

SAFETY DATA SHEET



Revision date: 13-Nov-2023

Revision Number 5

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product identifier

Product Name CHOLINE BITARTRATE

Product Code(s) 000000033836

Other means of identification

CAS No. 87-67-2

Chemical name Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, salt with [R-(R*,R*)]-2,3-dihydroxybutanedioic acid (1:1)

Synonyms Choline Bitartrate NF; Choline Bitartrate Special Mesh

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical applications.

Uses advised against No information available

Supplier

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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)

SIGNAL WORD

None

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)** None allocated**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical name	CAS No.	Weight-%
Choline bitartrate	87-67-2	>=98
Silica	7631-86-9	0.6-1.2

4. FIRST AID MEASURES**Description of first aid measures****General advice** For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.**Inhalation** Remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms occur.**Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.**Skin contact** Wash skin with soap and water. Get medical attention if irritation develops and persists.**Ingestion** Clean mouth with water and drink afterwards plenty of water. Do NOT induce vomiting. 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** Water spray. Foam. Dry chemical. Carbon dioxide (CO₂).**Unsuitable extinguishing media** High volume water jet.

Specific hazards arising from the chemical

Specific hazards arising from the chemical	<p>Combustible solid. Dust can form an explosive mixture with air. Avoid generation of dust. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Most organic dusts are combustible and according to the circumstances under which the combustion process occurs, such materials may cause fires and/or dust explosions. Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions). Dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC). When processed with flammable liquids/vapors/mists, ignitable (hybrid) mixtures may be formed with combustible dusts. Ignitable mixtures will increase the rate of explosion pressure rise and the Minimum Ignition Energy (the minimum amount of energy required to ignite dust clouds - MIE) will be lower than the pure dust in air mixture. The Lower Explosive Limit (LEL) of the vapour/dust mixture will be lower than the individual LELs for the vapors/mists or dusts.</p> <p>Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to damage or rupture the plant. If the shock wave from the primary explosion enters the surrounding area, it will disturb any settled dust layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large-scale explosions have resulted from chain reactions of this type. Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport. Build-up of electrostatic charge may be prevented by bonding and grounding. Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting. A sudden release of statically charged materials from storage or process equipment, particularly at elevated temperatures and/ or pressure, may result in ignition especially in the absence of an apparent ignition source. One important effect of the particulate nature of powders is that the surface area and surface structure (and often moisture content) can vary widely from sample to sample, depending on how the powder was manufactured and handled which means that it is virtually impossible to use flammability data published in the literature for dusts.</p>
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Hazardous combustion products Oxides of carbon. Oxides of nitrogen.

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, eyes, and clothing. Avoid breathing dust or spray mist. Ensure adequate ventilation. Do not touch or walk through spilled material. Keep people away from and upwind of spill/leak. Avoid generation of dust. Evacuate personnel to safe areas. Wash thoroughly after handling. Use personal protective equipment as required.

Other information Ventilate the area.

For emergency responders Shut off ignition sources. Clear area of all unprotected personnel. Use personal protection recommended in Section 8.

Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Remove ignition sources. Provide adequate ventilation. Do not touch or walk through spilled material.

Methods for cleaning up Cover with damp absorbent (inert material, sand or soil). Vacuum or sweep material and place in a disposal container. Use non-sparking tools. Avoid generation of dust. Use personal protective equipment as required. Pick up and transfer to properly labelled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Avoid contact with skin, eyes, and clothing. Avoid breathing dust or spray mist. Avoid generation of dust. May form flammable dust clouds in air. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharges. Use personal protection equipment. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice.

General hygiene considerations Regular cleaning of equipment, work area and clothing is recommended. Wash hands and face before breaks and immediately after handling the product. Wear suitable gloves and eye/face protection.

Conditions for safe storage, including any incompatibilities

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

Incompatible materials Strong oxidizing agents.

Poisons Schedule (SUSMP) None allocated

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/m³

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**

Ensure adequate ventilation, especially in confined areas. 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

Wear suitable protective clothing. Boots. Overalls.

Hand protection

Impervious gloves.

Respiratory protection

If determined by a risk assessment an inhalation risk exists, wear a dust mask/respirator 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**

Physical state	Powder
Appearance	Crystalline Powder
Color	White
Odor	Odourless to Faint Characteristic
Odor threshold	No information available

Property	Values	Remarks • Method
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	Not Applicable	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	

Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	Soluble in water	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	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.

Conditions to avoid

Conditions to avoid Avoid exposure to heat, sources of ignition, and open flame. Avoid contact with combustible substances. Static discharge (electrostatic discharge). Dust formation. Direct sunlight.

Incompatible materials

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products

Hazardous decomposition products Oxides of carbon. Oxides of nitrogen.

11. TOXICOLOGICAL INFORMATIONAcute toxicityInformation on likely routes of exposure

Product Information 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:

Inhalation May cause irritation.

Eye contact May cause irritation. Dust contact with the eyes can lead to mechanical irritation.

Skin contact	May cause irritation.
Ingestion	May cause gastrointestinal discomfort if consumed in large amounts.
Symptoms	No information available.

Numerical measures of toxicity - Product Information

No information available

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Silica	= 7900 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 2.2 mg/L (Rat) 1 h

See section 16 for terms and abbreviations

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

12. ECOLOGICAL INFORMATION**Ecotoxicity****Ecotoxicity** Avoid contaminating waterways.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Silica	EC50: =440mg/L (72h, Pseudokirchneriella subcapitata)	LC50: =5000mg/L (96h, Brachydanio rerio)	-	EC50: =7600mg/L (48h, Ceriodaphnia dubia)

Persistence and degradability**Persistence and degradability** No information available.**Bioaccumulative potential****Bioaccumulation** No information available.

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.

Contaminated packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers. Dispose of in accordance with federal, state and local regulations.

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) None allocated

International Inventories

AIIC All the constituents of this material are listed on the Australian Inventory of Industrial Chemicals.

Legend:

AIC- 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

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

Issuing Date: 13-Nov-2023

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 and Australian Botanical Products.

End of Safety Data Sheet