This SDS packet was issued with item:

078916230

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

078473661 078473679 078473687

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078916228 078916229



Version 1.1 Revision Date 12/09/2010

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

Product information

Product Name: BAYTRIL 100 MSDS Number: 122000007167

Use : veterinary medicine

Company

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

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

Hazard Communication (29CFR 1910.1200)

Inhalation Skin Contact Skin Absorption Eye Contact

Acute Inhalation HazardsMay cause respiratory tract irritation with symptoms of

coughing, sore throat and runny nose. Overexposure to vapor may produce dizziness, drowsiness, or nausea.

Acute Skin Hazards May cause irritation with symptoms of reddening and

itching.

Acute Eye Hazards May cause irritation with symptoms of reddening, tearing

and stinging.

Acute Ingestion Hazards Symptoms of ingestion may include abdominal pain,

nausea, vomiting, and diarrhea.

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Chronic Effects of Exposure Chronic exposure to the solvent can cause defatting of the

skin. Hearing loss has been associated with prolonged

inhalation of butyl alcohol.

Medical Conditions Aggrevated by

Exposure

Eye disorders, Skin disorders, Respiratory tract disorders

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredients:

Weight percent Components CAS-No. 1 - 5% Butan-1-ol 71-36-3

0.1 - 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. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: High volume water jet

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Specific hazards during fire fighting: Fire may cause evolution of: Hydrogen cyanide (hydrocyanic acid) Hydrogen fluoride nitrogen oxides (NOx) Carbon oxides

Special protective equipment for fire-fighters: 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: Keep away from/remove sources of ignition.

Further Accidental Release Notes

Keep away from/remove sources of ignition.

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.

Take measures to prevent the build up of electrostatic charge. Keep away from open flames, hot surfaces and sources of ignition.

Storage:

Keep away from direct sunlight.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Butan-1-ol (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)

PEL: 100 ppm, 300 mg/m3

DIN 51757

SAFETY DATA SHEET **BAYTRIL 100**

Version 1.1 Revision Date 12/09/2010

Alcohol derivative

US. Workplace Environmental Exposure Level (WEEL) Guides Time Weighted Average (TWA): 10 ppm, 44 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Colour: yellow, brownish
Odour: weak Alcohol
Boiling point/boiling range: no data available

Density: 1.08 g/cm3 at 68 °F (20 °C)

Vapour pressure: no data available
Viscosity, dynamic: no data available
Miscibility with water: completely miscible

pH: 8.9 - 10.9 at (68 °F (20 °C))

(undiluted)

Partition coefficient

(n-octanol/water): no data available

Flash point: 145 °F (62.78 °C) Ignition temperature: not determined

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: None known.

Thermal decomposition:

no data available

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Revision Date 12/09/2010

Hazardous decomposition products:

Hydrogen cyanide (hydrocyanic acid), Hydrogen fluoride, nitrogen oxides (NOx), Carbon oxides

11. TOXICOLOGICAL INFORMATION

Other information on toxicity:

Alcohol derivative

Dermal absorption possible

If inhaled: irritations, Shortness of breath, Cough

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

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

Acute oral toxicity:

Alcohol derivative LD50 rat: 1,230 mg/kg

Enrofloxacin

LD50 rat: > 5,000 mg/kg

Acute inhalation toxicity:

Butan-1-ol

LC50 rat: 8,000 mg/l

Skin irritation:

Alcohol derivative

rabbit

Result: non-irritant

Enrofloxacin

rabbit

Result: No skin irritation

Method: OECD Test Guideline 404

Eye irritation:

Alcohol derivative

rabbit

Result: Mild eye irritation

Enrofloxacin rabbit

Result: Mild eye irritation

Method: OECD Test Guideline 405

Version 1.1

Revision Date 12/09/2010

Sensitisation:

Enrofloxacin

Skin sensitization guinea pig

Result: Did not cause sensitization on laboratory animals.

Method: Buehler Test

Genotoxicity in vitro:

Butan-1-ol Ames test Result: negative

Micronucleus test Result: negative

Alcohol derivative Ames test Result: negative

Pharmaceutic effects:

Enrofloxacin Antibiotic

12. ECOLOGICAL INFORMATION

General advice:

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

Butan-1-ol

Acute Fish toxicity: LC50 1,200 mg/l

Test species: Leuciscus idus (Golden orfe) Duration of test: 48 h

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:

Butan-1-ol

EC50 1,983 mg/l

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

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Alcohol derivative EC50 400 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 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

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 (DOT)

Non-Regulated

Inland waterway transport

Non-Regulated

Railway transport

Non-Regulated

Sea transport (IMDG)

Non-Regulated

Air transport (ICAO / IATA cargo aircraft only)

Non-Regulated

Air transport (ICAO / IATA passenger and cargo aircraft)

Non-Regulated

15. REGULATORY INFORMATION

Version 1.1 Revision Date 12/09/2010

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

J

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

Butan-1-ol

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

Butan-1-ol Reportable quantity: 5000 lbs

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists Weight percent Components CAS-No.

