SAFETY DATA SHEETS

This SDS packet was issued with item:

078909033

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078909032

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

Product information VERAFLOX ORAL SUSP 2.5 % 15ML

Product Name:	Veraflox Oral Suspension
MSDS Number:	122000001946

Use : veterinary medicine

Company
BAYER HEALTHCARE LLC
Animal Health Division
12707 Shawnee Mission Parkway
(West 63rd)
Shawnee, KS 66216-1846
USA
(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

Emergency Overview

Form: liquid suspension

GHS Classification:

Germ cell mutagenicity : Category 2

GHS Label element:

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.
P281 Use personal protective equipment as required.
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 which do not result in classification:

None known.

Hazard Communication (29CFR 1910.1200)

3. COMPOSITION/INFORMATION ON INGREDIENTS

Weight percent	Components	CAS-No.
15 - 40%	Trade secret	

Other Ingredients

Weight percent	Components	CAS-No.
1 - 10%	Pradofloxacin Drug	195532-12-8
0.1 - 0.5%	Hexa-2,4-dienoic acid	110-44-1

4. FIRST AID MEASURES

General advice: Take off all contaminated clothing immediately.

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.

Contact Number: Use the Bayer Emergency Number in Section 1

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 firefighting: Fire may cause evolution of: Carbon monoxide (CO) Carbon dioxide (CO2)

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

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

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

Additional advice: No special precautions required.

Further Accidental Release Notes No special precautions required.

7. HANDLING AND STORAGE

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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory protection:
Recommended Filter type: Organic vapor with prefilter

Hand protection:
Chemically resistant gloves.

Eye protection:
Safety glasses

Other protective measures:
Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	suspension	
Colour:	No applicable information is available	
Odour:	No applicable information is available	
Odour Threshold:	No applicable information is available	
Melting point:	No applicable information is available	
Boiling point/boiling range:	No applicable information is available	
Density:	1.055 g/cm³ at 68 °F (20 °C)	
Bulk density:	No applicable information is available	
Vapour pressure:	No applicable information is available	
Viscosity, dynamic:	No applicable information is available	
Viscosity, kinematic:	No applicable information is available	
Flow time:	No applicable information is available	
Surface tension:	No applicable information is available	
Miscibility with water:	No applicable information is available	
Water solubility:	No applicable information is available	
pH:	5	DIN 51369
Relative density:	No applicable information is available	
Partition coefficient:	No applicable information is available	
Solubility(ies):	No applicable information is available	
Flash point:	No applicable information is available	
Flammability (solid, gas):	No applicable information is available	
Ignition temperature:	No applicable information is available	
Explosion limits:	No applicable information is available	

10. STABILITY AND REACTIVITY

Conditions to avoid: no data available

Materials to avoid: Oxidizing agents

Hazardous reactions: no data available

Thermal decomposition:

no data available

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

Oxidizing properties:

No statements available.

Impact Sensitivity:
no data available

11. TOXICOLOGICAL INFORMATION

Acute oral toxicity:
LD50 rat : >= 5,000 mg/kg
The substance or mixture has no acute oral toxicity
Method: OECD TG 423

Acute inhalation toxicity:
Trade secret
LC50 rabbit: > 317 mg/l, 2 h
The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity:
LD50 rat: > 4,000 mg/kg
May be harmful in contact with skin.

Acute toxicity (other routes of administration):
Pradofloxacin Drug
LD50 intraperitoneal rat: 200 - 500 mg/kg

Skin irritation:
rabbit
Result: No skin irritation
Method: OECD Test Guideline 404

Eye irritation:
rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Sensitisation:
Skin sensitization pig
Result: Did not cause sensitization on laboratory animals.
Method: OECD Test Guideline 406

Subacute, subchronic and prolonged toxicity:
Trade secret
NOEL 50,000 mg/kg, rat Oral, Exposure time 24 month

NOEL 1 mg/l, rat Inhalation, Exposure time 3 month
Number of exposures: once daily

Genotoxicity in vitro:
Trade secret
Ames test Bacteria
Dose: yes
Result: negative
Method: OECD TG 471

Mammalian cells
Result: negative
Method: OECD TG 476

Pradofloxacin Drug
Micronucleus test
Result: positive

Chromosome aberration test in vitro
Result: positive

V79-HPRT Forward Mutation Assay
Result: positive

Ames test
Result: positive

Genotoxicity in vivo:
Trade secret

Result: negative
Method: OECD TG 478

Pradofloxacin Drug

Result: negative
Method: Dominant lethale test

Micronucleus test, mouse
Result: positive

Unscheduled DNA Synthesis Test, rat
Result: negative

The genotoxic effect is attributable to the pharmacological mechanism of action.

Carcinogenicity:
Trade secret
rat:
Exposure time: 2 a
Number of exposures: once daily
Result: negative

Pradofloxacin Drug
Result: Animal testing did not show any carcinogenic effects.

Reproductive toxicity:
Trade secret
Application Route: Oral
rat, female: Test period: 18 d
NOAEL: 1600 mg/kg
Result: Animal testing did not show any effects on fertility.

Pradofloxacin Drug
Result: Impairment of fertility in animal studies at doses which are harmful to the parent animals.

Teratogenicity:
Trade secret
rat, male: Number of exposures: once daily
Test period: 15 d
NOAEL: 1600 mg/l
Result: No indication of teratogenic effects.

Pradofloxacin Drug
Result: Evidence of a teratogenic effect in animal studies at doses which are harmful to the parent animals.

Pharmaceutic effects:
antiinfective

Carcinogenicity:
No Carcinogenic substances as defined by IARC, NTP and/or OSHA

STOT - single exposure:
no data available

STOT - repeated exposure:
no data available

12. ECOLOGICAL INFORMATION

General advice:
Do not allow to enter surface waters or groundwater.

Toxicity to fish:
Trade secret
Acute Fish toxicity: LC50 40,613 mg/l
Test species: Pimephales promelas (fathead minnow) Duration of test: 96 h

Pradofloxacin Drug
Acute Fish toxicity: LC50 1,000 mg/l
Test species: Danio rerio (zebra fish) Test substance: Ciprofloxacin HCl Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:
Trade secret
LC50 18,340 mg/l
Test species: Ceriodaphnia dubia Duration of test: 48 h

Pradofloxacin Drug
EC50 176 mg/l
Test species: Daphnia magna (Water flea) Duration of test: 24 h
Test substance: Ciprofloxacin HCl

Toxicity to algae:
Trade secret
IC50 19,100 mg/l
tested on: Pseudokirchneriella subcapitata (green algae)

Pradofloxacin Drug
Cell multiplication inhibition test EC50 33 mg/l
tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h
Test substance: Ciprofloxacin HCl

Toxicity to bacteria:
Trade secret
NOEC 20,000 mg/l
tested on: Pseudomonas putida
Duration of test: 18 h

Biodegradability:
Trade secret
87 - 92 %, 28 d rapidly biodegradable
Method: OECD Test Guideline 301C

Bioaccumulation:
Trade secret

Bioconcentration factor (BCF)
0.09

13. DISPOSAL CONSIDERATIONS

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)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

14. TRANSPORT INFORMATION

Land transport (CFR)
Non-Regulated

US Sea transport (IMDG)
Non-Regulated

US Air transport (ICAO / IATA cargo aircraft only)
Non-Regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)
Non-Regulated

International IATA	- -
IMDG	- -

15. REGULATORY INFORMATION

Other regulations: No statements available.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)
Components
None

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required
Components
None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components
None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
15 - 40%	Trade secret	

California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Hazardous

16. OTHER INFORMATION

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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.