergency telephone number (Italy):112
Emergency telephone number Norway (Giftinformasjonen):+47 22 59 13 00
Emergency telephone number (UK):999 or 112

SECTION 2: Hazards identification

2.1. Classification of substance or mixture

CLP Classification, Comments This is a veterinary medicinal product, and is therefore not a subject to classification and labelling of chemicals.

Substance / mixture hazardous properties Irritating to the eyes, skin and respiratory system.

2.2. Label elements

Other EU labelling requirements This is a veterinary medicinal product, and is thus not a subject to classification and labelling of chemicals.

2.3. Other hazards

PBT / vPvB The chemical contains no PBT or vPvB substances.

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance	Identification	Classification	Contents
3-ethoxycarbonylanilinium methanesulphonate	CAS no.: 886-86-2 EC no.: 212-956-8	Skin Irrit. 2;H315; Eye Irrit. 2;H319; STOT SE3;H335;	100 %

Substance comments See section 16 for explanation of hazard statements (H) listed above.

SECTION 4: First aid measures

4.1. Description of first aid measures

General	Emergency telephone number: see section 1.4.
Inhalation	Fresh air and rest. Get medical attention if any discomfort continues.
Skin contact	Remove contaminated clothing. Wash the skin immediately with soap and water. Contact physician if irritation continues.
Eye contact	Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyes wide apart. Contact physician if irritation persists.
Ingestion	Rinse mouth with water. Drink a few glasses of water or milk. Do not induce vomiting. Get medical attention if any discomfort continues. Do not give victim anything to drink if he is unconscious.

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

Acute symptoms and effects	Eye contact: Irritating to eyes and may cause redness and burning. Inhalation: May cause respiratory irritation. Skin contact: The chemical irritates the skin and can cause itching, burning and redness.
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4.3. Indication of any immediate medical attention and special treatment needed

Other Information Treat symptomatically. No specific information from the manufacturer.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Dry-powder, carbon dioxide (CO ₂), water mist, foam.
Improper extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Fire and explosion hazards	Not flammable, but combustible.
Hazardous combustion products	May include, but is not limited to: Carbon monoxide (CO). Carbon dioxide (CO ₂). Sulphurous gases (SO _x). Nitrous gases (NO _x). Decomposition may produce toxic gases.

5.3. Advice for firefighters

Personal protective equipment	Use compressed air equipment when the chemical is involved in fire. In case of evacuation, an approved protection mask should be used. See also section 8.
Other Information	Containers close to fire should be removed immediately or cooled with water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	Provide adequate ventilation.
Personal protection measures	Use protective equipment as referred to in section 8. Avoid inhalation of vapours and contact with skin and eyes.

6.2. Environmental precautions

Environmental precautionary measures Do not allow to enter into sewer, water system or soil.

6.3. Methods and material for containment and cleaning up

Cleaning method Sweep up and place into an appropriate container.

Containment Collect in suitable containers and deliver as hazardous waste according to section 13.

6.4. Reference to other sections

Other instructions See also sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling Provide adequate ventilation. Avoid inhalation of vapours and contact with skin and eyes. Change contaminated clothing. Use protective equipment as referred to in section 8.
People with known hypersensitivity (allergy) to anesthetics like Tricaine Mesilate (Tricaine Methane Sulphonate) should not handle the veterinary medicinal product."

Protective Safety Measures

Advice on general occupational hygiene Wash hands after contact with the chemical. Change contaminated clothing and take off protective equipment before the meal. Do not smoke, drink or eat in the workplace.

7.2. Conditions for safe storage, including any incompatibilities

Storage Store in closed original container in a dry place. Store protected against heat and direct sunlight.

7.3. Specific end use(s)

Specific use(s) See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational Exposure limit values

Substance	Identification	Value	TWA Year
Respirable dust		8-hour TWA: 4 mg/m ³	
Total inhalable dust		8-hour TWA: 10 mg/m ³	
Total inhalable dust (Norway)		8-hour TWA: 10 mg/m ³	
Respirable dust (Norway)		8-hour TWA: 5 mg/m ³	
Other Information about threshold limit values	References (laws/regulations): EH40/2005 Workplace exposure limits, with later amendments. Norwegian regulation on exposure limits: "FOR-2011-12-06-1358 Forskrift om tiltaksverdier og grenseverdier for fysiske og kjemiske faktorer i arbeidsmiljøet samt smitterisikogrupper for biologiske faktorer (forskrift om tiltaks- og grenseverdier)". Italian regulation on exposure limits Allegato XXXVIII Valori limite di esposizione professionale (Italy) Contains no substances with occupational exposure limit values.		

