

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

 Version: 2.
 Revision Date 17.05.2011

Print Date 24.05.2011

DENAGARD 12.5 % SOLUTION

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Identification of the substance or mixture

Substance No. : 000070002048
 NAH Substance Code : A-20002 A
 Trade name : DENAGARD 12.5 % SOLUTION
 DENAGARD SOLUTION BUVABLE
 Product name : ASF307 SOL 12.5

Company : Novartis Animal Health Inc.
 Schwarzwaldallee 215
 CH - 4058 Basel
 Switzerland

Telephone : +41616971111
 Contact person : Phone (office hours) +41 61 697 30 65
 E-mail address : msds.nah@novartis.com

Emergency information

Emergency telephone number : **Phone (24 h) +41 61 696 33 33**
 Emergency information : concerning transport see emergency phone number in the shipping documents
 concerning storage see emergency phone number of local Novartis organization

2. HAZARDS IDENTIFICATION

Risk advice to man and the environment

Potential health effects : May cause eye and skin irritation.
 Potential environmental effects : Do not flush into surface water or sanitary sewer system.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature

Use : Antibiotic
 Type of preparation : Solution vet. use
 Active ingredient : ASF 307 Tiamulin fumarate

Hazardous components

Identification	CAS-No.	Symbol(s) Hazard pictograms	R-phrase(s) Hazard statements	Concentration (% w/w)
Tiamulin fumarate	55297-96-6	Xn GHS07	R36/37 H319, H335	12.20
Ethanol	64-17-5	F GHS02	R11 H225	5.00 - 10.00

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

4. FIRST AID MEASURES

General advice : If you feel unwell, seek medical advice (show the label where possible).
 When symptoms persist or in all cases of doubt seek medical advice.

Inhalation : Not a hazard under normal use conditions.

Skin contact : Wash off immediately with soap and plenty of water.

Eye contact : Rinse thoroughly with plenty of water for at least 15 minutes and consult a
 physician.

Ingestion : If accidentally swallowed obtain immediate medical attention. Rinse mouth with
 water. Drink water as a precaution.

Notes to physician
Poisoning Symptoms : No information available.

Antidote : No specific antidote is known! Apply symptomatic therapy.

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5. FIRE-FIGHTING MEASURES

- Combustibility** : yes
Suitable extinguishing media : Dry powder, foam, carbon dioxide (CO₂) or water spray (do not use water jet).
Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Swiss Fire Prevention Code : F4 L

6. ACCIDENTAL RELEASE MEASURES

- Methods for cleaning up** : Refer to protective measures listed in sections 7 and 8.
 Cover up product with absorptive material such as sand, soil, diatomaceous earth, etc.
 Pick up and transfer to properly labelled containers.
 Dispose of in an incinerator approved for chemicals.
 Treat contaminated surfaces with water.
 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.
Additional advice : Do not flush into surface water or sanitary sewer system.

7. HANDLING AND STORAGE

Handling

- Safe handling advice** : Handle in accordance with good industrial hygiene and safety practice.
 Avoid contact with skin, eyes and clothing.
 In addition to the measures taken usually in the chemical works like splashproof filling and measuring equipment (including vapour stripping) further personal protection measures may have to be implemented to avoid possible contact with the product.

Storage

- Novartis storage class** : 21.1
Storage temperature: : min. 2 °C - max. 25 °C
Other data : Store the product in closed original containers.
 Protect from light.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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

- Protective measures** : The use of technical measures should always have priority over the use of personal protective equipment.
 The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Personal protective equipment

Open handling

- Respiratory protection** : No personal respiratory protective equipment normally required.
Hand protection : Gloves
Eye protection : Safety glasses

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- Skin and body protection** : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
 Heavy duty cotton or synthetic fabric working clothes (e.g. overalls).
 Lab coat
- Hygiene measures** : Wash hands before breaks and at the end of workday.
 Shower or bathe at the end of working.
 Change clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Form** : liquid, aqueous solution
- Colour** : colourless - slightly yellowish
- Odour** : slight, alcoholic
- Density** : ca.1.2 g/ml
- pH** : 3.7 - 4.3
- Flash point** : Remarks: Solution contains >70 % water

10. STABILITY AND REACTIVITY

- Chemical Stability** : Stable under normal conditions.

11. TOXICOLOGICAL INFORMATION

- Acute oral toxicity** : LD50 > 2,000 mg/kg
 Species: rat
 Remarks: Derived from the active ingredient(s)
- Further information** : May cause eye and skin irritation.
 Derived from the active ingredient(s)

12. ECOLOGICAL INFORMATION
Ecotoxicity effects

- Toxicity to fish** : Remarks: no data available
- Toxicity to daphnia** : Remarks: no data available

Behaviour in environmental compartments
Elimination information (persistence and degradability)

- Biodegradability** : no data available

13. DISPOSAL CONSIDERATIONS

- Product** : Refer to protective measures listed in sections 7 and 8. Soak up with absorptive material such as sand, soil, diatomaceous earth, etc Pick up and transfer to properly labelled containers. Dispose of in an incinerator approved for chemicals. In accordance with internal, local and national regulations. 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** : Damaged Containers: Place original containers in specially marked larger ones. Check possibilities of recycling large empty containers, drums and barrels. Check possibilities of recycling not contaminated packaging material. Dispose of empty containers in an incinerator approved for chemicals. In accordance with internal, local and national regulations.

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14. TRANSPORT INFORMATION

Transport Condition : Transport + intermediate storage <=40°C

ADR/RID

 UN number : FREE
 Class : Not classified as dangerous good

IMDG

 UN number : FREE
 Class : Not classified as dangerous good

ICAO/IATA

 UN number : FREE
 Class : Not classified as dangerous good

Postal delivery - Switzerland : 1 allowed

15. REGULATORY INFORMATION

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Labelling

 Symbol(s) : --- The product is not subject of Directive 1999/45 EEC.
 classification not required

National legislation

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

16. OTHER INFORMATION
Text of R-phrases mentioned in Section 3

R36/37	: Irritating to eyes and respiratory system.
R11	: Highly flammable.
H319	: Causes serious eye irritation.
H335	: May cause respiratory irritation.
H225	: Highly flammable liquid and vapour.

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.