

# SAFETY DATA SHEET



## Enramycin Formulation

Version 3.3 Revision Date: 28.09.2024 SDS Number: 24570-00023 Date of last issue: 06.04.2024 Date of first issue: 22.10.2014

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### SECTION 1: IDENTIFICATION

Product name : Enramycin Formulation

#### Manufacturer or supplier's details

Company : Intervet Australia Pty Limited (trading as MSD Animal Health)

Address : 91-105 Harpin Street  
Bendigo 3550, Victoria Australia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Not a hazardous substance or mixture.

#### GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

#### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture if dispersed.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Talc	14807-96-6	>= 60 -<= 100
ENRAMYCIN B	34304-21-7	< 10

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### SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

# SAFETY DATA SHEET



## Enramycin Formulation

---

Version 3.3	Revision Date: 28.09.2024	SDS Number: 24570-00023	Date of last issue: 06.04.2024 Date of first issue: 22.10.2014
----------------	------------------------------	----------------------------	---

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If inhaled	When symptoms persist or in all cases of doubt seek medical advice.
In case of skin contact	: If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of eye contact	: Wash with water and soap. Get medical attention if symptoms occur.
If swallowed	: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
Most important symptoms and effects, both acute and delayed	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Protection of first-aiders	: Contact with dust can cause mechanical irritation or drying of the skin.
Notes to physician	: Dust contact with the eyes can lead to mechanical irritation. : No special precautions are necessary for first aid responders.
	: Treat symptomatically and supportively.

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## SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	: High volume water jet
Specific hazards during firefighting	: 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. Do not use a solid water stream as it may scatter and spread fire. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Nitrogen oxides (NO <sub>x</sub> )
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.
Hazchem Code	: 2Z

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## SECTION 6. ACCIDENTAL RELEASE MEASURES

**Enramycin Formulation**

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Version 3.3	Revision Date: 28.09.2024	SDS Number: 24570-00023	Date of last issue: 06.04.2024 Date of first issue: 22.10.2014
----------------	------------------------------	----------------------------	---

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Personal precautions, protective equipment and emergency procedures : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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**SECTION 7. HANDLING AND STORAGE**

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labelled containers.

# SAFETY DATA SHEET



## Enramycin Formulation

Version 3.3 Revision Date: 28.09.2024 SDS Number: 24570-00023 Date of last issue: 06.04.2024 Date of first issue: 22.10.2014

---

Materials to avoid : Store in accordance with the particular national regulations.  
No special restrictions on storage with other products.

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Talc	14807-96-6	TWA	2.5 mg/m <sup>3</sup>	AU OEL
		TWA (Respirable particulate matter)	2 mg/m <sup>3</sup>	ACGIH
ENRAMYCIN B	34304-21-7	TWA	5 mg/m <sup>3</sup> (OEB 1)	Internal

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : light brown

Odour : characteristic

Odour Threshold : No data available

pH : 5 - 8.5

# SAFETY DATA SHEET



## Enramycin Formulation

Version 3.3      Revision Date: 28.09.2024      SDS Number: 24570-00023      Date of last issue: 06.04.2024  
Date of first issue: 22.10.2014

---

Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	practically insoluble
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Dust can form an explosive mixture in air.

# SAFETY DATA SHEET



## Enramycin Formulation

Version 3.3      Revision Date: 28.09.2024      SDS Number: 24570-00023      Date of last issue: 06.04.2024  
Date of first issue: 22.10.2014

---

tions

Conditions to avoid : Avoid dust formation.  
Incompatible materials : None.  
Hazardous decomposition products : No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Talc:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Remarks: Based on data from similar materials

#### ENRAMYCIN B:

Acute oral toxicity : LD50 (Mouse): > 5,000 mg/kg  
LD50 (Rat): > 10,000 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Talc:

Species : Rabbit  
Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Talc:

Species : Rabbit  
Result : No eye irritation

#### ENRAMYCIN B:

Species : Rabbit  
Result : No eye irritation

# SAFETY DATA SHEET



## Enramycin Formulation

Version 3.3      Revision Date: 28.09.2024      SDS Number: 24570-00023      Date of last issue: 06.04.2024  
Date of first issue: 22.10.2014

---

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Talc:

Exposure routes : Skin contact  
Species : Humans  
Result : negative

### Chronic toxicity

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Talc:

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **ENRAMYCIN B:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

### Carcinogenicity

Not classified based on available information.

#### Components:

##### Talc:

Species : Mouse  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Result : negative

### Reproductive toxicity

Not classified based on available information.

# SAFETY DATA SHEET



## Enramycin Formulation

---

Version 3.3	Revision Date: 28.09.2024	SDS Number: 24570-00023	Date of last issue: 06.04.2024 Date of first issue: 22.10.2014
----------------	------------------------------	----------------------------	---

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### Components:

#### **Talc:**

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **STOT - single exposure**

Not classified based on available information.

#### **STOT - repeated exposure**

Not classified based on available information.

#### **Repeated dose toxicity**

### Components:

#### **ENRAMYCIN B:**

Species : Rat  
NOAEL : 1,000 mg/kg  
Application Route : Ingestion  
Exposure time : 6 Months

#### **Aspiration toxicity**

Not classified based on available information.

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## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

### Components:

#### **Talc:**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l  
Exposure time: 24 h

#### **ENRAMYCIN B:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 18 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

# SAFETY DATA SHEET



## Enramycin Formulation

Version  
3.3

Revision Date:  
28.09.2024

SDS Number:  
24570-00023

Date of last issue: 06.04.2024  
Date of first issue: 22.10.2014

---

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.96 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 0.083 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.045 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: 438.5 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

EC10: 0.045 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

#### **ENRAMYCIN B:**

Biodegradability : Result: Not readily biodegradable.  
Method: OECD Test Guideline 301B

#### **Bioaccumulative potential**

No data available

#### **Mobility in soil**

No data available

#### **Other adverse effects**

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

#### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

#### **International Regulations**

# SAFETY DATA SHEET



## Enramycin Formulation

Version 3.3 Revision Date: 28.09.2024 SDS Number: 24570-00023 Date of last issue: 06.04.2024 Date of first issue: 22.10.2014

---

### UNRTDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(ENRAMYCIN B)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(ENRAMYCIN B)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(ENRAMYCIN B)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

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

Not applicable for product as supplied.

### National Regulations

#### ADG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(ENRAMYCIN B)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : 2Z  
Environmentally hazardous : yes

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data

# SAFETY DATA SHEET



## Enramycin Formulation

Version 3.3 Revision Date: 28.09.2024 SDS Number: 24570-00023 Date of last issue: 06.04.2024 Date of first issue: 22.10.2014

---

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

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

Therapeutic Goods (Poisons Standard) Instrument : No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

### The components of this product are reported in the following inventories:

AICS : not determined  
DSL : not determined  
IECSC : not determined

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## SECTION 16: ANY OTHER RELEVANT INFORMATION

### Further information

Revision Date : 28.09.2024  
Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>  
Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.  
ACGIH / TWA : 8-hour, time-weighted average  
AU OEL / TWA : Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and

# SAFETY DATA SHEET



## Enramycin Formulation

Version  
3.3

Revision Date:  
28.09.2024

SDS Number:  
24570-00023

Date of last issue: 06.04.2024  
Date of first issue: 22.10.2014

---

Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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