

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Mamyzin
Product code:	A000593
Recommended use:	Ester of benzylpenicillin for subcutaneous or intramuscular injection for the treatment of mastitis, respiratory infections, footrot and uterine infections.
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau Auckland 2104 New Zealand
Telephone number:	Phone: +64 9 980 1600 Fax: +64 9 980 1601
Emergency telephone number:	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre : 0800 764 766 (0800 POISON) Fire Service, Ambulance : Dial 111
Date of issue:	18 September 2018
Date of review:	18 September 2018

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Powder with diluent for injection

Each vial of powder contains 5 g or 10 g of penethamate hydriodide.

Each vial of diluent contains water for injection with methylparahydroxybenzoate as a preservative.

Product components:

Powder

<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Diethylaminoethyl penicillin G, hydriodide	808-71-9	100%

Diluent

<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Water for injection	7732-18-5	99.85%
Methylparahydroxybenzoate	19438-10-9	0.15%

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.1E, 6.5B, 9.1A
Priority and secondary identifiers:	WARNING
Risk and safety phrases:	<p>Hazard Statement(s) H303 May be harmful if swallowed H317 May cause an allergic skin reaction H400 Very toxic to aquatic life</p> <p>Precautionary statement – Prevention P102 Keep out of reach of children P103 Read label before use P261 Avoid breathing dust P272 Contaminated work clothing should not be allowed out of the workplace P273 Avoid release to the environment P280 Wear protective gloves</p> <p>Precautionary statement – Response P101 If medical advice is needed, have product container or label at hand</p>

SAFETY DATA SHEET

Product Name: Mamyzin

Page 2 of 8
Reviewed on: 18 September 2018

P312 Call a POISON CENTRE or doctor/physician if you feel unwell
P302 + P352 IF ON SKIN: Wash with plenty of soap and water
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention
P321 N/A
P363 Wash contaminated clothing before reuse
P391 Collect spillage
Precautionary statement – Disposal
P501 Seal all wastes in labelled containers for subsequent recycling or disposal. Dispose of waste according to the applicable local and national regulations.

SECTION 4: FIRST AID MEASURES

Necessary first aid measures:	For advice, contact the National Poisons Centre on 0800 POISON (0800 764 766), or a doctor immediately. Animals developing an anaphylactic (life threatening) reactions, such as difficulty breathing or unconsciousness, must receive immediate medical attention. In case of self-injection, seek immediate medical attention. <u>Ingestion:</u> Do not induce vomiting. Wash out mouth thoroughly with water. <u>Eyes:</u> If in eyes, hold eyelids apart and flush the eyes continuously with running water. Remove contact lenses. Continue flushing for several minutes until all contaminants are washed out completely. Seek medical attention. <u>Skin:</u> Remove all contaminated clothing immediately. Wash affected area thoroughly with soap and water. Wash contaminated clothing before reuse or discard. Seek medical attention. <u>Inhalation:</u> If inhaled, remove affected person from contaminated area to fresh air. Apply artificial respiration if not breathing.
Workplace facilities:	No special facilities required.
Required instructions:	Observe good work practices and avoid skin contact. Wash hands and exposed skin before meals and after use. Do not eat or drink while using.
Notes for medical personnel:	Treat symptomatically. For animal injection only. Not for human use. Antidote: Epinephrine is indicated for anaphylactoid reactions.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:	Non-combustible material
Fire hazard properties:	Under fire conditions, this product may emit toxic and/or irritating fumes and gases including carbon monoxide and carbon dioxide.
Extinguishing media and methods:	Water spray, carbon dioxide, chemical powder or foam.
Hazchem code:	2Z
Recommended protective clothing:	Fire fighters should wear full protective clothing and self-contained breathing apparatus operated in positive pressure mode. Fight fire from safe location.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:	Increase ventilation. Evacuate all unprotected personnel. Wear sufficient respiratory protection and full protective clothing to prevent exposure. Sweep up material avoiding dust generation or dampen spilled material with water to avoid airborne dust, then transfer material to a suitable container. Wash surfaces well with soap and water. Seal all wastes in labelled containers for subsequent recycling or disposal. Dispose of waste according to the applicable local and national regulations. If contamination of sewers or waterways occurs, inform the local water and waste management authorities in accordance with local regulations.
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SAFETY DATA SHEET

Product Name: Mamyzin

Page 3 of 8
Reviewed on: 18 September 2018

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

Use only in a well-ventilated area. Avoid contact with clothing, skin or eyes and accidental injection. Use entire contents when first opened. Sterilise all injection apparatus before use. Avoid the use of strong disinfectants. If possible, avoid injection during wet weather or dusty conditions. Maintain high standards of personal hygiene i.e. washing hands prior to eating, drinking, smoking or using toilet facilities. Prevent the buildup of dust in the work atmosphere.

