

SAFETY DATA SHEETS

This SDS packet was issued with item:

078950026

N/A

SAFETY DATA SHEET



Oxy-Tet 200 Injection

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06/23/2020	122000009736	Date of first issue: 23.06.2020

SECTION 1. IDENTIFICATION

Product information

Product Name : Oxy-Tet 200 Injection
Synonyms : Bio-Mycin 200 Injection
Bivitop 200 Injection
SDS Number : 122000009736

Use : veterinary medicine

Company

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
USA
+1-877-Elanco1(+1-877-3526261)
elanco_sds@elanco.com

In case of emergency: CHEMTREC International: +1 703-527-3887 (24 hours)

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Eye irritation : Category 2A

Reproductive toxicity : Category 2

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.
H361 Suspected of damaging fertility or the unborn child.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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P308 + P313 IF exposed or concerned: Get medical advice/attention.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Oxytetracycline dihydrate	6153-64-6	20

SECTION 4. FIRST AID MEASURES

General advice : No hazards which require special first aid measures.

If inhaled : Not an expected entry route.

In case of skin contact : If skin reactions occur, contact a physician.

In case of eye contact : Flush eyes with water as a precaution.

If swallowed : In case of accidental ingestion, contact your regional poison center or physician immediately.

Most important symptoms and effects, both acute and delayed : No information available.

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

Notes to physician : No information available.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire-fighting : Fire may cause evolution of:
Carbon monoxide (CO)
Carbon dioxide (CO₂)

Further information : Prevent fire extinguishing water from contaminating surface water or the ground water system.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Avoid formation of aerosol.

Methods and materials for containment and cleaning up : Cover spilled product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labeled, closable containers.

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SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : No special protective measures against fire required.

Advice on safe handling : Avoid formation of aerosol.

Conditions for safe storage : Store at temperatures and conditions as indicated on the product label.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Polyethylene glycol 400	25322-68-3	TWA (aerosol)	10 mg/m ³	US WEEL
Magnesium oxide	1309-48-4	TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (fume, total particulate)	15 mg/m ³	OSHA Z-1
		TWA (fume, total particulate)	15 mg/m ³	OSHA Z-1
		TWA (Fume - total particulate)	10 mg/m ³	OSHA P0
		TWA (Fume - total particulate)	10 mg/m ³	OSHA P0

Personal protective equipment

Respiratory protection : Recommended Filter type:
Organic vapor with prefilter
None required for consumer use of this product.

Hand protection
Material : Chemically resistant gloves.

Remarks : None required for consumer use of this product.

Eye protection : Safety glasses
None required for consumer use of this product.

Protective measures : No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients.
Please consult label for end-user requirements.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

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Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point / range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Burning rate	:	No data available
Self-ignition	:	No data available
Burning number	:	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
Density	:	No data available
Bulk density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

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Impact sensitivity	:	No data available
Minimum ignition energy	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No data available
Chemical stability	:	No data available
Possibility of hazardous reactions	:	No data available
Conditions to avoid	:	No data available
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	Carbon monoxide (CO) Carbon dioxide (CO ₂)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate (ATE): > 5.000 mg/kg Method: Calculation method
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Components:

Oxytetracycline dihydrate:

Acute oral toxicity	:	LD50 (Rat): 4.800 mg/kg
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Serious eye damage/eye irritation

Components:

Oxytetracycline dihydrate:

Result	:	Eye irritation
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Carcinogenicity

IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
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OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
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NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
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Reproductive toxicity

Components:

Oxytetracycline dihydrate:

Reproductive toxicity - Assessment	:	Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.
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Further information

Components:

Oxytetracycline dihydrate:

Pharmaceutic effects

Remarks : Antibiotic

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Oxytetracycline dihydrate:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 75 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 4,27 mg/l

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Product:

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

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Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Serious eye damage or eye irritation
Reproductive toxicity

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Polyethylene glycol 400	25322-68-3	30 %
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Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

Magnesium oxide	1309-48-4
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Pennsylvania Right To Know

Magnesium oxide	1309-48-4
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Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

New York City Hazardous Substances

Magnesium oxide 1309-48-4

California List of Hazardous Substances

Magnesium oxide 1309-48-4

California Permissible Exposure Limits for Chemical Contaminants

Magnesium oxide 1309-48-4

International Regulations

Montreal Protocol (Ozone Depleting Substances) : Not applicable

Rotterdam Convention (Prior Informed Consent) : Not applicable

Stockholm Convention (Persistent Organic Pollutants) : Not applicable

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

TSCA : Substance(s) not listed on TSCA inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

Health - 2 Flammability - 1 Instability - 0 Others -

HMIS® IV:

Health - 2 Flammability - 1 Instability - 0 Others -

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
OSHA P0	:	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	:	8-hour, time-weighted average
OSHA P0 / TWA	:	8-hour time weighted average

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OSHA Z-1 / TWA	:	8-hour time weighted average
US WEEL / TWA	:	8-hr TWA

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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.

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