

## SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

## DENAGARD 10 % Premix

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

## 1.1 Product identifiers

Substance No.	:	000070002347
NAH Substance Code	:	A-20003 B
Trade name	:	DENAGARD 10% PREMIX Denagard 10 % DENAGARD 10% POWDER Denagard Premix 10 % DENAGARD 10% AMV Denagard 10 % premix DENAGARD 10% GF PREMIX Denagard 100 g/kg Denagard 100 mg/g
Product name	:	TIAMULIN FUMARATE COATED, PREMIX 10%
Type of preparation	:	Premix feed additive

## 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use	:	Veterinary medicinal product Antibiotic
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## 1.3 Details of the supplier of the safety data sheet

Company	:	Novartis Animal Health Canada Inc. 2000 Argentia Road Plaza 3, Suite 400 CDN- Mississauga, Ontario L5N 1V9 CANADA
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Telephone	:	(800) 387-6325
Customer Service	:	(905) 814-0830 or (800) 387-6325
Preparer Information	:	Health, Safety & Environmental Dept. Novartis Animal Health US, Inc. (712) 477-2811 [8:00 am – 5:00 pm M – F (CST)]
E-mail address	:	msds.nah@novartis.com

## 1.4 Emergency Contact

Emergency telephone number (CHEMREC)	:	(800) 424-9300 (24 hours / 7 days a week)
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## SECTION 2: HAZARDS IDENTIFICATION

## 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008.

Eye irritation Category 2	H319	
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Classification according to EU Directives 67/548/EEC or 1999/45/EC

Irritating to eyes and respiratory system.	R36/37
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### 2.2 Label elements

#### Labelling according to Regulation (EC) No. 1907/2006

 Hazard pictograms : 

Hazard pictograms : Exclamation mark

Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

 Precautionary statements : P264 Wash face, hands and any exposed skin thoroughly after handling.  
 : P280 Wear protective gloves/protective clothing/eye protection/face protection.

 : P305 + IF IN EYES: Rinse cautiously with water for several minutes.  
 P351 + Remove contact lenses, if present and easy to do. Continue rinsing.

 : P337 + If eye irritation persists: Get medical advice/ attention.  
 P313

: P501 Dispose of contents/ container to an approved incineration plant.

Hazardous components : Tiamulin hydrogen fumarate

#### Labelling according to EC Directives 67/548/EEC or 1999/45/EC

 Symbol(s) : 

Symbol(s) : Harmful

R-phrase(s) : R36/37 Irritating to eyes and respiratory system.

 S-phrase(s) : S22 Do not breathe dust.  
 : S24/25 Avoid contact with skin and eyes.  
 : S36 Wear suitable protective clothing.

Hazardous components : Tiamulin hydrogen fumarate

#### Further information

The product is a veterinary product and is not subject of Directives 67/548/EEC or 1999/45/EC or to Regulation (EC) No. 1272/2008.

Therefore the product does not need to be labeled according to the European directives and respective national laws.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous components

Identification	CAS-No.	Classification 67/548/EEC	Classification REGULATION (EC) No 1272/2008		Concentration (% w/w)
Tiamulin fumarate	55297-96-6	Xi, N R36/37 R50/53	Eye irrit. Cat. 2 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H319 H335 H400 H410	10.00

For the full text of the R-phrases mentioned in this Section, see Section 16.

For the full text of the H-Statements mentioned in this Section, see Section 16.

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**DENAGARD 10 % Premix****SECTION 4: FIRST AID MEASURES****4.1 Description of first aid measures**

General advice	: Remove the affected person from the danger zone to a well-ventilated room or to fresh air, and protect from undercooling. IN CASE OF SUSPECTED POISONING: Immediately call a physician.
Inhalation	: Remove to fresh air. Consult a physician if any symptoms develop and persist.
Skin contact	: Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Eye contact	: Rinse eyes with clean water for several minutes and immediately call a physician.
Ingestion	: Rinse mouth with water. If you feel unwell, seek medical advice (show the label where possible). Never give anything by mouth to an unconscious person. Do NOT induce vomiting.

