

Vetmulin® 12.5%

SAFETY DATA SHEET

Revised: July 2020

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SECTION 1: IDENTIFICATION

1.1. Product Identifier:

Material name: Tiamulin hydrogen fumarate
Trade name: Vetmulin® 12.5%
Product number: SMVE-00073

1.2. Manufacturer/Distributor:

Huvepharma, Inc.
 525 Westpark Drive, Suite 230
 Peachtree City, GA 30269
 Telephone: 1-770-486-7212
 Emergency telephone: 1-877-994-4883
 Contact: customerservice@huvepharma.us

1.3. Relevant identified uses and any restrictions:

Intended use: Veterinary pharmaceutical
Restrictions on use: For animal use only. Not for human use.

SECTION 2: HAZARD(S) IDENTIFICATION

2.1. Physical hazards	Not classified	
Health hazards	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2
	Sensitization, respiratory	Category 1
OSHA defined hazards	Flammable liquid	Category 4

Label elements



2.2. Signal word Warning

Hazard statement

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

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2.4. Precautionary statement(s):

Prevention

- P264 Wash hands thoroughly after handling.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P261 Avoid breathing dust.
 P271 Use only outdoors or in a well-ventilated area.

Response

- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P321 Specific treatment (see heading "After contact with skin" in item 4).
 P332 + P313 If skin irritation occurs: Get medical advice/attention.
 P362 + P364 Take off contaminated clothing and wash it before reuse.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P337 + P313 If eye irritation persists: Get medical advice/attention.
 P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 P312 Call a POISON CENTER or doctor/physician if you feel unwell.

Storage

- P403 + P233 Store in a well-ventilated place. Keep container tightly closed.
 P405 Store locked up.

Disposal

- P501 Dispose of contents/container in accordance with local/ regional/national/ international regulations.

2.5. Hazards not otherwise classified: None known.

Supplemental Information None

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	% content	CAS No/EC no	CLP classification
Tiamulin hydrogen fumarate	12.5	55297-96-6	H302 H315 H319 H335
Ethanol	< 10	64-17-5	H225 H319
Disodium phosphate anhydrous	< 1	7558-79-4	H319
Water for Injection	Up to 100	N/A	-

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Remaining components are non-hazardous and/or below required reporting limits.

SECTION 4: FIRST-AID MEASURES

4.1. First aid measures:

- **General:** People with known hypersensitivity to macrolides should avoid contact with the veterinary medicinal product.
Contaminated clothing must be taken off.
The person must receive immediate medical attention.
- **Eye contact:** Flush immediately with large amounts of water for at least 15 minutes. Eyelids should be held away from the eyeball to ensure thorough rinsing. Get medical attention if irritation persists.
- **Skin contact:** Wash area thoroughly with soap and water. Remove and wash contaminated clothing. Get medical attention if irritation persists.
- **Ingestion:** If swallowed, wash out mouth with water. Never give anything by mouth to an unconscious person. Get medical attention.
- **Inhalation:** Safely remove victim to fresh air. If not breathing, institute cardiopulmonary resuscitation (CPR). If breathing is difficult, ensure clear airway and give oxygen. Get medical attention if symptoms develop or persist.
- **Precautions to be considered:** In case of hypersensitivity to the substance, avoid direct contact.

4.2. **Most important symptoms and effects, both acute and delayed:** No data available.

4.3. **Recommended immediate medical attention and special treatment needed:** No data available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media:

Water spray, carbon dioxide, dry chemical powder or appropriate foam. Use extinguishing media suitable for surrounding fire.

5.2. Specific hazards arriving from the substance or mixture:

May emit toxic fumes under fire conditions. They are: carbon monoxide, carbon dioxide, nitrogen oxides, and sulphur oxides.

5.3. **Advice for firefighters:** As with all fires, evacuate personnel to safe area. Fire fighters should use self-contained breathing equipment and protective clothing.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions and protective equipment:

Wear suitable protective equipment and clothing. Ensure adequate ventilation. Avoid breathing mist or vapor. Avoid contact with skin and eyes.