Weight percentComponentsCAS-No1 - 5%Butan-1-ol71-36-3

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% Butan-1-ol 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

| NI I A 10-W Kating | |
|--------------------|---|
| Health | 2 |
| Flammability | 2 |
| Reactivity | 0 |
| Other | |

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

Version 1.1

Revision Date 12/09/2010

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.



MATERIAL SAFETY DATA SHEET

Date Printed: FEB 2009

PROPRANOLOL HYDROCHLORIDE INJECTION, USP

SECTION 1. PRODUCT AND COMPANY INFORMATION

Product Name: Propranolol Hydrochloride Supplier: West-Ward Pharmaceuticals

401 Industrial Way West Eatontown, NJ 07724 Phone (732 542 1191) Fax (732 720 6220)

Technical Phone: (800 631 2174)

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

| CAS No. | Description | % in final Product |
|-----------|---------------------------|--------------------|
| 318-98-9 | Propranolol Hydrochloride | 1mg/mL |
| 7732-18-5 | Water for Injection | QS |

Category: Anti-hypertensive

SECTION 3. HAZARDS IDENTIFICATION, EMERGENCY OVERVIEW

Route of Entry: Inhalation, eye/skin contact, or ingestion

Note: Propranolol is not significantly dialyzable. In the event of overdosage or exaggerated responce, the following measures should be employed:

Bradycardia Administer atropine (0.25mg to 1mg); if there is no response to vagal

blockade, administer isoproterenol cautiously.

Cardiac Failure Digitalization and diuretics.

Hypotension Vasopressors eg epinephrine.

Bronchospasm Administer isoproterenol and aminophylline.

Chemical List as Carcinogen:

NTP: No IARC: No OSHA: No



SECTION 4. FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Seek

medical attention.

Skin: Remove from source of exposure, wash affected area with soap and

water, seek medical attentio.

Inhalation: If difficulty with breathing, remove from exposure, administer oxygen.

Seek attention of a physician immediately. When appropriate and trained in CPR,

provide artificial respiration.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention

immediately. Never induce vomiting on an unconscious person

SECTION 5. FIRE AND EXPLOSION DATA

Fire and explosion Data

Closed Cup Flash Point:

Open Cup Flash Point

N/A

Fire Point:

Autoignition:

Lower Explosion Limit:

N/A

General Hazard: Not expected to support combustion. Fire Fighting Instructions: Evacuate personnel to safe area. Water

spray, dry chemical, foam or carbon dioxide. If possible contain and collect water used.

Fire Fighting Equipment: Firefighters should wear protective clothing and

self-contained breathing equipment.

Hazardous Combustion Products: Thermal decomposition may yield toxic smoke containing

Carbon dioxide, Carbon Monoxide and Nitrogen oxide.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Clean Up: Wear recommended personal protective equipment. Use an inert

. Wear recommended personal protective equipment. Ose an merc

absorbent material to clean affected area, and place in a properly labelled container for recovery or disposal. Prevent entry into waterways, sewers, drainage systems

and poorly ventilated areas. No specific decontamination or detoxification

procedures have been identified for this product.

Dispose of materials according to the applicable fedral, state and/ or local

regulations.

SECTION 7. HANDLING AND STORAGE

General Handling: When handling pharmaceutical products, avoid all contact and

inhalation of dust, fumes, mist, and/or vapors associated with product,

A dust/mist respirator (N95) may be necessary.

Storage Conditions: Store between 20° - 25°C (65° - 77°F). Protect from light, heat and freezing.



SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: N/A

Personal Protective Equipment

Eye protection: Safety glasses. Hand protection: Latex gloves.

Respiratory Protection: If aerosols are generated, a disposable dust/ mist respirator (N95).

Skin Protection: Labcoat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form/ Appearance: Clear solution
Boiling Point/ Boiling Range: Approx to Water.

Melting Point/ Melting Range: 165°C.

Freezing Point: Approx to Water.

