



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Denagard 12.5% Solution</b>
<b>Other means of identification</b>	
<b>Item Code</b>	AF7425
<b>Synonyms</b>	ASF307 Sol 12.5 * A-20002 A * Denagard 125 mg/ml solution * Denagard 12.5
<b>Recommended use</b>	Veterinary Product
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name</b>	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
<b>Phone:</b>	1-877-Elanco1 (1-877-352-6261)
<b>Email:</b>	<a href="mailto:lilly_msds@lilly.com">lilly_msds@lilly.com</a>
<b>Emergency Telephone Numbers:</b>	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973
<b>Transportation Emergency Telephone:</b>	CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Serious eye damage/eye irritation	Category 2
<b>OSHA defined hazards</b>	Not classified.	

### Label elements



<b>Signal word</b>	Warning
<b>Hazard statement</b>	
H319	Causes serious eye irritation.
<b>Precautionary statement</b>	
<b>Prevention</b>	
P264	Wash thoroughly after handling.
P280	Wear eye protection/face protection.
<b>Response</b>	
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.
<b>Storage</b>	Not available.
<b>Disposal</b>	
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	None.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Tiamulin Fumurate		55297-96-6	12.5
Ethanol		64-17-5	10
Citric Acid Monohydrate		5949-29-1	1.26

**Composition comments** Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Remove contact lenses, if present and easy to do. Immediately flush eyes with plenty of water for at least 15 minutes. Continue rinsing. If eye irritation persists: Get medical advice/attention.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	Causes serious eye irritation.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Dry powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	Not applicable.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Avoid breathing mist or vapor. Avoid contact with skin, eyes and clothing. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.  Small Spills: 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.
<b>Environmental precautions</b>	Not available.

### 7. Handling and storage

<b>Precautions for safe handling</b>	Provide adequate ventilation. Avoid contact with eyes, skin, and clothing. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store away from incompatible materials (see Section 10 of the SDS). Keep container tightly closed. Store in original tightly closed container.

### 8. Exposure controls/personal protection

#### Occupational exposure limits

##### 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/m <sup>3</sup> 1000 ppm

**US. NIOSH: Pocket Guide to Chemical Hazards**

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1900 mg/m <sup>3</sup> 1000 ppm

**Lilly (LEG)**

Components	Type	Value
Citric Acid Monohydrate (CAS 5949-29-1)	TWA (8hrs)	500 ug/m <sup>3</sup>

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	Novartis Internal Exposure Limit (NPIEL): 0.2 mg/m <sup>3</sup> 8 hour TWA (Tiamulin hydrogen fumarate)
<b>Appropriate engineering controls</b>	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.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves.
<b>Other</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	In case of insufficient ventilation, wear suitable respiratory equipment.
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	When using, do not eat, drink or 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**

<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Color</b>	Colourless to light yellow.

**Odor** Not available.

**Odor threshold** Not available.

**pH** 3.7 - 4.3

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** > 140.0 °F (> 60.0 °C)

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

**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** Not available.

<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Density</b>	1.02 g/ml
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	Not water reactive.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	None known.
<b>Hazardous decomposition products</b>	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)		
<u>Acute</u>		
<b>Dermal</b>		
LD50	Rabbit	> 2000 mg/kg (anhydrous)
<b>Oral</b>		
LD50	Rat	6730 mg/kg
Ethanol (CAS 64-17-5)		
<u>Acute</u>		
<b>Dermal</b>		
LD50	Rabbit	> 5000 mg/kg
<b>Inhalation</b>		
LC50	Rat	124.7 mg/l, 4 h
<b>Oral</b>		
LD50	Rat	7060 mg/kg
Tiamulin Fumurate (CAS 55297-96-6)		
<u>Acute</u>		
<b>Oral</b>		
LD50	Rat	2230 mg/kg
<b>Skin corrosion/irritation</b>	No irritation Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Causes serious eye irritation.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Due to partial or complete lack of data the classification is not possible.	
<b>Skin sensitization</b>	Due to partial or complete lack of data the classification is not possible.	
<b>Germ cell mutagenicity</b>	Due to partial or complete lack of data the classification is not possible.	

**Carcinogenicity** This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Due to lack of data the classification is not possible.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Ethanol (CAS 64-17-5) 1

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Ethanol (CAS 64-17-5) Known To Be Human Carcinogen

**Reproductive toxicity** Due to partial or complete lack of data the classification is not possible.

**Specific target organ toxicity - single exposure** May cause irritation to the respiratory system. (Active ingredient) Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure** Due to partial or complete lack of data the classification is not possible.

**Aspiration hazard** Not applicable.

**12. Ecological information**

**Ecotoxicity** Toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Citric Acid Monohydrate (CAS 5949-29-1)			
<b>Aquatic</b>			
<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)			
<b>Aquatic</b>			
<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
Tiamulin Fumurate (CAS 55297-96-6)			
<b>Aquatic</b>			
<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
<b>Terrestrial</b>			
Other	LC50	Earthworm (Eisenia foetida)	> 1000 mg/kg, 14 days
	NOEC	Earthworm (Eisenia foetida)	1000 mg/kg

**Persistence and degradability** Not available.

**Bioaccumulative potential** Not available.

**Partition coefficient n-octanol / water (log Kow)**

Ethanol -0.31  
Tiamulin Fumurate 5.93

**Mobility in soil** Not available.

**Other adverse effects** Not available.

**13. Disposal considerations**

**Disposal methods/information** Dispose of contents/container in accordance with local/regional/national/international regulations.

**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.

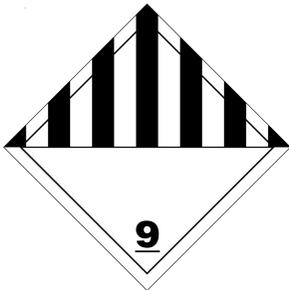
**IATA**

**UN number** UN3082  
**UN proper shipping name** Environmentally hazardous substance, liquid, n.o.s. (Tiamulin Fumurate)  
**Transport hazard class(es)**  
**Class** 9  
**Subsidiary risk** -  
**Packing group** III  
**Environmental hazards** Yes  
**ERG Code** 9L  
**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.  
**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 Fumurate) (TIAMULIN FUMARATE, PROPYLPARABEN)  
**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** Read safety instructions, SDS and emergency procedures before handling.  
 TIAMULIN FUMARATE  
 PROPYLPARABEN

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

**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.

**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 regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****Hazard categories**

Immediate Hazard - Yes  
 Delayed Hazard - No  
 Fire Hazard - No  
 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 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** 12-18-2015**Revision date** 01-25-2017**Version #** 02**Lilly Lab Code**

Health: 2  
 Fire: 0  
 Reactivity: 0

**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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**Revision information**

This document has undergone significant changes and should be reviewed in its entirety.