Approved handlers:

Not required

Conditions for safe storage:

Store in a dry, well-ventilated area, out of direct sunlight. Store in suitable, labelled containers. Keep containers closed when not in use. Store away from incompatible materials. Ensure that storage conditions comply with applicable local and national regulations.

Store site requirements:

Store below 30 °C

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:

No exposure standards have been established for the mixture. However, over- exposure to some chemicals may result in enhancement of pre-existing adverse medical conditions and/or allergic reactions and should be kept to the least possible levels.

Application in the workplace:

Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin contact.

Engineering controls:

This substance is hazardous and should be used with a local exhaust ventilation system, drawing solid/dust away from workers' breathing zone. If the engineering controls are not sufficient to maintain concentrations of particulates below the exposure standards. Suitable respiratory protection must be worn. Additional ventilation requirements are not expected under normal conditions of use. However if there is risk of airborne exposure, provide sufficient ventilation to keep airborne levels as low as possible.

Personal protection:

Respiratory Protection

None required, when used as intended. However, if engineering controls are not effective in controlling airborne exposure then an approved P2 or P3 respirator should be used.¹

Eye Protection

Safety glasses with side shields or chemical goggles are recommended. Final choice of appropriate eye/ face protection will vary according to individual circumstances. Eye protection devices should conform to relevant regulations.²

Hand Protection

None required, when used as intended. However, where exposure to the contents is likely wear gloves of impervious material such as PVC or neoprene gloves. Final choice of appropriate gloves will vary according to individual circumstances, i.e. methods of handling or according to risk assessments undertaken. Occupational protective gloves should conform to relevant regulations.³

Body Protection

Suitable protective workwear, e.g. cotton overalls buttoned at neck and wrist is recommended. Chemical resistant apron is recommended where large quantities are handled.

References:

1. Reference should be made to Australian Standards AS/ NZS 1715, Selection, Use and Maintenance of Respiratory Protective Devices; and AS/NZS 1716, Respiratory Protective Devices, in order to make any necessary changes

SAFETY DATA SHEET

Product Name: Mamyzin

Page 4 of 8
Reviewed on: 18 September 2018

for individual circumstances

2. Eye protection should conform with Australian/New Zealand Standard AS/NZS 1337 - Eye Protectors for Industrial Applications.
3. Reference should be made to AS/NZS 2161.1: Occupational protective gloves - Selection, use and maintenance.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data: Formulation type: Powder with diluent for injection
Appearance: Crystal white to slightly white powder
Specific gravity: Not available
Boiling Point: Not available
Melting Point: 178-179°C
Vapour Pressure: Not available
Solubility in Water: Slightly soluble (0.96% at 20 °C)
Flammability: Non-combustible material

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance: Stable under normal conditions of use and storage.
Conditions to avoid: Dust accumulation, heat and other sources of ignition.
Material to avoid: In aqueous solutions, ester is hydrolyzed to penicillin and free diethylaminoethanol.
Hazardous decomposition products: Under fire conditions this product may emit toxic and/or irritating fumes and gases including carbon monoxide and carbon dioxide.
Specific data: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation: **Toxicology Information**
Toxicity data for material given below.
Acute toxicity – Oral
LD50 (mouse): 1750 mg/kg
Ingestion
Ingestion of this product may irritate the gastric tract causing nausea and vomiting.
Inhalation
May cause respiratory irritation. Inhalation of product dust/vapours can cause irritation of the nose, throat and respiratory system. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin
Causes skin irritation. Skin contact will cause redness, itching and swelling. Repeated exposure may cause skin dryness and cracking and may lead to dermatitis. May cause an allergic skin reaction.
Eye
Causes serious eye irritation. On eye contact this product will cause tearing, stinging, blurred vision and redness.
Respiratory sensitisation
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sensitisation
May cause an allergic skin reaction.
Germ cell mutagenicity
Not considered to be a mutagenic hazard.
Carcinogenicity
Not considered to be a carcinogenic hazard.
Reproductive Toxicity
Not considered to be toxic to reproduction.
STOT-single exposure

SAFETY DATA SHEET

Product Name: Mamyzin

Page 5 of 8
Reviewed on: 18 September 2018

May cause respiratory irritation.
STOT-repeated exposure
Not expected to cause toxicity to a specific target organ.
Aspiration Hazard
Not expected to be an aspiration hazard.

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:

No ecological data available for this material.

Data organisation :

Persistence and degradability

As the substance is an antibiotic, it is likely that it may inhibit the growth of certain microorganisms in the biological treatment plants for sewage.

Mobility

Not available

Bioaccumulative Potential

Not available

Other Adverse Effects

Not available

Environmental risk and safety phrases:

Do not discharge this material into waterways, drains and sewers.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :

The disposal of the spilled or waste material and container must be done in accordance with applicable local and national regulations. Used needles should be placed in a designated sharps container.