8.2. Exposure controls

Limitation of exposure on workplace	Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded. The personal protective equipment must be CE-marked and the latest version of the standards shall be used. The protective equipment and the specified standards recommended below are only suggestions, and should be selected on advice from the supplier of such equipment. A risk assessment of the work place/work activities (the actual risk) may lead to other control measures. The protection equipments suitability and durability will depend on application.
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Respiratory protection

Respiratory protection	In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P2).
Reference to relevant standard	EN 143 (Respiratory protective devices. Particle filters. Requirements, testing, marking).

Hand protection

Hand protection	Use chemical resistant gloves. The chemical is solid and cannot penetrate normal glove materials.
Reference to relevant standard	BS-EN 374 (Protective gloves against chemicals and micro-organisms). BS-EN 420 (Protective gloves. General requirements and test methods).
Breakthrough time	No specific information from the manufacturer.
Thickness of glove material	No specific information from the manufacturer.
Additional hand protection measures	Replace gloves if signs of wear and tear.

Eye / face protection

Eye protection	Use tight fitting goggles if dust is generated.
Reference to relevant standard	EN 166 (Personal eye-protection. Specifications).

Skin protection

Skin protection (except hands)	Wear appropriate clothing to prevent reasonably probable skin contact.
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Appropriate environmental exposure control

Environmental exposure controls	Do not allow to enter into sewer, water system or soil.
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Other Information

Other Information	Emergency shower and eye wash facilities should be available at the workplace.
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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid. Crystalline powder. (Fine powder.)
Colour	White.
Odour	None.
Comments, Odour limit	Not specified by the manufacturer.
Comments, pH (as supplied)	Not specified by the manufacturer.
Melting point/melting range	Value: 147-150 °C
Comments, Boiling point / boiling range	Not specified by the manufacturer.
Comments, Flash point	Not specified by the manufacturer.
Comments, Evaporation rate	Not specified by the manufacturer.
Flammability (solid, gas)	Not specified by the manufacturer.
Comments, Explosion limit	Not specified by the manufacturer.
Comments, Vapour pressure	Not specified by the manufacturer.
Comments, Vapour density	Not specified by the manufacturer.

Comments, Specific gravity	Not specified by the manufacturer.
Solubility in water	Insoluble in cold water.
Comments, Partition coefficient: n-octanol / water	Not relevant for a mixture.
Comments, Spontaneous combustability	Not specified by the manufacturer.
Comments, Decomposition temperature	Not specified by the manufacturer.
Comments, Viscosity	Not relevant.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

9.2. Other information

Other physical and chemical properties

Comments	No further information is available.
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SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	No test data available.
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10.2. Chemical stability

Stability	The chemical is stable under normal conditions of storage and use.
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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	Arise in contact with incompatible materials (see section 10.5) and/or under inappropriate conditions (see section 10.4).
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10.4. Conditions to avoid

Conditions to avoid	Moisture.
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10.5. Incompatible materials

Materials to avoid	Acids, acid chlorides, acid anhydrides, chloroformates and strong oxidizing agents.
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10.6. Hazardous decomposition products

Hazardous decomposition products	None under normal conditions. See also section 5.2.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological Information:

LD50 oral	Value: 4000 mg/kg Animal test species: rabbit
LD50 oral	Value: 2400 mg/kg Animal test species: mouse
LD50 oral	Value: 5200 mg/kg Animal test species: rat
LD50 dermal	Value: 170 mg/kg Animal test species: mouse Comments: (Intravenous)

Acute toxicity, Mixture estimate

Assessment of acute toxicity classification	Based on available data, the classification criteria are not met.
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Potential acute effects

Inhalation	Dust may irritate the respiratory system.
Skin contact	Irritates the skin. May cause redness, stinging and itching.
Eye contact	Irritating to eyes and may cause redness, watering and stinging.

Ingestion	May cause discomfort if swallowed.
Assessment corrosion / irritation classification	Irritating to skin.
Aspiration hazard	Based on available data, the classification criteria are not met.
Assessment eye damage or irritation, classification	Causes serious eye irritation.

