

SAFETY DATA SHEET

FLOXAN

Version 2.0

Revision Date 02/23/2015

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

Product information

Product Name:
FLOXAN

Use : veterinary medicine unfinished

Company

MICROWISE COMPANY FOR Animal Health
MICROWISE

11516 DONNA DR Tampa FL 33637 USA

In case of emergency: +18133301934

2. HAZARDS IDENTIFICATION

Emergency Overview

WARNING! Combustible Liquid Colour: yellow, brownish Odour: weak, Alcohol.
May cause eye, skin, and respiratory tract irritation.

GHS Classification:

Eye irritation : Category 2

GHS Label element:

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

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Precautionary statements**: Prevention:**

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ 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.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredients:

Weight percent	Components	CAS-No.
1 - 5%	n-butanol	71-36-3
10%	Enrofloxacin	93106-60-6
1 - 5%	Alcohol derivative	

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.

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Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Fire may cause evolution of: Hydrogen cyanide (hydrocyanic acid) Hydrogen fluoride Nitrogen oxides (NOx) Carbon oxides

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

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. Use adequate ventilation.

Methods for 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.

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. Do not refrigerate.

No special protective measures against fire required.

Storage:

Keep away from direct sunlight.

Storage temperature: < 104 °F (< 40 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**n-butanol (71-36-3)**

US. ACGIH Threshold Limit Values

Time Weighted Average (TWA): 20 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Ceiling Limit Value and Time Period (if specified): 50 ppm, 150 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Skin designation: Can be absorbed through the skin.



US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

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PEL: 100 ppm, 300 mg/m³

Alcohol derivative

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides
Time Weighted Average (TWA): 10 ppm, 44.20 mg/m³

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:	No applicable information is available	
Colour:	yellow, brownish	
Odour:	weak, Alcohol	
Odour Threshold:	No applicable information is available	
Melting point:	No applicable information is available	
Boiling point/boiling range:	No applicable information is available	
Density:	1.08 g/cm ³ at 68 °F (20 °C)	DIN 51757
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:	completely miscible	
Water solubility:	No applicable information is available	
pH:	8.9 - 10.9 at (68 °F (20 °C)) (undiluted)	
Relative density:	No applicable information is available	
Partition coefficient:	No applicable information is available	
Solubility(ies):	No applicable information is available	
Flash point:	145 °F (62.78 °C)	
Flammability (solid, gas):	No applicable information is available	
Ignition temperature:	No applicable information is available	
Explosion limits:	No applicable information is available	

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10. STABILITY AND REACTIVITY

Conditions to avoid: Do not allow product to come in contact with:
Exposure to light.

Materials to avoid: Oxidizing agents

Hazardous reactions: No data available

Thermal decomposition:

No data available

Hazardous decomposition products:

Hydrogen cyanide (hydrocyanic acid), Hydrogen fluoride, Nitrogen oxides (NO_x), Carbon oxides

Oxidizing properties:

No statements available.

Impact sensitivity:

No data available

11. TOXICOLOGICAL INFORMATION

Other information on toxicity:

n-butanol

Liver and kidney injuries may occur.

After absorption of large quantities Dizziness, Liver disorders, drowsiness, headaches, Weakness

Other information on toxicity:

Alcohol derivative

Dermal absorption possible

If inhaled: irritations, Shortness of breath, Cough

If swallowed: Vomiting, Nausea, Irritation of mucous membranes in the mouth, throat, gullet and gastro-intestinal tract after swallowing.

Systemic toxicity headaches, Nausea, CNS disorders, Convulsions, Unconsciousness, cessation of breathing

Acute oral toxicity:

n-butanol

LD50 Rat: 790 mg/kg

Alcohol derivative

LD50 Rat: 1,230 mg/kg

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Enrofloxacin

LD50 Rat: > 5,000 mg/kg

The substance or mixture has no acute oral toxicity

Acute inhalation toxicity:

n-butanol

LC50 Rat: 8000 ppm, 4 h

Alcohol derivative

Harmful if inhaled.

Enrofloxacin

LC50 Rat: > 2.937 mg/l, 4 h

The substance or mixture has no acute inhalation toxicity

An LC50/inhalation/4h/rat could not be determined because no mortality of rats was observed at the maximum achievable concentration.

Acute dermal toxicity:

n-butanol

LD50 Rabbit: 3,400 mg/kg

Alcohol derivative

LD50 Rabbit: > 2,000 mg/kg

Enrofloxacin

LD50 Rabbit: > 2,000 mg/kg

Skin irritation:

n-butanol

Rabbit

Result: Mild skin irritation

Method: OECD 404

Alcohol derivative

Rabbit

Result: No skin irritation

Method: OECD 404

Enrofloxacin

Rabbit

Result: No skin irritation

Method: OECD 404

Eye irritation:

n-butanol

Rabbit

Result: Causes serious eye damage.

