

1. Identification

Product identifier	Denagard 10 Premix
Other means of identification	
Item Code	AF7400
Synonyms	Denagard 10
Recommended use	Antibiotic feed additive for the control and treatment of certain swine bacterial diseases.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Company Name	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
Phone:	1-877-Elanco1 (1-877-352-6261)
Emergency Telephone:	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973
Email:	elanco_sds@elanco.com
Transportation Emergency Telephone:	CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Sensitization, respiratory
OSHA defined hazards	Combustible dust
Category 1	
Label elements	
	
Signal word	Danger
Hazard statement	
H334	May form combustible dust concentrations in air. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statement	
Prevention	
P261	Avoid breathing dust.
P284	In case of inadequate ventilation wear respiratory protection.
Response	
P304 + P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
Storage	Not available.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
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	2.2
Rice Hulls		Not established	93
Mineral Oil		8042-47-5	4

Composition comments

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

4. First-aid measures

Inhalation

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

Skin contact

Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Indication of immediate medical attention and special treatment needed

Swine being treated with Denagard® should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, and semduramicin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

General information

NOT FOR HUMAN USE! Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Apply extinguishing media carefully to avoid creating airborne dust.

Unsuitable extinguishing media

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

Specific hazards arising from the chemical

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

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. Use water spray to cool unopened containers.

Specific methods

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

General fire hazards

May form combustible dust concentrations in air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Collect dust using a vacuum cleaner equipped with HEPA filter. This product is miscible in water. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions

7. Handling and storage

Precautions for safe handling

Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Practice good housekeeping.

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures.

8. Exposure controls/personal protection

Occupational exposure limits

U.S. - OSHA Components	Type	Value	Form
Rice Hulls	TWA	10 mg/m3	dust

Comments: (Grain dust)

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

Components	Type	Value	Form
Mineral Oil (CAS 8042-47-5)	PEL	5 mg/m3	Mist.
ACGIH			
Components	Type	Value	Form
Rice Hulls	TWA	4 mg/m3	dust
Comments: (Grain dust)			
US. ACGIH Threshold Limit Values			
Components	Type	Value	Form
Mineral Oil (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.
US. NIOSH: Pocket Guide to Chemical Hazards			
Components	Type	Value	Form
Mineral Oil (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
Biological limit values	No biological exposure limits noted for the ingredient(s).		
Exposure guidelines	Novartis Internal Exposure Limit (NPIEL): 0.2 mg/m3 8 hour TWA (Tiamulin hydrogen fumarate)		
Appropriate engineering controls	If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits.		
Individual protection measures, such as personal protective equipment			
Eye/face protection	Safety glasses with side shields recommended.		
Skin protection			
Hand protection	Chemical resistant gloves.		
Other	Wear suitable protective clothing.		
Respiratory protection	Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an approved respirator with sufficient protection factor to control exposure below the OEL.		
Thermal hazards	Not available.		
General hygiene considerations	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	Solid.
Form	Granular Crystals.
Color	Not available.
Odor	Very Slight
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	No test data 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.
Solubility(ies)	
Solubility (water)	Soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

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	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Keep away from heat, sparks and open flame. Minimize dust generation and accumulation. Avoid high humidity conditions. 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
Mineral Oil (CAS 8042-47-5)		
Acute		
Dermal		
LD		> 2000 mg/kg
Inhalation		
LC50		> 5.2 mg/l, 4 hr
Oral		
LD		> 5000 mg/kg No mortality.
Tiamulin hydrogen fumarate (CAS 55297-96-6)		
Acute		
Oral		
LD50	Rat	2230 mg/kg
Skin corrosion/irritation	Rabbit: No skin irritation. (Active ingredient(s)) Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Rabbit: Mild eye irritation. (active ingredient) Based on available data, the classification criteria are not met.	
Respiratory or skin sensitization		
Respiratory sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled. (Grain dust)	
Skin sensitization	Guinea pig: Not a skin sensitizer. (Active ingredient(s)) Based on available data, the classification criteria are not met.	

Germ cell mutagenicity	In vitro and in vivo tests did not show mutagenic effects. (Active ingredient(s)) Based on available data, the classification criteria are not met.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No effects identified in animal studies. (Active ingredient(s)) Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Mineral Oil (CAS 8042-47-5) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity	No effects identified in animal studies. (Active ingredient(s)) Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure	Respiratory tract irritation. (active ingredient) Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	No significant target organ toxicity reported. (active ingredient) Based on available data, the classification criteria are not met.
Aspiration hazard	Not applicable.
Further information	Did not show carcinogenic, teratogenic or mutagenic effects in animal experiments.

12. Ecological information

Ecotoxicity	Harmful to aquatic life with long lasting effects.
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Components	Species	Test Results
Mineral Oil (CAS 8042-47-5)		
Aquatic		
<i>Acute</i>		
Crustacea	LC50	Daphnia magna > 100 mg/l, 48 h
Fish	LC50	Oncorhynchus mykiss > 100 mg/l, 96 h
<i>Chronic</i>		
Fish	NOAEL	Oncorhynchus mykiss > 1000 mg/l, 28 d
Tiamulin hydrogen fumarate (CAS 55297-96-6)		
Aquatic		
Algae	EC50	Green algae (Selenastrum capricornutum) 0.165 mg/l
Crustacea	EC50	Daphnia magna 40 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna) 4.2 mg/l, 21 days
Fish	LC50	Rainbow trout, donaldson trout (Oncorhynchus mykiss) 5.2 mg/l, 96 hours
Terrestrial		
Soil	LC50	Earthworm (Eisenia foetida) > 1000 mg/kg, 14 days
	NOEC	Earthworm (Eisenia foetida) 1000 mg/kg

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

Partition coefficient n-octanol / water (log Kow)

Tiamulin hydrogen fumarate 3.77, (pH 9)

Mobility in soil	No data available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose of contents/container in accordance with local/regional/national/international regulations.
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14. Transport information

DOT	Not regulated as dangerous goods.
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IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**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.

US state regulations**California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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 02-24-2017

Revision date 01-25-2019

Version # 03

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 SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY 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.

For additional information contact:

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