Delayed effects / repeated exposure

Sensitisation	The chemical contains small amount of allergy-causing material which may give rise to allergy to sensitive persons. Based on available data, the classification criteria are not met.
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	Based on available data the classification criteria are not met.

Carcinogenic, Mutagenic or Reprotoxic

Carcinogenicity	Based on available data, the classification criteria are not met.
Mutagenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	The chemical is not classified as harmful to the environment.
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12.2. Persistence and degradability

Persistence and degradability	Parts of the chemical are degradable.
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12.3. Bioaccumulative potential

Bioaccumulative potential	No data available on bioaccumulation.
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12.4. Mobility in soil

Mobility	Insoluble in water. Sinks in water.
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12.5. Results of PBT and vPvB assessment

PBT assessment results	The chemical contains no PBT-substances.
vPvB evaluation results	The chemical contains no vPvB substances.

12.6. Other adverse effects

Other adverse effects / Remarks	Do not allow to enter into sewer, water system or soil.
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Specify the appropriate methods of disposal	Used solution shall be filtered through a charcoal filter. Clinical waste from veterinary establishments are not allowed to deposit. Carbon filter with medicine must be disposed of in a proper manner. The waste code (EWC-Code) is intended as a guide. The user must select a code if the use differs from the one mentioned below.
EWC waste code	EWC: 18 02 06 chemicals other than those mentioned in 18 02 05
Other Information	Do not empty into drains.

SECTION 14: Transport information

14.1. UN number

Comments	Not considered as dangerous goods under UN, IMO, ADR/RID or IATA/ICAO regulations.
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14.2. UN proper shipping name

Comments	Not relevant.
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14.3. Transport hazard class(es)

Comments Not relevant.

14.4. Packing group

Comments Not relevant.

14.5. Environmental hazards

Comments Not relevant.

14.6. Special precautions for user

Special safety precautions for user Not relevant.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Pollution category Not relevant.

SECTION 15: Regulatory information

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

References (laws/regulations)

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP-regulation) with later amendments.
 Commission Regulation (EU) No 453/2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
 The List of Wastes (England) (Amendment) Regulations 2005. (SI 2005 No. 895).
 The List of Wastes Regulations (Northern Ireland) 2005.
 Dangerous Goods regulations
 DIRECTIVE 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

FOR-2012-06-16 nr 622 Norwegian regulation on classification, labeling and packaging of substances and mixtures (CLP), with later amendments.
 FOR-2008-05-30 nr 516 Norwegian regulation on the registration, evaluation, authorization and restriction of chemicals (REACH Regulation), with later amendments.
 Norwegian regulations on waste, no. 930/2004, from the Ministry of Environment.
 Dangerous Goods regulations.
 Norwegian regulation FOR-2007-01-16 nr 50 on the use of veterinary medicines, as amended.

15.2. Chemical safety assessment

Chemical safety assessment performed No

SECTION 16: Other information

Supplier's notes The information contained in this SDS must be made available to all those who handle the product.

List of relevant H-phrases (Section 2 and 3).
 H315 Causes skin irritation.
 H335 May cause respiratory irritation.
 H319 Causes serious eye irritation.

Abbreviations and acronyms used
 ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
 RID: The Regulations concerning the International Carriage of Dangerous Goods by Rail
 IMDG: The International Maritime Dangerous Goods Code
 ICAO-TI: International Civil Aviation Organization - Technical Instructions for

	<p>the Safe Transport of Dangerous Goods by Air IATA: The International Air Transport Association LD50: Lethal dose, is the amount of a substance given to a group of test animals, which causes the death of 50%. Log Pow: Partition coefficient: n-octanol / water PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative EWC: European Waste Code (a code from the EU's common classification system for waste) Infectious waste: waste from medical or veterinary treatment and/or related to research containing viable microorganisms or their toxins which are known or believed to cause disease in humans or other living organisms.</p>
Important data sources used to construct the safety data sheet	Suppliers Safety data sheet dated: 14.10.2013
Information which has been added, deleted or revised	New Safety Data Sheet.
Checking quality of information	This SDS is quality controlled by Kiwa Teknologisk Institutt in Norway, certified according to the Quality Management System requirements specified in ISO 9001:2008.
Version	1
Responsible for safety data sheet	Pharmaq AS
Prepared by	Kiwa Teknologisk Institutt as, Norway v/ Maria Andersen