6.2. Emergency procedures:

Prevent spilled material from flowing onto adjacent land or into streams, ponds or lakes. Dike spilled liquid. Absorb liquid with dry sand or earth. Do not return spilled liquid to the original container.

6.3. Methods and materials for containment:

Carefully wipe the spillage with absorbent material and discard. Place material in a dry container and cover. Remove from the area. Flush spill area with water.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling:

Use personal protective equipment while handling the product. Avoid contact with eyes, skin, and clothing. Wear appropriate personal protective equipment. Provide adequate ventilation.

7.2. Conditions for safe storage, including any incompatibilities:

Protect from direct sunlight. Store in the original container, tightly closed.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Exposure controls:

Occupational Exposure Limits:

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Ethanol (CAS 64-17-5)	PEL	1900 mg/m ³

Recommended monitoring procedures: None

Biological Limit Values: No biological exposure limits noted for the ingredients

Derived no-effect level (DNEL): Not available

Predicted no-effect concentrations (PNECs): Not available

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8.2. Engineering controls:

Ventilation:	Local exhaust hood:	Recommended
	General exchange:	Recommended

8.3. Personal protective measures:

Direct contact with the skin, eyes and mucous membranes should be avoided by wearing personal protective equipment, impermeable rubber gloves and safety glasses when mixing or handling the product.

In case of accidental eye contact, irrigate the eyes thoroughly with clean running water immediately. Seek medical advice if irritation persists.

Contaminated clothing should be removed and any splashes on to the skin should be washed off immediately.

Wash hands after use.

Accidental ingestion should be avoided. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

People with known hypersensitivity to tiamulin should avoid contact with the product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Physical and chemical properties:

- | | |
|---|--|
| • Appearance: | Colorless to slight yellow solution |
| • Upper/lower flammability or explosive limits: | 45 g/m ³ (lower limit) |
| • Odor: | No data available |
| • Vapor pressure: | No data available |
| • Odor threshold: | No data available |
| • Vapor density: | No data available |
| • pH: | From 3.5 to 4.5 |
| • Relative density: | No data available |
| • Melting point/freezing point: | 146-152°C (tiamulin hydrogen fumarate) |
| • Solubility(ies): | Freely soluble in methanol; soluble in water and ethanol |
| • Initial boiling point and boiling range: | No data available |
| • Flash point: | No data available |
| • Evaporation rate: | No data available |
| • Flammability (solid, gas): | No data available |
| • Auto-ignition temperature: | No data available |
| • Decomposition temperature: | No data available |
| • Viscosity: | No data available |
| • Explosive properties: | No data available |
| • Oxidizing properties: | No data available |

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9.2. Other information:

Specific optical rotation (0.5% in dioxane):	From +24.0° to +28.0° (tiamulin hydrogen fumarate)
pKa:	7.64
Minimum cloud ignition temperature	400°C
Minimum ignition energy	Between 3 mJ and 10 mJ
Electrical volume resistivity:	2 10 ¹² Ωm
Density:	1.005 - 1.015 g/ml
UV absorption of aqueous solution (tiamulin hydrogen fumarate):	
• At 400 nm (1:20, 1 cm)	Not less than 0.150
• At 650 nm (1:20, 1 cm)	Not less than 0.030

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Non-reactive.

10.2. Chemical stability:

Stable under normal conditions.

10.3. Other:

- **Possibility of hazardous reactions:** No data available.
- **Conditions to avoid:** High temperature, contact with incompatible materials.
- **Incompatible material:** None known.
- **Hazardous decomposition products:** Does not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects General Information:

a) acute toxicity:

Components		Species	Test results
			LD50
Tiamulin Fumarate (CAS 55297-96-6)	Acute Oral	Rat	2230 mg/kg
Ethanol (CAS 64-17-5)	Dermal	Rabbit	>5000 mg/kg
	Inhalation	Rat	124.7 mg/l, 4 hr
	Oral	Rat	7060 mg/kg

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- | | |
|---------------------------------------|-------------------|
| b) skin corrosion/irritation: | No data available |
| c) serious eye damage/irritation: | No data available |
| d) respiratory or skin sensitization: | No data available |

SECTION 12: ECOLOGICAL INFORMATION

Environmental overview:

No environmental data for the mixture or formulation. The environmental information for ingredient(s) or related material(s) are presented.

