

# SAFETY DATA SHEET



Revision date: 12-Nov-2021

Revision Number 4

## 1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

### Product identifier

**Product Name** BROMHEXINE HYDROCHLORIDE

**Product Code(s)** 000000033798

### Other means of identification

**CAS No.** 611-75-6

### Recommended use of the chemical and restrictions on use

**Recommended use** Pharmaceutical applications. Expectorant.

**Uses advised against** No information available.

### Supplier

Ixom Operations Pty Ltd (Bronson & Jacobs division) - incorporated in Australia  
ABN:51 600 546 512  
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Villawood NSW 2163  
Australia

Telephone Number: +61 2 8717 2929

Facsimile: +61 2 9755 9611

### Emergency telephone number

Emergency telephone number **1 800 033 111 (ALL HOURS)**

Please ensure you refer to the limitations of this Safety Data Sheet as set out in the "Other Information" section at the end of this Data Sheet.

## 2. HAZARDS IDENTIFICATION

### GHS Classification

Not classified as dangerous goods in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG)

Not classified as a hazardous chemical in accordance with the criteria of Safe Work Australia - Globally Harmonized System (GHS)

### Label elements

#### **Hazard statements**

**Other hazards which do not result in classification**

May form combustible dust concentrations in air

**General Hazards** Dust can form an explosive mixture with air**Poisons Schedule (SUSMP)** 2**3. COMPOSITION/INFORMATION ON INGREDIENTS****Substance**

Chemical name	CAS No.	Weight-%
Bromhexine hydrochloride	611-75-6	98.5-100

**4. FIRST AID MEASURES****Description of first aid measures****General advice** Show this safety data sheet to the doctor in attendance.**Emergency telephone number** Poisons Information Center, Australia: 13 11 26  
Poisons Information Center, New Zealand: 0800 764 766**Inhalation** Remove to fresh air. Call a physician if symptoms occur.**Eye contact** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention if symptoms occur.**Skin contact** Wash skin with soap and water. Call a physician if symptoms occur.**Ingestion** Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.**Most important symptoms and effects, both acute and delayed****Symptoms** No information available.**Indication of any immediate medical attention and special treatment needed****Note to physicians** Treat symptomatically.**5. FIRE FIGHTING MEASURES****Suitable Extinguishing Media****Suitable Extinguishing Media** Dry chemical, CO<sub>2</sub>, water spray or alcohol-resistant foam.**Unsuitable extinguishing media** No information available.**Specific hazards arising from the chemical****Specific hazards arising from the chemical** Combustible material. Dust can form an explosive mixture with air. Avoid generation of dust.**Hazardous combustion products** Carbon oxides. Nitrogen oxides. Hydrogen chloride. Hydrogen bromide.

**Special protective actions for fire-fighters**

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**6. ACCIDENTAL RELEASE MEASURES****Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Avoid contact with skin and eyes. Avoid breathing dust or spray mist. Avoid generation of dust. Ensure adequate ventilation. Do not touch or walk through spilled material. Remove all sources of ignition. Take precautionary measures against static discharges. Evacuate personnel to safe areas. Wash thoroughly after handling.

**For emergency responders** Use personal protection recommended in Section 8.

**Environmental precautions**

**Environmental precautions** See Section 12 for additional Ecological Information.

**Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. Use non-sparking tools.

**7. HANDLING AND STORAGE****Precautions for safe handling**

**Advice on safe handling** Avoid contact with skin and eyes. Avoid breathing dust or spray mist. Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Avoid generation of dust. Ground and bond all lines and equipment associated with product system. All equipment should be non-sparking and explosion proof. Take precautionary measures against static discharges.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from foodstuffs and sources of heat or ignition. Keep container closed when not in use.

This material is a Scheduled Poison and must be stored, maintained and used in accordance with the relevant regulations.

**Incompatible materials** None known based on information supplied.

**Poisons Schedule (SUSMP)** 2

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Control parameters**

**Exposure Limits** No value assigned for this specific material by Safe Work Australia. However, Workplace

Exposure Standard(s) for particulates:

Dusts not otherwise classified: 8hr TWA = 10 mg/m<sup>3</sup>

As published by Safe Work Australia Workplace Exposure Standards for Airborne Contaminants.

TWA - The time-weighted average airborne concentration of a particular substance when calculated over an eight-hour working day, for a five-day working week.

These Workplace Exposure Standards are guides to be used in the control of occupational health hazards. All atmospheric contamination should be kept to as low a level as is workable. These workplace exposure standards should not be used as fine dividing lines between safe and dangerous concentrations of chemicals. They are not a measure of relative toxicity.

### Appropriate engineering controls

#### **Engineering controls**

Apply technical measures to comply with the occupational exposure limits.

If in the handling and application of this material, safe exposure levels could be exceeded, the use of engineering controls such as local exhaust ventilation must be considered and the results documented. If achieving safe exposure levels does not require engineering controls, then a detailed and documented risk assessment using the relevant Personal Protective Equipment (PPE) (refer to PPE section below) as a basis must be carried out to determine the minimum PPE requirements.

### Individual protection measures, such as personal protective equipment

The selection of PPE is dependent on a detailed risk assessment. The risk assessment should consider the work situation, the physical form of the chemical, the handling methods, and environmental factors.

OVERALLS, SAFETY SHOES, SAFETY GLASSES, GLOVES, DUST MASK.



#### **Eye/face protection**

Glasses.

#### **Skin and body protection**

Protective shoes or boots. Wear suitable protective clothing. Overalls.

#### **Hand protection**

Impervious gloves.

#### **Respiratory protection**

If determined by a risk assessment an inhalation risk exists, wear a dust mask meeting the requirements of AS/NZS 1715 and AS/NZS 1716.

