

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Bivatop 200
Product code:	A006867
Recommended use:	For the treatment of conditions caused by, or associated with oxytetracycline-sensitive organisms and infections in cattle, sheep and pigs.
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City 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:	17 May 2018
Date of review:	26 June 2018

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Aqueous solution

Product components:

<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Oxytetracycline	6153-64-6	200 g/L
Other		To 100%

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.9B, 9.1B
Priority and secondary identifiers:	WARNING
Risk and safety phrases:	6.9B (single and repeated exposure) – harmful to human target organs or systems 9.1B Ecotoxic in the aquatic environment
	Hazard Statement(s) H371 May cause damage to organs by the oral route H373 May cause damage to organs through prolonged or repeated exposure by the oral route H411 Toxic to aquatic life with long lasting effects.
	Precautionary statement – Prevention P103 Read label before use. P260 Do not breathe dust/fume/gas/mist/vapours/spray. P264 Wash contaminated skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P273 Avoid release to the environment.
	Precautionary statement – Response P309+P311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician. P314 Get medical advice/attention if you feel unwell. P391 Collect spillage.
	Precautionary statement – Storage P405 Store locked up.

SAFETY DATA SHEET

Product Name: Bivatop 200

Page 2 of 7
Reviewed on: 26 June 2018

Precautionary statement – Disposal

P501 In the case of a substance that is in compliance with a HSNO approval other than a Part 6A (Group Standards) approval, a label must provide a description of one or more appropriate and achievable methods for the disposal of a substance in accordance with the Hazardous Substances (Disposal) Regulations 2001. This may also include any method of disposal that must be avoided. See Section 13 for disposal details.

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.

Ingestion: Do not induce vomiting. Wash out mouth thoroughly with water. Seek immediate medical attention.

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. If symptoms develop seek medical attention.

Skin: Wash affected area thoroughly with soap and water. If symptoms develop seek medical attention.

Inhalation: If inhaled, remove affected person from contaminated area. Keep at rest until recovered. If symptoms develop and/or persist seek medical attention.

Accidental self-injection: In the event of self-administration, seek medical attention and show the package leaflet to the medical practitioner.

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. Launder protective clothing separately from other clothing, and before each reuse.

Notes for medical personnel:

Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:

Non flammable

Fire hazard properties:

Under fire conditions Bivatop 200 may emit toxic and/or irritating fumes including oxides of nitrogen, carbon monoxide and carbon dioxide.

Extinguishing media and methods:

Extinguish small fires using dry chemical powder. For large fires use water spray, fog or foam.

Hazchem code:

3Z

Recommended protective clothing:

When fighting a major fire wear full protective clothing including self-contained breathing apparatus operated in positive pressure mode. Fight fire from a safe location.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:

Wear suitable personal protective equipment and clothing. For a small liquid spill: Wipe up or soak up using an inert non-combustible absorbent material. Collect the material and place into a suitable labelled container for disposal. If contamination of sewers or waterways occurs inform the local water and waste management authorities in accordance with local regulations.

For a large liquid spill: Increase ventilation. If possible contain the spill. Place inert absorbent material onto spillage. Collect the material and place into a suitable labelled container. Do not dilute material but contain. 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

SAFETY DATA SHEET

Product Name: Bivatop 200

Page 3 of 7
Reviewed on: 26 June 2018

authorities in accordance with local regulations.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

Use as directed on label or package insert. Avoid generating mist/vapours. Use in a well ventilated area. Prevent exposure without protection in order to lessen the possibility of disorders. Take care to avoid accidental injection. Use entire contents when first opened. Sterilise all injection apparatus before use. If possible avoid injection during wet weather or dusty conditions. Maintain high standards of personal hygiene i.e. Wash hands prior to eating, drinking, smoking or using toilet facilities.

Conditions for safe storage:

Store in a cool, dry, well-ventilated area, out of direct sunlight. Protect from light and freezing. Keep only in original container. Store away from incompatible materials. Ensure that storage conditions comply with applicable local and national regulations.

Store site requirements:

Store below 25 °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:

None required, when used as intended. However, if there is risk of airborne exposure, use with good general ventilation. If mists or vapours are produced, local exhaust ventilation should be used.

Personal protection:

Respiratory Protection

Industrial application: Use with good general ventilation. If engineering controls are not effective in controlling airborne exposure then an approved respirator with a replaceable vapor/mist filter should be used. Refer to relevant regulations for further information concerning respiratory protective requirements.¹

Eye Protection

Industrial application: Safety glasses with side shields, chemical goggles or full-face shield as appropriate should be used. Final choice of appropriate eye/face protection will vary according to individual circumstances. Eye protection devices should conform to relevant regulations.²

Hand Protection

Wear impervious chemical resistant 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 for individual circumstances.