**4.2 Most important symptoms/effects, acute and delayed**

Poisoning Symptoms	: No information available.
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**4.3 Indication of any immediate medical attention and special treatment needed**

Antidotes	: No specific antidote is known! Apply symptomatic therapy.
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**SECTION 5: FIREFIGHTING MEASURES****5.1 Extinguishing media**

Suitable extinguishing media	: Dry powder, foam, carbon dioxide (CO2) or water spray (do not use water jet).
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**5.2 Special hazards arising from the substance or mixture**

Hazardous decomposition products	: Exposure to decomposition products may be a hazard to health.
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**5.3 Advice for firefighters**

Special protective equipment for firefighters	: Use respirator to protect from fumes.
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Further information	: Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
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**SECTION 6: ACCIDENTAL RELEASE MEASURES****6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions	: Refer to protective measures listed in sections 7 and 8.
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**6.2 Environmental precautions**

Environmental precautions	: Do not flush into surface water or sanitary sewer system.
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**6.3 Methods and materials for containment and cleaning up**

Methods for cleaning up	: Pick up and transfer to properly labelled containers. Knock down dust with water spray jet. Treat contaminated surfaces with water. Put washing water in containers too, to avoid any contamination of surface and ground water, water supplies and drains. Hose down the area for a prolonged period. Heavily contaminated soil layers have to be dig out. Spilled product cannot be used further and must be disposed of. If safe disposal is not possible, contact the manufacturer, the dealer or the local representative.
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**SECTION 7: HANDLING AND STORAGE**
**7.1 Precautions for safe handling**

Safe handling advice	:	Avoid contact with skin, eyes and clothing. Avoid dust formation. In addition to the measures taken usually in the chemical works like dustproof filling and measuring equipment (including dust extraction), further personal protection measures may have to be implemented to avoid possible contact with the product. Remove all sources of ignition. Take precautionary measures against static discharges.
<b>Storage</b>		
Advice on common storage	:	Keep away from food, drink and animal feeding stuffs. Store the product in closed original containers.
Novartis storage class	:	20.2
Storage temperature:	:	min. 2 °C - max. 25 °C
Other data	:	Protect from direct sunlight. Protect from humidity.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**
**8.1 Control parameters**
**Components with workplace control parameters**

Identification	CAS-No.	Notes	Exposure limit(s)
Tiamulin fumarate	55297-96-6	Novartis Internal Exposure Limit (NPIEL) 8 h TWA	0.2 mg/m <sup>3</sup>

**8.2 Exposure controls**

<b>Protective measures</b>	:	The use of technical measures should always have priority over the use of personal protective equipment.
<b>Personal protective equipment</b>		
<b>Open handling</b>		
Respiratory protection	:	Reusable half mask (EN140).
Hand protection	:	Rubber gloves Type: Chloroprene (Neoprene, CR)
Eye protection	:	Safety glasses (EN166)
Skin and body protection	:	Lightweight protective clothing
Hygiene measures	:	Shower or bathe at the end of working. Wash hands before breaks and immediately after handling the product. Thoroughly clean protective gear.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**9.1 Information on basic physical and chemical properties**

Physical state	:	solid
Form	:	Powder
Colour	:	white - cream
Odour	:	slight
Minimum ignition energy	:	> 30 - < 100 mJ Method: MIKE-3 Test temperature: 25 °C Remarks: with inductivity

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Autoignition temperature	:	320 °C Remarks: Ignition temperature of dust Method: BAM
Ignition temperature	:	320 °C Ignition temperature of dust Method: BAM
Impact Sensitivity	:	Mechanical sensitivity (shock) not shock sensitive Hit test: no detonation Method: Lütolf 5 kg at 80 cm
Dust explosion	:	Dust explosion: positive Minimum ignition energy: < 1 J Method: Hartmann tube
	:	St1 Ignition energy: 10,000 J Method: 20 l sphere
Thermal decomposition	:	Exothermic reaction: no exothermic reaction up to 500 °C Method: Lütolf - Air open cup - dynamic - as is Heating rate: 2.5 °C/min Test temperature: 500 °C
	:	Exothermic reaction: first exothermic reaction at 150 - 350 °C Method: Grewer - with airstream - as is Heating rate: 1.2 °C/min Test temperature: 350 °C Delta T temperature: 10 °C Size of vessel: 8 ml
	:	Due to the thermic decomposition behaviour a self decomposition (deflagration) can be excluded.
Burning number	:	3: Local combustion or smouldering, with at most slight spreading. at 25 °C 5: Burns like firework, or slow, steady burning with flame. at 100 °C

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## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Reactivity : Stable under recommended storage conditions.

