

SAFETY DATA SHEET



Enramycin Formulation

Version 3.2 Revision Date: 06.04.2024 SDS Number: 24603-00022 Date of last issue: 26.09.2023
Date of first issue: 22.10.2014

Section 1: Identification

Product identifier : Enramycin Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive
Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 2

GHS Label elements, including precautionary statements

Hazard pictograms :



Signal word : Warning

Hazard statements : H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.

Response:
P391 Collect spillage.

SAFETY DATA SHEET



Enramycin Formulation

Version 3.2	Revision Date: 06.04.2024	SDS Number: 24603-00022	Date of last issue: 26.09.2023 Date of first issue: 22.10.2014
----------------	------------------------------	----------------------------	---

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Talc	14807-96-6	>= 90 -<= 100
ENRAMYCIN B	34304-21-7	>= 2.5 -< 10

Section 4: First-aid measures

Description of necessary first-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap.
Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : No special precautions are necessary for first aid responders.

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam

SAFETY DATA SHEET



Enramycin Formulation

Version 3.2 Revision Date: 06.04.2024 SDS Number: 24603-00022 Date of last issue: 26.09.2023 Date of first issue: 22.10.2014

Unsuitable extinguishing media : Carbon dioxide (CO₂)
Dry chemical
High volume water jet

Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : 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_x)

Special protective actions for fire-fighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.
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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

Environmental precautions

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

Methods for 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.

SAFETY DATA SHEET



Enramycin Formulation

Version 3.2	Revision Date: 06.04.2024	SDS Number: 24603-00022	Date of last issue: 26.09.2023 Date of first issue: 22.10.2014
----------------	------------------------------	----------------------------	---

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

Precautions for safe handling

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, including any incompatibilities

Conditions for safe storage : Keep in properly labelled containers.
Store in accordance with the particular national regulations.

Materials to avoid : No special restrictions on storage with other products.

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Talc	14807-96-6	PEL (long term)	2 mg/m ³	SG OEL
		TWA (Res- pirable par- ticle)	2 mg/m ³	ACGIH

SAFETY DATA SHEET



Enramycin Formulation

Version 3.2 Revision Date: 06.04.2024 SDS Number: 24603-00022 Date of last issue: 26.09.2023 Date of first issue: 22.10.2014

		ticulate mat- ter)		
ENRAMYCIN B	34304-21-7	TWA	5 mg/m ³ (OEB 1)	Internal

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face 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 protection : Work uniform or laboratory coat.

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 : Chemical-resistant gloves

Material

Section 9: Physical and chemical properties

Appearance : powder

Colour : light brown

Odour : characteristic

Odour Threshold : No data available

pH : 5 - 8.5

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 : No data available

SAFETY DATA SHEET



Enramycin Formulation

Version 3.2 Revision Date: 06.04.2024 SDS Number: 24603-00022 Date of last issue: 26.09.2023
Date of first issue: 22.10.2014

flammability limit

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

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Dust can form an explosive mixture in air.

Conditions to avoid : Avoid dust formation.

Incompatible materials : None.

Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

SAFETY DATA SHEET



Enramycin Formulation

Version 3.2 Revision Date: 06.04.2024 SDS Number: 24603-00022 Date of last issue: 26.09.2023
Date of first issue: 22.10.2014

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

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

SAFETY DATA SHEET



Enramycin Formulation

Version
3.2

Revision Date:
06.04.2024

SDS Number:
24603-00022

Date of last issue: 26.09.2023
Date of first issue: 22.10.2014

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.

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.

SAFETY DATA SHEET



Enramycin Formulation

Version
3.2

Revision Date:
06.04.2024

SDS Number:
24603-00022

Date of last issue: 26.09.2023
Date of first issue: 22.10.2014

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.

Section 12: Ecological information

Toxicity

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

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

SAFETY DATA SHEET



Enramycin Formulation

Version 3.2 Revision Date: 06.04.2024 SDS Number: 24603-00022 Date of last issue: 26.09.2023
Date of first issue: 22.10.2014

M-Factor (Acute aquatic toxicity) : 10
M-Factor (Chronic aquatic toxicity) : 1
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

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.

Section 14: Transport information

International Regulations

UNRTDG

UN number : UN 3077
UN proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(ENRAMYCIN B)
Transport hazard class(es) : 9
Packing group : III
Labels : 9
Environmental hazards : yes

SAFETY DATA SHEET



Enramycin Formulation

Version 3.2 Revision Date: 06.04.2024 SDS Number: 24603-00022 Date of last issue: 26.09.2023
Date of first issue: 22.10.2014

IATA-DGR

UN/ID No. : UN 3077
UN proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(ENRAMYCIN B)
Transport hazard class(es) : 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)
Transport hazard class(es) : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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 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 specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable
Regulations

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

AICS : not determined

DSL : not determined

SAFETY DATA SHEET



Enramycin Formulation

Version 3.2 Revision Date: 06.04.2024 SDS Number: 24603-00022 Date of last issue: 26.09.2023
Date of first issue: 22.10.2014

IECSC : not determined

Section 16: Other information

Revision Date : 06.04.2024

Further information

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)

SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

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 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

SAFETY DATA SHEET



Enramycin Formulation

Version
3.2

Revision Date:
06.04.2024

SDS Number:
24603-00022

Date of last issue: 26.09.2023
Date of first issue: 22.10.2014

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.

SG / EN