2. Eye protection should conform with Australian/New Zealand

SAFETY DATA SHEET

Product Name: Bivatop 200

Page 4 of 7
Reviewed on: 26 June 2018

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: Liquid
Presentation: Amber glass injection vials
Specific gravity: Not available
Boiling Point: Not available
Vapour Pressure: Not available
Solubility in Water: Not available
Flammability: Non-flammable

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance: Stable under normal conditions of use and storage.
Conditions to avoid: Extreme temperatures and direct sunlight
Material to avoid: Not available
Hazardous decomposition products: Under fire conditions this product may emit toxic and/or irritating fumes including oxides of nitrogen, carbon monoxide and carbon dioxide.
Hazardous polymerization: Not available
Specific data: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity data:

Acute Toxicity - Oral
LD50(rat): 4800 mg/kg (value for the active ingredient)

Ingestion
Ingestion unlikely due to form of product. Ingestion of this product may irritate the gastric tract causing nausea and vomiting or other systemic effects.

Inhalation
Not a likely source of exposure. Inhalation of product vapours may cause irritation of the nose, throat and respiratory system.

Skin
Unlikely due to form of product. If contact occurs may cause redness, itching and irritation.

Eye
Unlikely due to form of product. If contact occurs may cause eye irritation with tearing, stinging, blurred vision and redness.

Respiratory sensitisation
Not expected to be a respiratory sensitiser.

Skin Sensitisation
Not expected to be a skin sensitiser.

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.

SAFETY DATA SHEET

Product Name: Bivatop 200

Page 5 of 7
Reviewed on: 26 June 2018

STOT-single exposure

May cause damage to organs by oral.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure by oral.

Aspiration Hazard

Not expected to be an aspiration hazard.

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:

Toxic to aquatic life with long lasting effects.

Data organisation :

Persistence and degradability

Not available

Mobility

Not available

Bioaccumulative Potential Not available

Other Adverse Effects Not available

Acute Toxicity - Fish

LC50: 75 mg/kg/96h (value for the active ingredient)

Environmental risk and safety phrases:

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

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :

Dispose of waste according to applicable local and national regulations. Do not allow into drains or watercourses or dispose of where ground or surface waters may be affected. Wastes including emptied containers are controlled wastes and should be disposed of in accordance with all applicable local and national regulations.

Used needles should be placed in a designated sharps container.

Product Disposal:

Product wastes are controlled wastes and should be disposed of in accordance with all applicable local and national regulations. This product can be disposed through a licensed commercial waste collection service. In this specific case the product is a combustible substance and therefore can be sent to an approved high temperature incineration plant for disposal.

Personal protective clothing and equipment as specified in Section 8 of this SDS must be worn during handling and disposal of this product. The ventilation requirements as specified in the same section must also be followed, and the precautions given in Section 7 of this SDS regarding handling must also be followed.

Do not dispose into the sewerage system. Do not discharge into drains or watercourses or dispose where ground or surface waters may be affected.

In New Zealand, the disposal agency or contractor must comply with the New Zealand Hazardous Substances (Disposal) Regulations 2001. Further details regarding disposal can be obtained on the EPA New Zealand website under specific group standards.

Container Disposal:

SAFETY DATA SHEET

Product Name: Bivatop 200

Page 6 of 7
Reviewed on: 26 June 2018

	<p>The container or packaging must be cleaned and rendered incapable of holding any substance. It can then be disposed of in a manner consistent with that of the substance it contained. In this instance the packaging can be disposed through a commercial waste collection service.</p> <p>Alternatively, the container or packaging can be recycled if the hazardous residues have been thoroughly cleaned or rendered non-hazardous.</p> <p>In New Zealand, the packaging (that may or may not hold any residual substance) that is lawfully disposed of by householders or other consumers through a public or commercial waste collection service is a means of compliance with regulations.</p>
--	--

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: 3082

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (OXYTETRACYCLINE DIHYDRATE)

Packing Group: III

EMS: F-A, S-F

Special Provisions: 274 335 969

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: 3082

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (OXYTETRACYCLINE DIHYDRATE).

Packing group: III

Packaging instructions (passenger & cargo): 964

SAFETY DATA SHEET

Product Name: Bivatop 200

Page 7 of 7
Reviewed on: 26 June 2018

Packaging instructions (cargo only): 964
Hazard label: Miscellaneous
Special provisions: A97, A158, A197
U.N. Number: 3082
U.N. proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (OXYTETRACYCLINE DIHYDRATE)
Transport hazard class(es): 9
Packing group: III
Hazchem code: 3Z
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. A006867
See www.foodsafety.govt.nz for registration conditions

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

Approved pursuant to the HSNO Act, Approval Code HSR002357
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.