1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product informationVERAFLOX ORAL SUSP 2.5 % 15ML

Product Name: Veraflox Oral Suspension
Synonyms: PRADO SUSP 2,5 % M/V 5 ML 224 ORAL
Veraflox
SDS Number: 122000001946

Use : veterinary medicine

Company
Bayer HealthCare, LLC
Animal Health Division
12707 Shawnee Mission Parkway
(West 63rd)
Shawnee, KS 66216-1846
UNITED STATES OF AMERICA
(800) 633-3796

In case of emergency: (800) 422-9874
Chemtrec: (800) 424-9300
BAYER INFORMATION PHONE:(800) 633-3796
INTERNATIONAL:(703) 527-3887

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification according to national GHS implementation:
Germ cell mutagenicity, Category 2 (H341)

Label elements

Labelling according to national GHS implementation:

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.

Hazardous components which must be listed on the label:

Components:	**CAS-No.**
Pradofloxacin Drug	195532-12-8

Other hazards

Other hazards which do not result in classification:
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a mixture.

Aqueous solution

Hazardous components

Amberlite IRP 64
Concentration [Weight percent] 9.48
CAS-No.: 80892-32-6
CAS name: Amberlite IRP 64

GHS Classification:

Eye Irrit. 2A H319

Pradofloxacin Drug
Concentration [Weight percent] 2.37
CAS-No.: 195532-12-8
CAS name: 3-Quinolinecarboxylic acid, 8-cyano-1-cyclopropyl-6-fluoro-1,4-dihydro-7-[(4aS,7aS)-octahydro-6H-pyrrolo[3,4-b]pyridin-6-yl]-4-oxo-

GHS Classification:

Acute Tox. 4 H302
Muta. 2 H341

contains

Propane-1,2-diol
Concentration [Weight percent] 28.5819
CAS-No.: 57-55-6
CAS name: 1,2-Propanediol (8CI, 9CI)

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

Description of first aid measures

General advice: Follow label or package insert instructions.

If inhaled: Remove to fresh air. Call a physician immediately.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: If swallowed, seek medical advice immediately and show this container or label.

Most important acute symptoms/effects

Indication of any immediate medical attention and special treatment needed

5. FIREFIGHTING MEASURES

Extinguishing media

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

Unsuitable extinguishing media: High volume water jet

Special hazards arising from the substance or mixture

Specific hazards during firefighting: 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.

Advice for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Follow label or package insert instructions.

Environmental precautions

Methods and materials for containment and cleaning up

Methods for 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.

Reference to other sections

Additional advice: No special precautions required.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling:
Avoid formation of aerosol. Only handle product with local exhaust ventilation. Avoid contact with skin, eyes and clothing.

No special protective measures against fire required.

Conditions for safe storage, including any incompatibilities

Specific end use(s)

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
Pradofloxacin Drug	195532-12-8	OEL (Bayer)	0.5 mg/m³	

Hazardous components without workplace control parameters

Components	CAS-No.
Amberlite IRP 64	80892-32-6

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 : Wear suitable protective equipment.
Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form:	suspension	
Colour:	No statements available.	
Odour:	No statements available.	
Melting point/range:	No statements available.	
Boiling point/boiling range:	No statements available.	
Density:	1.055 g/cm³ at 20 °C	
Bulk density:	Not applicable	
Vapour pressure:	No statements available.	
Viscosity, dynamic:	No statements available.	
Viscosity, kinematic:	No statements available.	
Flow time:	No statements available.	
Surface tension:	No statements available.	
Water solubility:	No statements available.	
Solubility(ies):	No statements available.	
pH:	5	DIN 51369
Corrosive to metal:	No statements available.	
Partition coefficient (n-octanol/water):	Pradofloxacin Drug log Pow: 0.42	
Flash point:	No statements available.	
Inflammability (solid, gaseous):	Not applicable	
Explosion limits:	No statements available.	

Other information

Miscibility with water:	No statements available.

10. STABILITY AND REACTIVITY

Reactivity
No statements available.

Reactions with water / air:
No statements available.

Ignition temperature:
Pradofloxacin Drug
> 500 °C
Burning number:

Pradofloxacin Drug
1 at 20 °C Method: VDI 2263

Chemical stability
No statements available.

Thermal decomposition:
No data available

Dust explosion characteristic number:
Not applicable

Dust explosion class:
Not applicable

Impact sensitivity:

No data available

Hazardous reactions:

No data available

Explosive properties:

No statements available.

Possibility of hazardous reactions

deflagration ability:
No statements available.

Smoldering combustion:
No statements available.

Conditions to avoid
No data available

Minimum ignition energy:
No data available

Oxidizing properties:
No statements available.

Incompatible materials

Materials to avoid:
Oxidizing agents

Hazardous decomposition products
Carbon monoxide (CO), Carbon dioxide (CO2)

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 Drug:

Acute oral toxicity	:	LD50 (Rat): 1,000 - 2,000 mg/kg Assessment: Harmful if swallowed.
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Assessment: May be harmful in contact with skin.
Acute toxicity (other routes of administration)	:	LD50 (Rat): 200 - 500 mg/kg Application Route: intraperitoneal

Skin corrosion/irritation

Product:

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

Components:

Pradofloxacin Drug:

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 Drug:

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 Drug:

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 Drug:

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 : Method: 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 attributable to the pharmacological mechanism of action.

Germ cell mutagenicity - : Positive result(s) from in vivo somatic cell mutagenicity tests

Assessment	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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Amberlite IRP 64:

Ecotoxicology Assessment

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

Pradofloxacin Drug:

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 daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 176 mg/l Exposure time: 24 h Test substance: Ciprofloxacin HCl
Toxicity to algae	:	EC50 (Desmodesmus subspicatus (green algae)): 33 mg/l Exposure time: 72 h Test Type: Cell multiplication inhibition test Test substance: Ciprofloxacin HCl

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Pradofloxacin Drug:

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.

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)

14. TRANSPORT INFORMATION

US Land transport (CFR)
non-regulated

Sea transport (IMDG)
non-regulated

Air transport (IATA)
non-regulated

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 311/312 Hazards : Chronic Health Hazard

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

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

California Prop. 65 This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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

Breakdown of the preparation yields at least one new substance.

TSCA Not On TSCA Inventory
Amberlite IRP 64
Pradofloxacin Drug

TSCA list

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

No substances are subject to a Significant New Use Rule.

16. OTHER INFORMATION

Full text of H-Statements mentioned in chapters 2 and 3

H302 Harmful if swallowed.

H319	Causes serious eye irritation.
H341	Suspected of causing genetic defects.

Further information

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.