Vapor Pressure: N/A.
Relative Vapor Density: N/A.
Percent Volatiles: N/A.
pH: 2.8-4.0

Molecular Weight: 295.80

Solvent Solubility: Soluble in water

SECTION 10. STABILITY AND REACTIVITY DATA.

Stability: Stable under most conditions

Conditions to Avoid: Avoid freezing and excessive heat.

Hazardous Polymerization: N/A

Hazardous Decomposition or By-products: May include Carbon and Nitrogen Oxides.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

| Compound | Type | Route | Species | Dosage |
|---------------------------|------|-------|---------|------------------------|
| Propranolol Hydrochloride | LD50 | Oral | Rat | 466 mg/kg |
| | LD50 | ΙP | Rat | 76 mg/kg |
| | LD50 | SC | Rat | 115 mg/kg |
| | LD50 | IV | Rat | 21 mg/kg |
| | LD50 | Oral | Mouse | 320 mg/kg |
| | LD50 | ΙP | Mouse | 80 mg/kg |
| | LD50 | SC | Mouse | 208 mg/kg |
| | LD50 | IV | Mouse | 18 mg/kg |
| | LD50 | Oral | Rabbit | 600 mg/kg |
| | LD50 | IV | Rabbit | 12.5 mg/m ³ |

Other: Additional reproductive health data is available from the National Institute for

Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical

Substances (RTECS)

Exposure to propranolol and other beta-adrenergic blockade drugs may mask signs and symptoms of acute hypoglycemia in labile insulin-dependent diabetics. There maybe difficulty adjusting insulin dosage. Similarly may mask clinical signs of hyperthyroidism and interfere with thyroid function tests.

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SECTION 12. ECOLOGICAL INFORMATION

Information is currently not available on the environmental impact of Propranolol. Handle in a manner to prevent spills or release to the environment.

SECTION 13. DISPOSAL CONSIDERATIONS

Dispose of by incineration at an approved /permitted incinerator. Review local, state, and federal regulations for your regulatory area.

SECTION 14. TRANSPORT INFORMATION

UN/NA Number: N/A US DOT Hazard Class: N/A Proper Shipping Name: N/A

Shipping Label: N/A

SECTION 15. REGULATORY INFORMATION

U.S. Regulatory Information: not regulated.

SECTION 16. OTHER INFORMATION

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Bayer HealthCare



SAFETY DATA SHEET **BAYTRIL 100**

Version 2.0 Revision Date 02/23/2015

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

Product information

Product Name: BAYTRIL 100 MSDS Number: 122000007167

Use : veterinary medicineunfinished

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

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.

Version 2.0 Revision Date 02/23/2015

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.

Version 2.0 Revision Date 02/23/2015

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

No special precautions required.

Release Notes

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)

DIN 51757

SAFETY DATA SHEET **BAYTRIL 100**

Version 2.0 Revision Date 02/23/2015

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/cm³ at 68 °F (20 °C)

Bulk density:

Vapour pressure:

Viscosity, dynamic:

Viscosity, kinematic:

Flow time:

No applicable information is available
Surface tension:

No applicable information is available
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):
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 (NOx), 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

Version 2.0

Revision Date 02/23/2015

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.

Version 2.0

Revision Date 02/23/2015

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.

Version 2.0

Revision Date 02/23/2015

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

EnrofloxacinLC50 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

International IATA non-regulated 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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Baytril® Injectable Solution <= 2,5%

Version 4.0 Revision Date 04/22/2015

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

Product information

Product Name: Baytril® Injectable Solution <= 2,5%

SDS Number: 122000001098

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

CAUTION! Colour: yellowish Form: liquid Odour: nearly odourless.

Inhalation may cause nausea or dizziness. May cause respiratory tract irritation. May cause skin irritation. May cause eye irritation.

GHS Classification:

Serious eye damage : Category 1

GHS Label element:

Hazard pictograms



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.

Baytril® Injectable Solution <= 2,5%

Version 4.0 Revision Date 04/22/2015

Precautionary statements : Prevention:

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.

P310 Immediately call a POISON CENTER or doctor/ physician.

Other hazards which do not result in classification:

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredients:

 Weight percent
 Components
 CAS-No.

 1 - 5%
 n-butanol
 71-36-3

 2.5%
 Enrofloxacin
 93106-60-6

4. FIRST AID MEASURES

General advice: Take off all contaminated clothing immediately. Consult a physician if necessary.

If inhaled: Remove to fresh air.

