SAFETY DATA SHEET
(in accordance with Regulation (EU) 2015/830)

121210-Tiamulin hydrogen fumarate USP

Version: 1
Revision date: 10/10/2017
Print date: 10/10/2017

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.
Product Name: Tiamulin hydrogen fumarate USP
Product Code: 121210
Chemical Name: Tiamulin hydrogen fumarate USP
CAS No: 55297-96-6
EC No: 259-581-6
Registration No: N/D

1.2 Relevant identified uses of the substance and uses advised against.
For manufacturing, processing, laboratory or repacking use only
Uses advised against:
Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.
Company: DC FINE CHEMICALS Ltd.
Address: Hill Top, 88
City: NW11 6DY London (United Kingdom)
Telephone: +44 (20) 7586 6800
Fax: +44 (20) 7504 1701
E-mail: info@dcfinechemicals.com
Web: www.dcfinechemicals.com

1.4 Emergency telephone number: (Only available during office hours)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance.
In accordance with Regulation (EU) No 1272/2008:
Acute Tox. 4 : Harmful if swallowed.

2.2 Label elements.
Labelling in accordance with Regulation (EU) No 1272/2008:
Pictograms:

![Warning]

Signal Word: Warning
H statements: H302 Harmful if swallowed.
P statements:
P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/If you feel unwell.
P330 Rinse mouth.
P501 Dispose of contents / container according to the regulation.

Contains:
Tiamulin hydrogen fumarate USP

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2.3 Other hazards.
In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.
Chemical Name: Tiamulin hydrogen fumarate USP
CAS No: 55297-96-6
EC No: 259-581-6
Registration No: N/D

3.2 Mixtures.
Not Applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.
In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

Inhalation.
Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.
Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Don’t let the person rub the affected eye.

Skin contact.
Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

Ingestion.
If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed.
Harmful Product, prolonged exposure due to inhalation may cause anaesthetic effects and the need for immediate medical assistance.

4.3 Indication of any immediate medical attention and special treatment needed.
In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Do not induce vomiting. If the person vomits, clear the respiratory tract.

SECTION 5: FIREFIGHTING MEASURES.

The product is NOT classified as flammable, in case of fire the following measures should be taken:

5.1 Extinguishing media.
Suitable extinguishing media:
Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:
Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance.
Special risks:
Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.
Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

**Fire protection equipment.**
According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

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### SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 **Personal precautions, protective equipment and emergency procedures.**
For exposure control and individual protection measures, see section 8.

6.2 **Environmental precautions.**
Prevent the contamination of drains, surface or subterranean waters, and the ground.

6.3 **Methods and material for containment and cleaning up.**
The contaminated area should be immediately cleaned with an appropriate de-contaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

6.4 **Reference to other sections.**
For exposure control and individual protection measures, see section 8. For later elimination of waste, follow the recommendations under section 13.

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### SECTION 7: HANDLING AND STORAGE.

7.1 **Precautions for safe handling.**
For personal protection, see section 8. Never use pressure to empty the containers. They are not pressure-resistant containers. In the application area, smoking, eating, and drinking must be prohibited. Follow legislation on occupational health and safety. Keep the product in containers made of a material identical to the original.

7.2 **Conditions for safe storage, including any incompatibilities.**
Store according to local legislation. Observe indications on the label. Recommended storage temperature: +2 - +8°C. Keep far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills. The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 **Specific end use(s).**
Not available

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### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 **Control parameters.**
The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 **Exposure controls.**

**Measures of a technical nature:**
Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

<table>
<thead>
<tr>
<th>Concentration:</th>
<th>100 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uses:</td>
<td>For manufacturing, processing, laboratory or repacking use only</td>
</tr>
</tbody>
</table>

**Breathing protection:**

- PPE: Filter mask for protection against gases and particles.
- Characteristics: «CE» marking, category III. The mask must have a wide field of vision and an anatomically designed form in order to be sealed and watertight.
- CEN standards: EN 136, EN 140, EN 405

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Appearance: Solid
Colour: N.A./N.A.
Odour: N.A./N.A.
Odour threshold: N.A./N.A.

