



SAFETY DATA SHEET

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 Category 1

OSHA defined hazards Combustible dust

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
P284

Avoid breathing dust.
In case of inadequate ventilation wear respiratory protection.

Response

P304 + P341
P342 + P311

IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
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.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

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)		
<u>Acute</u>		
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)		
<u>Acute</u>		
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.

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.

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.

14. Transport information

DOT

Not regulated as dangerous goods.

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 Not applicable.

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

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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 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.

For additional information contact:

Elanco Animal Health

0011+1-877-352-6261

0011+1-800-428-4441