12.1. Toxicity

Blue-green algae (*Anabaena flos-aquae*) 72-hour median effective concentration EC₅₀ (growth): 0.29 mg/L.

Green algae (*Selensastrum capricornutum*) 72-hour median effective concentration EC₅₀ (growth): 0.165 mg/L.

Daphnia magna 48-hour median effective concentration EC₅₀ (immobilization): 40 mg/L.

Daphnia magna 48-hour median effective concentration EC₅₀ (reproduction): 5.4 mg/L.

Daphnia magna 48-hour median effective concentration EC₅₀ (survival): 67 mg/L.

Fish (*Oncorhynchus mykiss*) 96-hour median lethal concentration LC₅₀: 20 mg/L.

Collembolans (*Folsomia fimetaria*) median lethal concentration LC₅₀: ≥ 5000 mg/kg.

Collembolans (*Folsomia fimetaria*) median effective concentration EC₅₀ (reproduction): 475 mg/kg.

Enchytraeids (*Enchytraeus crypticus*) No observed effect concentration NOEC (survival): > 5000 mg/kg.

Earthworms (*Apporectodea caliginosa*) 14-day median lethal concentration LC₅₀: > 1000 mg/kg.

12.2. Persistence and degradability: No data available.

Log Kow: -0.05-0.02; 0.27-0.51; 0.9; 2.1-2.2
(respectively at pH 4.1, 5, 6, 7).

Pka: 7.64

Water solubility (25°C): 5.8% w/v.

12.3. Bioaccumulation potential: No data available.

12.4. Mobility in soil: No data available.

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12.5. Results of PBT and VPVB assessment: Tiamulin is not classified as a PBT or vPvB substance.

12.6. Other adverse effects: No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: TRANSPORT INFORMATION

General Information:

Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

DOT

Not regulated as dangerous goods.

IATA

UN number	UN3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (Tiamulin Fumarate)
Transport hazard class(es)	
Class	9
Subsidiary risk	--
Packing group	III
Environmental hazards	Yes
ERG Code	9L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

IMDG

UN Number	UN3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tiamulin Fumarate) (TIAMULIN FUMARATE, PROPYLPARABEN)

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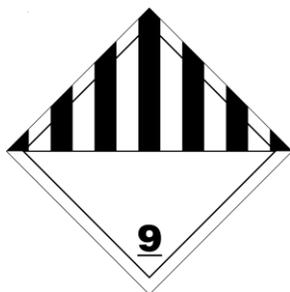
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Transport hazard class(es)

Class	9
Subsidiary risk	--
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Not available.
TIAMULIN FUMARATE PROPYLPARABEN	

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

IATA; IMDG



Marine pollutant



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SECTION 15: REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

OSHA Classification	This product is a Class II combustible liquid as defined under the OSHA Hazard Communication Standard.
FFDCA	This product is regulated under the US Federal Food, Drug and Cosmetics Act.
Waste Classification	If discarded in its manufactured form, this product is a solid waste under RCRA (U.S.) and CEPA (Canada). However, it is the responsibility of the user to determine at the time of disposal whether a material containing the product or derived from the product should be classified as a solid or hazardous waste. See Section 13 for additional information.
EPCRA/SARA III	This product contains no toxic chemicals at or above the <i>de-minimis</i> threshold subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR 372.
International Regulations	This product may be regulated by various countries' drug-regulating agencies.
California Proposition 65	This product is in compliance with California Proposition 65.

SECTION 16: OTHER INFORMATION

Classification of the chemical:

Health:	1
Fire:	2
Reactivity:	0

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End of Safety Data Sheet