SAFETY DATA SHEETS

This SDS packet was issued with item:

078950778

N/A

SAFETY DATA SHEET

Veraflox® Oral Suspension

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06/19/2020	122000001946	Date of first issue: 19.06.2020

SECTION 1. IDENTIFICATION

Product information
Product Name : Veraflox® Oral Suspension
SDS Number : 122000001946

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
Germ cell mutagenicity : Category 2

GHS label elements
Hazard pictograms :

Signal word : Warning

Hazard statements : H341 Suspected of causing genetic defects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : Aqueous suspension

Components

Chemical name	CAS-No.	Concentration (% w/w)
Amberlite IRP 64	80892-32-6	9,48
Pradofloxacin	195532-12-8	2,37

SECTION 4. FIRST AID MEASURES

General advice : If you feel unwell, seek medical advice (show the label where possible).

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.
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

Methods and materials for containment and cleaning up : Suppress (knock down) gases/vapours/mists with a water spray jet.
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Place in closed containers. Label for proper disposal.

SECTION 7. HANDLING AND STORAGE

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

fire and explosion

Advice on safe handling : Industrial uses:
Avoid formation of aerosol.
Use with local exhaust ventilation.
Avoid contact with skin, eyes and clothing.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propane-1,2-diol	57-55-6	TWA	10 mg/m³	US WEEL
		TWA	10 mg/m³	US WEEL
Pradofloxacin	195532-12-8	Bayer OES	0,5 mg/m³	

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.
For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.
Wear suitable protective equipment.
Please consult label for end-user requirements.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

pH : 5
Method: DIN 51369

Density : 1,055 g/cm³ (68 °F / 20 °C)

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Explosive properties : No data available

Oxidizing properties : No data available

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 (CO2)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : LD50 (Rat): >= 5.000 mg/kg
Method: OECD 423
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute dermal toxicity : LD50 (Rat): > 4.000 mg/kg
Assessment: May be harmful in contact with skin.

Components:

Amberlite IRP 64:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

Pradofloxacin:

Acute oral toxicity : LD50 (Rat): 1.000 - 2.000 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Assessment: The component/mixture is minimally toxic after single contact with skin.

Skin corrosion/irritation

Product:

Species : Rabbit
Method : OECD 404
Result : No skin irritation

Components:

Pradofloxacin:

Species	:	Rabbit
Method	:	OECD 404
Result	:	No skin irritation

Serious eye damage/eye irritation

Product:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD 405

Components:

Amberlite IRP 64:

Species	:	Rabbit
Result	:	Moderate eye irritation

Pradofloxacin:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD 405

Respiratory or skin sensitisation

Product:

Test Type	:	Skin sensitisation
Species	:	Pig
Method	:	OECD 406
Result	:	Did not cause sensitisation on laboratory animals.

Components:

Pradofloxacin:

Test Type	:	Skin sensitisation
Species	:	Guinea pig
Method	:	Magnusson and Kligmann maximization test
Result	:	Does not cause skin sensitisation.

Germ cell mutagenicity

Components:

Amberlite IRP 64:

Genotoxicity in vitro	:	Test Type: Ames test Result: negative

Pradofloxacin:

Genotoxicity in vitro	:	Test Type: Micronucleus test Result: positive Test Type: Chromosome aberration test in vitro

Result: positive

Test Type: V79-HPRT Forward Mutation Assay
Result: positive

Test Type: Ames test
Result: positive

Genotoxicity in vivo : Test Type: Dominant lethale test
Result: negative

Test Type: Micronucleus test
Species: Mouse
Result: positive

Test Type: DNA damage and/or repair
Species: Rat
Result: negative

Remarks: The genotoxic effect is due to the pharmocologic effectiveness.

Germ cell mutagenicity - Assessment : Positive result(s) from in vivo somatic cell mutagenicity tests supported by positive results from in vitro mutagenicity assays or chemical structure activity relationship to known germ cell mutagens

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.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

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.

Repeated dose toxicity

Components:

Amberlite IRP 64:

NOAEL : 1.000 mg/kg
Exposure time : 90-day

Further information

Product:

Pharmaceutic effects
Remarks : anti infective

Components:

Pradofloxacin:

Pharmaceutic effects
Remarks : Antibiotic

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Amberlite IRP 64:

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Pradofloxacin:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 1.000 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity
Test substance: Ciprofloxacin HCl

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): 33 mg/l
Test Type: Cell multiplication inhibition test
Test substance: Ciprofloxacin HCl

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Pradofloxacin:

Partition coefficient: n-octanol/water : log Pow: 0,42

Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : Do not allow to enter surface waters or groundwater.

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
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 : Chronic Health Hazard

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.

US State Regulations

Massachusetts Right To Know
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know
Propane-1,2-diol 57-55-6

New York City Hazardous Substances
No components listed on the New York City Hazardous Substances List

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

Full text of other abbreviations

US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA	:	8-hr TWA

Revision Date : 06/19/2020

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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