Oxygen or artificial respiration if needed.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water.

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

In case of eye contact: Immediately flush eye(s) with plenty of water. If eye irritation persists, consult a specialist.

If swallowed: If the patient is conscious, rinse out mouth with water and have the patient drink a glass of water or milk to dilute the material.

Contact Number: Use the Bayer Emergency Number in Section 1

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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: 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.

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 contact with skin, eyes and clothing.

No special protective measures against fire required.

Storage:

Store at temperatures and conditions as indicated on the product label.

Storage temperature: 32 - 104 °F (0 - 40 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory protection:

not required

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Hand protection:

Chemically resistant gloves.

Eye protection:

Safety glasses

Safety glasses with side-shields

Other protective measures:

Use general room ventilation.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form: liquid Colour: yellowish

Odour: nearly odourless

Odour Threshold: No applicable information is available Melting point: No applicable information is available Boiling point/boiling range: No applicable information is available

Density: 1.003 g/cm³ at 68 °F (20 °C)

Bulk density:

Vapour pressure:

No applicable information is available

Viscosity, dynamic:

Viscosity, kinematic:

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: miscible

Water solubility: No applicable information is available

pH: 10.8 - 11.5

Relative density:

Partition coefficient:

Solubility(ies):

No applicable information is available
No applicable information is available
No applicable information is available
> 129.92 - 138.92 °F (> 54.4 - 59.4 °C)

Flammability (solid, gas): Does not sustain combustion.

Comparable data on substance.

Ignition temperature: No applicable information is available Explosion limits: No applicable information is available

10. STABILITY AND REACTIVITY

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

Exposure to light.

Heat

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Protect from frost.

Materials to avoid: Oxidizing agents

Hazardous reactions: No data available

Thermal decomposition:

No data available

Hazardous decomposition products:

Nitrogen oxides (NOx), Carbon oxides

Flammability (solid, gas):

Does not sustain combustion. Method: Comparable data on substance.

Oxidizing properties:

No statements 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

Acute oral toxicity:

Acute toxicity estimate (ATE) > 2,000 mg/kg May be harmful if swallowed. Method: Calculation method Calculated for GHS Classification and Labelling.

Acute inhalation toxicity:

n-butanol

LC50 Rat: 8000 ppm, 4 h

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

Enrofloxacin

LD50 Rabbit: > 2,000 mg/kg

Skin irritation:

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n-butanol Rabbit

Result: Mild 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

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

Enrofloxacin

Skin sensitization guinea pig

Result: Did not cause sensitisation on laboratory animals.

Method: Buehler Test

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

Enrofloxacin Ames test Result: negative

Genotoxicity in vivo:

n-butanol

Micronucleus test, Mouse

Result: No evidence of a genotoxic effect.

Method: OECD 474

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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

Pharmaceutic effects:

anti infective

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.

STOT - repeated exposure:

No data available

12. ECOLOGICAL INFORMATION

General advice:

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

n-butanol

Acute Fish toxicity: LC50 1,730 mg/l

Test species: Pimephales promelas (fathead minnow) 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

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Enrofloxacin EC0 > 10 mg/l

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

Toxicity to bacteria:

Enrofloxacin EC0 0.003 mg/l

tested on: Pseudomonas putida

Toxicity on soil-dwelling organisms

EnrofloxacinLC50 1000 ppm

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

Biodegradability:

n-butanol

98 %, 28 d rapidly biodegradable

Method: OECD 301 E

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

International IATA non-regulated

IMDG non-regulated

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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

Exempt from SARA Section 311/312

Categories

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

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 | 0 |
| Reactivity | 0 |
| Other | 0 |

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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.





Section 1. Identification

GHS product identifier

: Propranolol Hydrochloride Injection, USP

Synonyms

: Not available.

Product code

NDC 0143-9872-01, NDC 0143-9872-10

Chemical family

Not available.

Product type

Container information

: Not available. : Not available.

Identified uses

: Anti-hypertensive.

Supplier's details

: West-Ward Pharmaceuticals

401 Industrial Way Eatontown NJ 07724 Phone (732 542 1191) Fax (732 720 6220)

Emergency telephone number (with hours of operation)

: CHEMTREC, U.S.: 1-800-424-9300 International: +1-703-527-3887

24/7

Section 2. Hazards identification

OSHA/HCS status

: While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture Not classified.

GHS label elements

Signal word

: No signal word.