SECTION 14: TRANSPORT INFORMATION

Relevant information:

This material is classified as a Class 9 – Miscellaneous Substances

Must not be loaded in the same freight container or on the same vehicle with:

- Class 1: Explosives

Class 9 dangerous goods that contain organic matter must not be loaded in the same bulk container or tankwagon with dangerous goods of Division 5.1 unless the Class 9 and Division 5.1 dangerous goods are in separate compartments of a bulk container or tankwagon.

Goods of packing group II or III may be loaded in the same freight container or on the same vehicle if transported in segregation devices. Segregation devices may be used to segregate Dangerous goods of Class 9 when the nature of those dangerous goods requires them to be segregated from dangerous goods of Class 3, 4, 5, 6 or 8 or from food items.

Marine Transport (IMO/IMDG):

Classified as Dangerous Goods by the criteria of the International Maritime Dangerous Goods Code (IMDG Code) for transport by sea.

Class/Division: 9

UN No: 3077

Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (PENETHEMATE HYDRIODIDE) (MARINE POLLUTANT)

SAFETY DATA SHEET

Product Name: Mamyzin

Page 6 of 8
Reviewed on: 18 September 2018

Air Transport (ICAO/IATA):

Classified as Dangerous Goods by the criteria of the International Air Transport Association (IATA) Dangerous Goods Regulations for transport by air.

Class/Division: 9

UN No: 3077

Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (PENETHEMATE HYDRIODIDE)

U.N. Number

3077

UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (PENETHEMATE HYDRIODIDE)

Transport hazard class(es)

9

Packing Group

III

Hazchem Code

2Z

Special Precautions for User

Not available

IERG Number

47

IMDG Marine pollutant

Yes

Transport in Bulk

Not available

Other requirements:

This material is classified as a Class 9 – Miscellaneous Substances
Must not be loaded in the same freight container or on the same vehicle with:

- Class 1: Explosives

Class 9 dangerous goods that contain organic matter must not be loaded in the same bulk container or tankwagon with dangerous goods of Division 5.1 unless the Class 9 and Division 5.1 dangerous goods are in separate compartments of a bulk container or tankwagon.

Goods of packing group II or III may be loaded in the same freight container or on the same vehicle if transported in segregation devices. Segregation devices may be used to segregate Dangerous goods of Class 9 when the nature of those dangerous goods requires them to be segregated from dangerous goods of Class 3, 4, 5, 6 or 8 or from food items.

Marine Transport (IMO/IMDG):

Classified as Dangerous Goods by the criteria of the International Maritime Dangerous Goods Code (IMDG Code) for transport by

SAFETY DATA SHEET

Product Name: Mamyzin

Page 7 of 8
Reviewed on: 18 September 2018

sea.

Class/Division: 9

UN No: 3077

Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS
SUBSTANCE, SOLID, N.O.S. (SODIUM SELENATE) (MARINE
POLLUTANT)

Packing Group: III EMS : F-A, S-F

Special Provisions: 274 335 966 967 969

Air Transport (ICAO/IATA):

Classified as Dangerous Goods by the criteria of the International
Air Transport Association (IATA) Dangerous Goods Regulations
for transport by air.

Class/Division: 9

UN No: 3077

Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS
SUBSTANCE, SOLID, N.O.S. (SODIUM SELENATE)

Packaging Instructions (passenger & cargo): 956

Packaging Instructions (cargo only): 956 Hazard Label:
Miscellaneous

Special Provisions: A97, A158, A179, A197

U.N. Number

3077

UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(SODIUM SELENATE)

Transport hazard class(es)

9

Packing Group

III

Hazchem Code

2Z

Special Precautions for User

Not available

IERG Number

47

IMDG Marine pollutant

Yes

Transport in Bulk

Not available

SECTION 15: REGULATORY INFORMATION

Regulatory status:

Registered pursuant to the ACVM Act 1997, No. A000593
See www.foodsafety.govt.nz for registration conditions

Restricted Veterinary Medicine
For use only under the authority or prescription of a veterinarian.

SAFETY DATA SHEET

Product Name: Mamyzin

Page 8 of 8
Reviewed on: 18 September 2018

Approved pursuant to the HSNO Act, Approval Code HSR002165
See www.epa.govt.nz for approval conditions

HSNO and ACVM controls: Refer to Section 3

SECTION 16: OTHER INFORMATION

Additional information: For product information visit the Boehringer Ingelheim website
www.boehringer-ingelheim.co.nz
While the information set forth is believed to be accurate as of the date hereof, BOEHRINGER INGELHEIM makes no warranty with respect hereto and disclaims all liability from reliance thereon.