



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Bisolvon® Solution for Injection (0.3 %)

Product No.: Not applicable

MSDS ID#: Not applicable

GHS Product Identifier: Not applicable

Molecular Formula: Mixture, not applicable

Molecular Weight: Mixture, not applicable

CAS Number: Mixture, not applicable

Chemical Family: Expectorant

Manufacturer:

Boehringer Ingelheim Vetmedica, Inc.

2621 North Belt Hwy

St. Joseph, MO 64506-2002

Transportation Emergency: For Chemical
Emergency Spill, Leak, Fire, Exposure, or
Accident Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300

Outside USA and Canada: +1 703-527-3887

(collect calls accepted)

Medical Emergency (24HR): (866) 638-2226

Non-Emergency Telephone: (800) 821-7467

Intended Use: Solution for animal injection.

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid

Color: No data available

Odor: No data available



WARNING!

For use in animals only.

Not for human use.

Precautionary Statements

Keep only in original container.

Do not refrigerate or freeze.

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Avoid contact with eyes, skin and clothing.

Wear suitable gloves and eye/face protection.

Wash thoroughly with soap and water after handling.

In case of contact with eyes, flush with gently flowing fresh water thoroughly.

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

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Spills: Sweep spilled substance into appropriate waste container.

Dispose of contents and container in accordance with applicable local authority requirements.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

Potential Health Effects

Inhalation: Not expected to be an inhalation hazard with prescribed use.

Eye Contact: Not expected to be a hazard to the eye with prescribed use. Exposure to liquid in eye may cause eye irritation.

Skin Contact: Not expected to be a hazard to the skin. May cause skin irritation or sensitization by contact. Can cause hypersensitive reactions.

Ingestion: Not expected to be an ingestion hazard with prescribed use. Ingestion may cause nausea and systemic effects.

Injection: Swelling at injection site may occur.

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity).

Target Organ(s): Skin, Central nervous system.

OSHA Regulatory Status: Non-Hazardous

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Bromhexine hydrochloride	210-280-8	611-75-6	0.3 %	---	---

Components not listed are not hazardous or are below reportable limits.

The full texts for all R-Phrases are displayed in Section 16, if applicable.

4 FIRST AID MEASURES

General: Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Skin Contact: Wash with soap and water. Get medical attention if symptoms occur.

Ingestion: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Injection: In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

Note to Physician: For animal use only. Not for human use. Treatment for Bromhexine Hydrochloride overdose should be symptomatic and supportive.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with material appropriate for surrounding environment.

Unsuitable Extinguishing Media: None known

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, hydrogen chloride, bromine.

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate personal protective equipment (See Section 8).

Spill Cleanup Methods: STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Absorb or cover with dry earth, sand or other non-combustible material. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

Environmental Precautions: Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7 HANDLING AND STORAGE

Handling: HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Use with adequate ventilation. Wash hand thoroughly after handling.

Storage: Keep only in the original container. Do not refrigerate or freeze. Store out of direct sunlight.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
Bromhexine hydrochloride	BIEL*	TWA	125 µg/m ³	Category: 2
Bromhexine hydrochloride	BIEL*	STEL (15 minute)	400 µg/m ³	---
Bromhexine hydrochloride	BIEL*	STEL (1 hour)	200 µg/m ³	---

*BIEL is the BI (Boehringer Ingelheim) Exposure Control Level. Where lower governmentally imposed occupational exposure limits exist, such limits should take precedence.

Engineering Controls: Not generally required when handling vials or containers. Good ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Respiratory Protection: Not generally required when handling vials or containers. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

Europe: Wear appropriate personal protective equipment according to the Council Directive 89/686/EEC (4) and the appropriate CEN standards.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Hygiene Measures: Eye bath, washing facilities.

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: No data available
Odor: No data available
Odor Threshold: No data available
Physical State: Liquid
pH: No data available
Melting Point: No data available
Freezing Point: May No data available
Boiling Point: No data available
Flash Point: No data available
Flammability Limit – Upper (%): No data available
Flammability Limit – Lower (%): No data available
Evaporation rate: No data available
Vapor Pressure: No data available
Vapor Density (Air=1): No data available
Specific Gravity: No data available
Solubility: No data available
Partition Coefficient (n-Octanol/water): No data available
Autoignition Temperature: No data available
Decomposition Temperature: No data available

10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Excessive heat.

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity:

Chemical Name	Test Results
Bromhexine hydrochloride	Oral (Rat) LD50: 6000 mg/kg

Chronic Toxicity: Possible hypersensitization (development of abnormal sensitivity).

Listed Carcinogens: None listed

12 ECOLOGICAL INFORMATION

Ecotoxicity: No data available

Persistence and degradability: No data available

Mobility in soil: No data available

Other adverse effects: No data available

Germany WGK: Class 2 water endangering

13 DISPOSAL CONSIDERATIONS

General Information: Dispose of in accordance with local, state, federal, national or international regulations.

Disposal Methods: No specific disposal method required. Do not empty into drains. Dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by disposal.

RCRA Information: Not applicable

14 TRANSPORT INFORMATION

DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15 REGULATORY INFORMATION

Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS Classification: Non-controlled

Inventory Status

This material is listed on the following inventories: AICS, EINECS, DSL, and NZIoC.

This material is **not** listed on the following inventories: TSCA, IECSC, ENCS, PICCS, and KECL. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

Canada CEPA Schedule 1 – None listed

US Regulations

FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

CERCLA Hazardous Substance List (40 CFR 302.4): None listed or below concentration threshold.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): None listed or below concentration threshold.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): None listed or below concentration threshold.

SARA Title III

Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A): None listed or below concentration threshold.

Section 311/312 (40 CFR 370): Non-hazardous

Section 313 Toxic Release Inventory (40 CFR 372): None listed or below concentration threshold.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None listed.

Massachusetts Right-To-Know List: None listed.

Minnesota Hazardous Substances List: None listed.

New Jersey Right-To-Know List: None listed.

Pennsylvania Right-To-Know List: None listed.

Rhode Island Right-To-Know List: None listed.

European Regulations

Austria MAK List (Annex I): None listed.

Denmark (Annex 3.6): None listed.

Germany (Dangerous Substances Ordinance 2004, Annex III): None listed or below concentration threshold.

Norway (List of Dangerous Substance): None listed.

Sweden (Annex 3): None listed.

Switzerland (Toxins List 1): None listed or below concentration threshold.

16	OTHER INFORMATION
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Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1	0	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	0	0	N/A

* – Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

EU Symbol and R Phrase Definitions:

None available

ABBREVIATIONS:

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

pph – parts per hour

ppm – parts per million

References:

1. Bisolvon[®] Solution for Injection (0.3 %), PC-ID 78568, MSDS and Label
2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
3. GHS Manual

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 04/05/2012

Revision Information: 4/29/2013

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