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SAFETY DATA SHEET

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

Telephone 1-336-387-1000 SDS E-mail lilly_msds@lilly.com

SDS telephone 1-877-Elanco1 (1-877-352-6261)

Emergency Telephone Elanco Product Technical Support / Human or Animal Exposure Reporting:

Numbers 1-888-545-5973

Transportation Emergency Telephone: CHEMTREC 1-800-424-9300

(Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazardsFlammable liquidsCategory 3Health hazardsSerious eye damage/eye irritationCategory 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.

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3. Composition/information on ingredients

Mixtures

Common name and synonyms	CAS number	%
	55297-96-6	12.3
	64-17-5	7 - 13
	7782-85-6	1 - 5
	5949-29-1	1 - 5
	Common name and synonyms	55297-96-6 64-17-5 7782-85-6

Other components below reportable levels

4. First-aid measures

Move to fresh air. Call a physician if symptoms develop or persist. Inhalation

Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical Skin contact

attention if irritation develops and persists.

Eve 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.

Rinse mouth. Get medical attention if symptoms occur. Ingestion

Eve irritation.

Most important

symptoms/effects, acute and

delaved

Indication of immediate medical attention and special treatment needed

General information

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.

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

Unsuitable extinguishing

media

Specific hazards arising from the chemical

Special protective equipment

and precautions for firefighters

Fire fighting equipment/instructions

Specific methods

General fire hazards

Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO2).

Do not use water jet as an extinguisher, as this will spread the fire.

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.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

Use standard firefighting procedures and consider the hazards of other involved materials.

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.

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	Туре	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	Туре	Value	
Ethanol (CAS 64-17-5)	STEL	1000 ppm	
US. OSHA Table Z-1 Limits for Air	Contaminants (29 CFR 1910.1000)	
Components	Туре	Value	
Ethanol (CAS 64-17-5)	PEL	1900 mg/m3	
		1000 ppm	
US. NIOSH: Pocket Guide to Chem	ical Hazards		
Components	Туре	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

Liquid. **Physical state Form** Liquid. Color Clear. Odor Odorless. Not available. **Odor threshold** 3.5 - 4.5 pН Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

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 Not available.

(n-octanol/water)

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 Hazardous polymerization does not occur.

reactions

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.

Material name: Denagard® (Tiamulin) Liquid Concentrate 5751 Version #: 01 Issue date: 05-27-2015

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)

<u>Acute</u> 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)

<u>Acute</u>

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

Skin corrosion/irritation Due to partial or complete lack of data the classification is not possible.

Serious eye damage/eye

Causes serious eye irritation.

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 toxicityThis 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.

Material name: Denagard® (Tiamulin) Liquid Concentrate 5751 Version #: 01 Issue date: 05-27-2015

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

Components		Species	Test Results
Citric Acid Monohydrat	te (CAS 5949-29-1)		
Aquatic			
Acute			
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			
Fish	LC50	Rainbow Trout	13 g/l, 96 hr
Acute			
Algae	EC50	Algae	1450 mg/l, 8 d
Crustacea	LC50	Daphnia	9.3 g/l, 48 hr
Sodium Phosphate Dib	oasic, heptahydrate	(CAS 7782-85-6)	
Aquatic			
Acute			
Crustacea	EC50	Daphnia magna	3580 mg/l, 48 hr
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	5600 mg/l, 96 hr
Tiamulin Hydrogen Fu	marate (CAS 55297	7-96-6)	
	LC50	Earthworm (Eisenia foetida)	> 1000 mg/kg, 14 days
	NOEC	Earthworm (Eisenia foetida)	1000 mg/kg
Aquatic			
Acute			
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

UN1993 **UN** number

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

Transport hazard class(es)

Class 3 Subsidiary risk Label(s) None Packing group Ш

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)

Allowed.

Transport hazard class(es)

3 **Class** Subsidiary risk Ш Packing group **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 Cargo aircraft only Allowed.

IMDG

UN1993 **UN** number

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

Not established.

Transport hazard class(es)

3 **Class** Subsidiary risk Ш Packing group

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

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

Not regulated.

(SDWA)

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) Canada

Non-Domestic Substances List (NDSL) No

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

Toxic Substances Control Act (TSCA) Inventory

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

05-27-2015 Issue date

Version #

United States & Puerto Rico

Health: 1 **Lilly Lab Code**

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

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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

No

product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health 0011+1-877-352-6261 0011+1-800-428-4441

Material name: Denagard® (Tiamulin) Liquid Concentrate