

1. Identification

Product identifier Denagard® (Tiamulin) Liquid Concentrate
Other means of identification None.
Recommended use Veterinary Pharmaceutical
Recommended restrictions None known.
Manufacturer/Importer/Supplier/Distributor information
Manufacturer
Company Name Novartis Animal Health
Address 3200 Northline Avenue, Suite 300
 Greensboro, NC 27408
 1-336-387-1000
Telephone 1-336-387-1000
SDS E-mail lilly_msds@lilly.com
SDS telephone 1-877-Elanco1 (1-877-352-6261)
Emergency Telephone Numbers Elanco Product Technical Support / Human or Animal Exposure Reporting:
 1-888-545-5973
 Transportation Emergency Telephone: CHEMTREC 1-800-424-9300
 (Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards Flammable liquids Category 3
Health hazards Serious eye damage/eye irritation Category 2A
OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement
 H226 Flammable liquid and vapor.
 H319 Causes serious eye irritation.

Precautionary statement
Prevention
 P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
 P240 Ground/bond container and receiving equipment.
 P243 Take precautionary measures against static discharge.
 P280 Wear protective gloves/eye protection/face protection.

Response
 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.
 P370 + P378 In case of fire: Use appropriate media to extinguish.

Storage
 P403 + P235 Store in a well-ventilated place. Keep cool.

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

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental Information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Tiamulin Hydrogen Fumarate		55297-96-6	12.3
Ethanol		64-17-5	7 - 13
Sodium Phosphate Dibasic, heptahydrate		7782-85-6	1 - 5
Citric Acid Monohydrate		5949-29-1	1 - 5

Other components below reportable levels

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Eye irritation.
Indication of immediate medical attention and special treatment needed	Treat symptomatically. Thermal burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital.
General information	Take off all contaminated clothing immediately. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse. NOT FOR HUMAN USE!

5. Fire-fighting measures

Suitable extinguishing media	Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	Vapors may form explosive mixtures with air. Vapors may travel considerable distance to a source of ignition and flash back. During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Flammable liquid and vapor.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Keep combustibles (wood, paper, oil, etc.) away from spilled material.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions

7. Handling and storage

Precautions for safe handling

Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. When using do not smoke. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use non-sparking tools and explosion-proof equipment. Avoid contact with eyes. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store in a well-ventilated place. Keep in an area equipped with sprinklers. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG)

Components

Type

Value

Citric Acid Monohydrate (CAS 5949-29-1)

TWA (8hrs)

500 ug/m3

Sodium Phosphate Dibasic, heptahydrate (CAS 7782-85-6)

STEG (15min)

3 mg/m3

TWA (8hrs)

1 mg/m3

US. ACGIH Threshold Limit Values

Components

Type

Value

Ethanol (CAS 64-17-5)

STEL

1000 ppm

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

Components

Type

Value

Ethanol (CAS 64-17-5)

PEL

1900 mg/m3

1000 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components

Type

Value

Ethanol (CAS 64-17-5)

TWA

1900 mg/m3

1000 ppm

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection

Wear appropriate chemical resistant gloves.

Other

Wear appropriate chemical resistant clothing.

Respiratory protection	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.
Thermal hazards	Not available.
General hygiene considerations	When using do not smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Liquid.
Color	Clear.
Odor	Odorless.
Odor threshold	Not available.
pH	3.5 - 4.5
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	112.0 °F (44.4 °C)
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	1.05 g/ml
Solubility(ies)	
Solubility (water)	Soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Percent volatile	87 %

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Citric Acid Monohydrate (CAS 5949-29-1)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg (anhydrous)
Oral		
LD50	Rat	6730 mg/kg
Ethanol (CAS 64-17-5)		
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	124.7 mg/l, 4 h
Oral		
LD50	Rat	7060 mg/kg
Sodium Phosphate Dibasic, heptahydrate (CAS 7782-85-6)		
Acute		
Oral		
LD50	Rat	12930 mg/kg
Tiamulin Hydrogen Fumarate (CAS 55297-96-6)		
Acute		
Oral		
LD50	Mouse	650 - 770 mg/kg
	Rat	1830 - 2740 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Due to partial or complete lack of data the classification is not possible.
Serious eye damage/eye irritation	Causes serious eye irritation.
Respiratory or skin sensitization	
Respiratory sensitization	Not a respiratory sensitizer.
Skin sensitization	Due to partial or complete lack of data the classification is not possible.
Germ cell mutagenicity	Result in genetic toxicity assays (in vitro and in vivo): Negative (Tiamulin hydrogen fumarate)
Carcinogenicity	Animal testing did not show any carcinogenic effects. (Tiamulin hydrogen fumarate)
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not an aspiration hazard.