### 10.2 Chemical stability

Chemical Stability : Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Dust may form explosive mixture in air.

### 10.4 Conditions to avoid

Conditions to avoid : Extremes of temperature and direct sunlight.

### 10.5 Incompatible materials

Materials to avoid : no data available

### 10.6 Hazardous decomposition products

Hazardous decomposition products : Carbon dioxide (CO<sub>2</sub>)  
Carbon monoxide  
nitrogen oxides (NO<sub>x</sub>)  
Sulphur dioxide

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**DENAGARD 10 % Premix****SECTION 11: TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects**

Acute oral toxicity	:	LD50 > 2,230 mg/kg Species: Rat Remarks: Information refers to the active ingredient.
	:	LD50 710 mg/kg Species: Mouse Remarks: Information refers to the active ingredient.
Skin irritation	:	No skin irritation Species: rabbit Remarks: Information refers to the active ingredient.
Eye irritation	:	Irritating to eyes. Species: Humans Remarks: Information refers to the active ingredient.
Sensitisation	:	not sensitizing Species: guinea pig Remarks: Information refers to the active ingredient.
Mutagenicity (in vitro)	:	negative Ames test salmon. typhimurium Remarks: Information refers to the active ingredient.
Mutagenicity (in vivo)	:	negative Remarks: Information refers to the active ingredient. Species: Mouse Micronucleus test
Further information	:	Irritating to eyes and respiratory system (human). Derived from the active ingredient(s)

**SECTION 12: ECOLOGICAL INFORMATION****12.1 Toxicity**

Toxicity to fish	:	LC50 5.2 mg/l Species: Oncorhynchus mykiss (rainbow trout) Remarks: Information refers to the active ingredient.
Toxicity to daphnia	:	EC50 40 mg/l Species: Daphnia magna (water flea) Remarks: Information refers to the active ingredient.
Toxicity to algae	:	EC50 0.165 mg/l Species: Pseudokirchneriella subcapitata (green algae) Remarks: Information refers to the active ingredient.
	:	EC50 0.165 mg/l Species: Selenastrum capricornutum (green algae) Remarks: Information refers to the active ingredient.
Toxicity to soil organisms	:	LC50 > 1,000 mg/kg Species: Eisenia foetida (earthworm) Remarks: Derived from the active ingredient(s)

**12.2 Persistence and degradability**

Biodegradability	:	no data available
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### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Product	: Refer to protective measures listed in sections 7 and 8. Pick up and transfer to properly labelled containers. Dispose of in an incinerator approved for chemicals. Spilled product cannot be used further and must be disposed of. If safe disposal is not possible, contact the manufacturer, the dealer or the local representative.
Contaminated packaging	: Dispose of empty containers in an incinerator approved for chemicals. Damaged Containers: Place original containers in specially marked larger ones. Check possibilities of recycling large empty containers, drums and barrels.

### SECTION 14: TRANSPORT INFORMATION

Transport Condition : NORMAL: Transport + intermediate storage &lt;=40°C

#### Land transport (ADR/RID)

UN number	: FREE
Class	: Not classified as dangerous good

#### Sea transport (IMDG)

UN number	: FREE
Class	: Not classified as dangerous good

#### Air transport (ICAO/IATA)

UN number	: FREE
Class	: Not classified as dangerous good

Postal delivery - Switzerland : 1 allowed

### SECTION 15: REGULATORY INFORMATION

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

##### National legislation

Weight limit (Switzerland - StFV) : 200,000 kg

Swiss Fire Prevention Code : F4 S

#### 15.2 Chemical Safety Assessment

Assessment : A Chemical Safety Assessment is not required for this substance.

### SECTION 16: OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3
Full text of H-Statements referred to under sections 2 and 3.

R36/37	: Irritating to eyes and respiratory system.
R50/53	: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
H319	: Causes serious eye irritation.
H335	: May cause respiratory irritation.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.