#### **Environmental exposure controls**

No information available.

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

### Information on basic physical and chemical properties

<b>Physical state</b>	Crystalline Solid
<b>Appearance</b>	Powder
<b>Color</b>	White or Almost Off-white

**Odor** No information available.  
**Odor threshold** No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	No data available	None known
<b>pH (as aqueous solution)</b>	No data available	None known
<b>Melting point / freezing point</b>	239-243°C	None known
<b>Boiling point / boiling range</b>	No data available	None known
<b>Flash point</b>	No data available	None known
<b>Evaporation rate</b>	No data available	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Water solubility</b>	Sparingly soluble	None known
<b>Solubility(ies)</b>	No data available	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>	No data available	None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known

Other information

## 10. STABILITY AND REACTIVITY

Reactivity

**Reactivity** No information available.

Chemical stability

**Stability** Stable under normal conditions.

Explosion data

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.

**Hazardous polymerization** Hazardous polymerization does not occur.

Conditions to avoid

**Conditions to avoid** Dust formation. Exposure to light. Static discharge (electrostatic discharge). Heat, flames and sparks.

Incompatible materials

**Incompatible materials** None known based on information supplied.

**Hazardous decomposition products**

**Hazardous decomposition products** Carbon oxides. Nitrogen oxides. Hydrogen chloride. Hydrogen bromide.

**11. TOXICOLOGICAL INFORMATION****Acute toxicity****Information on likely routes of exposure**

<b>Product Information</b>	No adverse health effects expected if the chemical is handled in accordance with this Safety Data Sheet and the chemical label. Symptoms or effects that may arise if the chemical is mishandled and overexposure occurs are:
<b>Inhalation</b>	May cause irritation.
<b>Eye contact</b>	Dust contact with the eyes can lead to mechanical irritation.
<b>Skin contact</b>	Contact with dust can cause mechanical irritation or drying of the skin.
<b>Ingestion</b>	May cause gastrointestinal discomfort if consumed in large amounts.
<b>Symptoms</b>	No information available.

**Numerical measures of toxicity - Product Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Bromhexine hydrochloride	= 6 g/kg ( Rat )	-	-

See section 16 for terms and abbreviations

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	Not applicable.

**12. ECOLOGICAL INFORMATION****Ecotoxicity**

**Ecotoxicity** Keep out of waterways.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Bromhexine hydrochloride	-	-	-	48hr EC50 Daphnia magna: >100 mg/L

#### Persistence and degradability

**Persistence and degradability** No information available.

#### Bioaccumulative potential

**Bioaccumulation** This chemical shows a low bioaccumulation potential.

Chemical name	Partition coefficient
Bromhexine hydrochloride	log Pow = 0.45 (estimated)

#### Mobility

**Mobility in soil** No information available.

#### Other adverse effects

### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

**Waste from residues/unused products** Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

### 14. TRANSPORT INFORMATION

#### **ADG**

Not classified as Dangerous Goods by the criteria of the Australian Dangerous Goods Code (ADG Code) for transport by Road and Rail; NON-DANGEROUS GOODS.

#### **IATA**

Not classified as Dangerous Goods by the criteria of the International Air Transport Association (IATA) Dangerous Goods Regulations for transport by air; NON-DANGEROUS GOODS.

#### **IMDG**

Not classified as Dangerous Goods by the criteria of the International Maritime Dangerous Goods Code (IMDG Code) for transport by sea; NON-DANGEROUS GOODS.

### 15. REGULATORY INFORMATION

#### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### National regulations

##### Australia

Not classified as dangerous goods in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG)

Not classified as a hazardous chemical in accordance with the criteria of Safe Work Australia - Globally Harmonized System (GHS)

See section 8 for national exposure control parameters

**Poisons Schedule (SUSMP)** 2

### International Inventories

**AIIC** This material is listed on the Australian Inventory of Industrial Chemicals.

#### **Legend:**

- Australian Inventory of Industrial Chemicals

### International Regulations

**The Montreal Protocol on Substances that Deplete the Ozone Layer** Not applicable

**The Stockholm Convention on Persistent Organic Pollutants** Not applicable

**The Rotterdam Convention** Not applicable

## 16. OTHER INFORMATION

Supplier Safety Data Sheet 04/ 2019

**Reason(s) For Issue:** 5 Yearly Revised Primary SDS

**Issuing Date:** 12-Nov-2021

This Safety Data Sheet has been prepared by Ixom Operations Pty Ltd (Toxicology and SDS Services).

#### **Revision Note:**

The symbol (\*) in the margin of this SDS indicates that this line has been revised.

#### **Key or legend to abbreviations and acronyms used in the safety data sheet**

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
C	Carcinogen		

#### **Key literature references and sources for data used to compile the SDS**

EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AEGl(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australian Industrial Chemicals Introduction Scheme (AICIS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)



National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
RTECS (Registry of Toxic Effects of Chemical Substances)  
World Health Organization

**Disclaimer**

**This SDS summarises to our best knowledge at the date of issue, the chemical health and safety hazards of the material and general guidance on how to safely handle the material in the workplace. Since Ixom Operations Pty Ltd cannot anticipate or control the conditions under which the product may be used, each user must, prior to usage, assess and control the risks arising from its use of the material.**

**If clarification or further information is needed, the user should contact their Bronson & Jacobs representative or Ixom Operations Pty Ltd at the contact details on page 1.**

**Ixom Operations Pty Ltd's responsibility for the material as sold is subject to the terms and conditions of sale, a copy of which is available upon request.**

**Bronson and Jacobs incorporating the businesses of Woods and Woods and Keith Harris.**

**End of Safety Data Sheet**