12. Ecological information

Ecotoxicity	Toxic to aquatic life with long lasting effects.
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Components	Species	Test Results
Citric Acid Monohydrate (CAS 5949-29-1)		
Aquatic		
<i>Acute</i>		
Crustacea	LC50	Water flea (Daphnia magna) 1535 mg/l, 24 hours (anhydrous)
Fish	LC50	Carp (Leuciscus idus melanotus) 440 mg/l, 96 hours (anhydrous)
Ethanol (CAS 64-17-5)		
Aquatic		
<i>Acute</i>		
Fish	LC50	Rainbow Trout 13 g/l, 96 hr
Algae	EC50	Algae 1450 mg/l, 8 d
Crustacea	LC50	Daphnia 9.3 g/l, 48 hr
Sodium Phosphate Dibasic, heptahydrate (CAS 7782-85-6)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Daphnia magna 3580 mg/l, 48 hr
Fish	LC50	Rainbow trout, donaldson trout (Oncorhynchus mykiss) 5600 mg/l, 96 hr
Tiamulin Hydrogen Fumarate (CAS 55297-96-6)		
	LC50	Earthworm (Eisenia foetida) > 1000 mg/kg, 14 days
	NOEC	Earthworm (Eisenia foetida) 1000 mg/kg
Aquatic		
<i>Acute</i>		
Algae	EC50	Green algae (Selenastrum capricornutum) 0.165 mg/l
Crustacea	EC50	Daphnia magna 40 mg/l, 48 hours
Fish	LC50	Rainbow trout, donaldson trout (Oncorhynchus mykiss) 5.2 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Ethanol -0.31

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

Waste codes The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

14. Transport information

DOT

UN number UN1993
UN proper shipping name Flammable liquid, n.o.s. (contains ethanol)
Transport hazard class(es)
Class 3
Subsidiary risk -
Label(s) None
Packing group III
Environmental hazards
Marine pollutant Yes

Special precautions for user A flammable liquid with a flashpoint at or above 100° F (38° C) that does not meet the definition of any other hazard class may be reclassified as a combustible liquid per 49 CFR 173.120(b).

Special provisions IB3, T1, T4, TP1

Packaging exceptions 150

Packaging non bulk 203

Packaging bulk 241

IATA

UN number UN1993

UN proper shipping name Flammable liquid, n.o.s. (contains ethanol)

Transport hazard class(es)

Class 3

Subsidiary risk -

Packing group III

Environmental hazards Yes

ERG Code 3L

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Other information

Passenger and cargo aircraft Allowed.

Cargo aircraft only Allowed.

IMDG

UN number UN1993

UN proper shipping name FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHANOL)

Transport hazard class(es)

Class 3

Subsidiary risk -

Packing group III

Environmental hazards

Marine pollutant Yes

EmS F-E, S-E

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

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

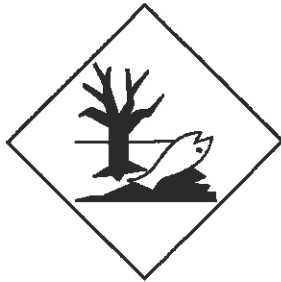
DOT



IATA; IMDG



Marine pollutant



15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
One or more components are not listed on TSCA.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Ethanol (CAS 64-17-5) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Ethanol (CAS 64-17-5)

US. New Jersey Worker and Community Right-to-Know Act

Ethanol (CAS 64-17-5)

US. Pennsylvania Worker and Community Right-to-Know Law

Ethanol (CAS 64-17-5)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Ethanol (CAS 64-17-5) Listed: April 29, 2011
Listed: July 1, 1988

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Ethanol (CAS 64-17-5) Listed: October 1, 1987

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 05-27-2015
Version # 01
Lilly Lab Code Health: 1
Fire: 2
Reactivity: 0

List of abbreviations

STEG: Short Term Exposure Guideline
STEL: Short Term Exposure Limit
PEL: Permissible Exposure Limit
TWA: Time Weighted Average

Disclaimer

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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