Method: OECD 405

Alcohol derivative

Rabbit

Result: No eye irritation

Method: OECD 405

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Enrofloxacin
Rabbit
Result: Mild eye irritation
Method: OECD 405

Sensitisation:

n-butanol
Skin sensitization guinea pig
Result: Did not cause sensitisation on laboratory animals.
Method: OECD 406

Alcohol derivative
guinea pig
Result: Did not cause sensitisation on laboratory animals.
Method: Magnusson and Kligmann maximization test

Enrofloxacin
Skin sensitization guinea pig
Result: Did not cause sensitisation on laboratory animals.
Method: Buehler Test

Subacute, subchronic and prolonged toxicity:

Alcohol derivative
NOEL 400 mg/kg, Rat, Exposure time 90-day

Genotoxicity in vitro:

n-butanol
Ames test
Result: negative

Micronucleus test
Result: negative

In vitro gene mutation study in mammalian cells Hamster V79-cells
Result: No evidence of a genotoxic effect. Method: OECD 476

Alcohol derivative
Ames test
Result: negative

Enrofloxacin
Ames test
Result: negative

Genotoxicity in vivo:

n-butanol
Micronucleus test, Mouse
Result: No evidence of a genotoxic effect.
Method: OECD 474

Alcohol derivative
Result: No indication of mutagenic effects.

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Enrofloxacin
Micronucleus test, Mouse
Result: No indication of clastogenic effects.

Reproductive toxicity:

n-butanol
NOAEL: 2000 ppm
Result: Animal testing did not show any effects on fertility.
Method: OECD Test Guideline 416

Teratogenicity:

Alcohol derivative
Result: Did not show teratogenic effects in animal experiments.

Pharmaceutic effects:

Enrofloxacin
Antibiotic

Carcinogenicity:

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

Experience with human exposure:

Components:

71-36-3 :
May cause skin irritation and/or dermatitis.

STOT - single exposure:

Components:

71-36-3 :
Assessment: May cause drowsiness or dizziness.

100-51-6 :

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure:

Components:

100-51-6 :

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

12. ECOLOGICAL INFORMATION

General advice:

Do not allow to enter surface waters or groundwater.

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Toxicity to fish:

n-butanol

Acute Fish toxicity: LC50 1,730 mg/l

Test species: Pimephales promelas (fathead minnow) Duration of test: 96 h

Alcohol derivative

Acute Fish toxicity: LC50 10 mg/l

Test species: Lepomis macrochirus (Bluegill) Duration of test: 96 h

Enrofloxacin

Acute Fish toxicity: LC0 > 10 mg/l

Test species: Salmo gairdneri Duration of test: 96 h

Acute Fish toxicity: LC0 > 9.6 mg/l

Test species: Lepomis macrochirus (Bluegill) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:

n-butanol

EC50 1,983 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 48 h

Alcohol derivative

EC50 55 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 24 h

Enrofloxacin

EC0 > 10 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 48 h

Toxicity to algae:

Alcohol derivative

IC50 > 100 mg/l

Duration of test: 72 h

Toxicity to bacteria:

Alcohol derivative

EC50 71.4 mg/l

tested on: Photobacterium phosphoreum

Duration of test: 0.5 h

Enrofloxacin

EC0 0.003 mg/l

tested on: Pseudomonas putida

Toxicity on soil-dwelling organisms

Enrofloxacin LC50 1000 ppm

Test species: Eisenia fetida (earthworms) Duration of test: 28 d

Biodegradability:

n-butanol

98 %, 28 d rapidly biodegradable

Method: OECD 301 E

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Alcohol derivative
92 - 96 %, 28 d rapidly biodegradable
Method: OECD 301 C

Photodegradation:

Enrofloxacin
Water
half-life time (direct Photolysis): > 240 h

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

<u>International IATA</u>	non-regulated
IMDG	non-regulated

15. REGULATORY INFORMATION

Other regulations: No statements available.

US. Toxic Substances Control Act This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.

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

SARA Section 311/312 Hazard Categories

Exempt from SARA Section 311/312

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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

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components

n-butanol

Reportable quantity: 5000 lbs

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
1 - 5%	n-butanol	71-36-3
1 - 5%	Alcohol derivative	

New Jersey Environmental Hazardous Substances List and/or New Jersey RTK Special Hazardous Substances Lists

Weight percent	Components	CAS-No.
1 - 5%	n-butanol	71-36-3

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

NFPA 704M Rating

Health	2
Flammability	2
Reactivity	0
Other	

0=Insignificant 1=Slight 2=Moderate 3=High 4=Extreme

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.



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