Hazard statements

: No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable. Response : Not applicable. **Storage** : Not applicable. **Disposal** Not applicable. **Hazards not otherwise** None known.

classified

Hazards not otherwise

classified (HNOC)

: None known.





Section 3. Composition/information on ingredients

Substance/mixture : Mixture
Other means of : Not available.
identification

CAS number/other identifiers

CAS number : Not applicable.

Product code : NDC 0143-9872-01, NDC 0143-9872-10

| Ingredient name | % | CAS number |
|-----------------|-----------------------------------|----------------------------------|
| Water | 0 - 0.01 60 - 100 As needed | 318-98-9 7732-18-5 77-92-9 |

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower

eyelids. Check for and remove any contact lenses. Get medical attention if irritation

occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get

medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position

comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 Ingestion
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large

quantities have been ingested or inhaled.

Specific treatments: No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.





Section 4. First aid measures

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media

: None known.

Specific hazards arising from the chemical

: No specific fire or explosion hazard.

Hazardous thermal decomposition products

: No specific data.

Special protective actions for fire-fighters

: No special measures are required.

Special protective equipment for fire-fighters

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders:

: If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill

: Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill

: Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.



Section 7. Handling and storage

Precautions for safe handling

Protective measures

Advice on general occupational hygiene

- : Put on appropriate personal protective equipment (see Section 8).
- : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls

Environmental exposure controls

- : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period.

Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

: Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.





Section 9. Physical and chemical properties

Appearance

Physical state : Liquid.
Color : Clear.

Odor : Not available.
Odor threshold : Not available.
pH : 2.8 to 4
Melting point : Sublimes.

Boiling point : Similar to water.

Flash point : Not available.

Evaporation rate : Not available.

Flammability (solid, gas) : Not available.

Lower and upper explosive : Not available.

(flammable) limits

Vapor pressure : Not available.
Vapor density : Not available.
Relative density : Not available.
Solubility in water : Soluble in water.
Partition coefficient: n- : Not available.

octanol/water

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Not available.

Section 10. Stability and reactivity

Reactivity: No specific test data related to reactivity available for this product or its ingredients.

: Under normal conditions of storage and use, hazardous reactions will not occur.

Chemical stability: The product is stable.

Possibility of hazardous reactions

Conditions to avoid : No specific data.

Incompatible materials: Not available.

Hazardous decomposition

products

: Carbon and nitrogen oxides.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

There is no data available.

Irritation/Corrosion

There is no data available.

Sensitization





Section 11. Toxicological information

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure

: Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate : No kno

effects

: No known significant effects or critical hazards.

Potential delayed effects: No known significant effects or critical hazards.

Long term exposure

Potential immediate : No known significant effects or critical hazards.

effects

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.
 Carcinogenicity : No known significant effects or critical hazards.
 Mutagenicity : No known significant effects or critical hazards.
 Teratogenicity : No known significant effects or critical hazards.
 Developmental effects : No known significant effects or critical hazards.





Section 11. Toxicological information

Fertility effects

: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

There is no data available.

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

Soil/water partition coefficient (Koc)

Not available.

Other adverse effects

: No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

| | DOT | IMDG | IATA |
|----------------------------|----------------|----------------|----------------|
| UN number | Not regulated. | Not regulated. | Not regulated. |
| UN proper shipping name | - | - | - |
| Transport hazard class(es) | - | - | - |
| Packing group | - | - | - |
| | | | |





Propranolol Hydrochloride Injection, USP

Section 14. Transport information

| Environmental hazards | No. | No. | No. |
|------------------------|-----|-----|-----|
| Additional information | - | - | - |

AERG: Not applicable

Special precautions for user : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in

the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL

Not available.

73/78 and the IBC Code

Section 15. Regulatory information

U.S. Federal regulations

: TSCA 8(a) CDR Exempt/Partial exemption: Not determined United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112

(b) Hazardous Air **Pollutants (HAPs)** : Not listed

Clean Air Act Section 602

Class I Substances

: Not listed

Clean Air Act Section 602

Class II Substances

: Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals

(Essential Chemicals)

: Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

No products were found.

SARA 313

No products were found.

State regulations

Massachusetts : None of the components are listed. **New York** : None of the components are listed. **New Jersey** : None of the components are listed. **Pennsylvania** : None of the components are listed.

California Prop. 65





Section 15. Regulatory information

No products were found.

Section 16. Other information

History

Date of issue mm/dd/yyyy : 08/15/2015

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Prepared by : KMK Regulatory Services Inc.

Key to abbreviations : ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships,

1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

UN = United Nations

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.