Melting point: 148 ºC
Boiling Point: 585 ºC
Flash point: >110 ºC
Evaporation rate: N.A./N.A.
Inflammability (solid, gas): N.A./N.A.
Lower Explosive Limit: N.A./N.A.
Upper Explosive Limit: N.A./N.A.
Vapour pressure: N.A./N.A.
Vapour density: N.A./N.A.
Relative density: N.A./N.A.
Solubility: N.A./N.A.
Liposolubility: N.A./N.A.
Hydrosolubility: N.A./N.A.
Partition coefficient (n-octanol/water): N.A./N.A.
Auto-ignition temperature: N.A./N.A.
Decomposition temperature: N.A./N.A.
Viscosity: N.A./N.A.
Explosive properties: N.A./N.A.

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Oxidizing properties: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

9.2 Other information.
Pour point: N.A./N.A.
Blink: N.A./N.A.
Kinematic viscosity: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.
The product does not present hazards by their reactivity.

10.2 Chemical stability.
Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.
The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.
Avoid any improper handling.

10.5 Incompatible materials.
Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.
No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on toxicological effects.
Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin. Splatters in the eyes can cause irritation and reversible damage.

Toxicological information.

<table>
<thead>
<tr>
<th>Name</th>
<th>Acute toxicity</th>
<th>Type</th>
<th>Test</th>
<th>Kind</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tiamulin hydrogen fumarate USP</td>
<td>Oral</td>
<td>DL50</td>
<td>rat</td>
<td></td>
<td>841 mg/kg</td>
</tr>
<tr>
<td>CAS No: 55297-96-6</td>
<td>Dermal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC No: 259-581-6</td>
<td>Inhalation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a) acute toxicity;
Product classified:
Acute toxicity (Oral), Category 4: Harmful if swallowed.

b) skin corrosion/irritation;
Not conclusive data for classification.

c) serious eye damage/irritation;
Not conclusive data for classification.

d) respiratory or skin sensitisation;
Not conclusive data for classification.

e) germ cell mutagenicity;
Not conclusive data for classification.

f) carcinogenicity;
Not conclusive data for classification.

g) reproductive toxicity;
Not conclusive data for classification.

h) STOT-single exposure;
Not conclusive data for classification.

i) STOT-repeated exposure;
Not conclusive data for classification.

j) aspiration hazard;
Not conclusive data for classification.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.
There is no information available on the biodegradability of the substances present.

12.2 Persistence and degradability.
There is no information available on the degradability of the substances present.
No information is available regarding the degradability.No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.
No information is available regarding the bioaccumulation.

12.4 Mobility in soil.
No information is available about the mobility in soil.
The product must not be allowed to go into sewers or waterways.
Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.
No information is available about the results of PBT and vPvB assessment of the product.

12.6 Other adverse effects.
No information is available about other adverse effects for the environment.

SECTION 13 DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.
Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

SECTION 14: TRANSPORT INFORMATION.

Transport following ADR rules for road transport, RID rules for railway, ADN for inner waterways, IMDG for sea, and ICAO/IATA for air transport.

Land: Transport by road: ADR, Transport by rail: RID.
Transport documentation: Consignment note and written instructions

Sea: Transport by ship: IMDG.
Transport documentation: Bill of lading

Air: Transport by plane: ICAO/IATA.
Transport document: Airway bill.

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14.1 UN number.
UN No: UN2811

14.2 UN proper shipping name.
Description:
ADR: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS TIAMULIN HYDROGEN FUMARATE USP), 6.1, PG III, (E)
IMDG: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS TIAMULIN HYDROGEN FUMARATE USP), 6.1, PG III
ICAO/IATA: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS TIAMULIN HYDROGEN FUMARATE USP), 6.1, PG III

14.3 Transport hazard class(es).
Class(es): 6.1

14.4 Packing group.
Packing group: III

14.5 Environmental hazards.
Marine pollutant: No

14.6 Special precautions for user.
Labels: 6.1

Provisions concerning carriage in bulk ADR:
VC1 Carriage in bulk in sheeted vehicles, sheeted containers or sheeted bulk containers is permitted.
VC2 Carriage in bulk in closed vehicles, closed containers or closed bulk containers is permitted.
AP7 Carriage in bulk shall only be as a full load.
Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): F-A,S-A
Proceed in accordance with point 6.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code.
The product is not transported in bulk.

SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by Directive 2012/18/EU (SEVESO III).
The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.
The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.
No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Classification codes:
Acute Tox. 4 : Acute toxicity (Oral), Category 4

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Abbreviations and acronyms used:
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CEN: European Committee for Standardization.
PPE: Personal protection equipment.
IATA: International Air Transport Association.
ICAO: International Civil Aviation Organization.
RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.

Key literature references and sources for data:
http://eur-lex.europa.eu/homepage.html
http://echa.europa.eu/


The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.