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SAFETY DATA SHEETS

According to the UN GHS revision 9

Version: 1.1
Creation Date: July 15, 2019
Revision Date: May 26, 2024

SECTION 1: Identification

1.1 GHS Product identifier

Product name Busulfan

1.2 Other means of identification

Product number C4X-1455
Other names Myleran; 4-methylsulfonyloxybutyl methanesulfonate; Mitostan

1.3 Recommended use of the chemical and restrictions on use

Identified uses For laboratory and Industrial use only.
Uses advised against no data available

1.4 Supplier's details

Company CATO Research Chemicals Inc.
Address 3/F,Building B,No.179 BASIGO, Guangpu Rd East,Huangpu Dist,Guangzhou
Telephone +86-20-81960175

1.5 Emergency phone number

Emergency phone number +86-20-81960175
Service hours 'Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

Acute toxicity - Category 3, Oral
Acute toxicity - Category 2, Dermal
Acute toxicity - Category 2, Inhalation
Carcinogenicity, Category 1B

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word Danger
Hazard statement(s)
H301 Toxic if swallowed
H310 Fatal in contact with skin
H330 Fatal if inhaled
H350 May cause cancer

Precautionary statement(s)
Prevention
P264 Wash ... thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P262 Do not get in eyes, on skin, or on clothing.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P271 Use only outdoors or in a well-ventilated area.
P284 [In case of inadequate ventilation] wear respiratory protection.
P203 Obtain, read and follow all safety instructions before use.

Response	P301+P316 IF SWALLOWED: Get emergency medical help immediately. P321 Specific treatment (see ... on this label). P330 Rinse mouth. P302+P352 IF ON SKIN: Wash with plenty of water/... P316 Get emergency medical help immediately. P361+P364 Take off immediately all contaminated clothing and wash it before reuse. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P320 Specific treatment is urgent (see ... on this label). P318 IF exposed or concerned, get medical advice.
Storage	P405 Store locked up. P403+P233 Store in a well-ventilated place. Keep container tightly closed.
Disposal	P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

2.3 Other hazards which do not result in classification

no data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Busulfan	Busulfan	55-98-1	200-250-2	100%

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

If inhaled

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

Following ingestion

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this compound may include nausea, vomiting, diarrhea, impotence, sterility, amenorrhea, fetal malformation, depression of erythropoiesis leading to aplastic anemia, diffuse pulmonary fibrosis, precipitation of uric acid in kidney tubules and hemorrhages. ACUTE/CHRONIC HAZARDS: When heated to decomposition this compound emits toxic fumes of SOx. It is an experimental carcinogen. (NTP, 1992)

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

Emergency and supportive measures. Maintain an open airway and assist ventilation if necessary. Treat coma, seizures, hypotension, and arrhythmias if they occur. Treat nausea and vomiting with metoclopramide and fluid loss caused by gastroenteritis with intravenous crystalloid fluids. Antineoplastic agents

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Fires involving this material should be controlled using a dry chemical, carbon dioxide or Halon extinguisher. (NTP, 1992)

5.2 Specific hazards arising from the chemical

Flash point data for this chemical are not available. It is probably combustible. (NTP, 1992)

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours.Avoid contacting with skin and eye. Use personal protective equipment.Wear chemical impermeable gloves. Ensure adequate ventilation.Remove all sources of ignition. Evacuate personnel to safe areas.Keep people away from and upwind of spill/leak.

6.2 Environmental precautions

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Collect and arrange disposal. Keep the chemical in suitable and closed containers for disposal. Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

7.2 Conditions for safe storage, including any incompatibilities

Commercially available busulfan for injection concentrate should be stored in unopened ampules at 2-8 deg C. The manufacturer states that, when diluted as directed in 0.9% sodium chloride injection or 5% dextrose injection, busulfan solutions are stable for up to 8 hours when stored at room temperature (approximately 25 deg C), and the busulfan infusion must be completed during the 8-hour time period. Solutions of busulfan diluted in 0.9% sodium chloride injection also have been shown to be stable when refrigerated at 2-8 deg C for up to 12 hours, during which time the infusion must be completed.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

Biological limit values

no data available

8.2 Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

Thermal hazards

no data available

SECTION 9: Physical and chemical properties and safety characteristics

Physical state	PHYSICAL DESCRIPTION: White crystals or powder. (NTP, 1992)
Colour	White needles
Odour	no data available
Melting point/freezing point	273°C(lit.)
Boiling point or initial boiling point and boiling range	167°C
Flammability	no data available
Lower and upper explosion limit/flammability limit	no data available
Flash point	18°C(lit.)
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	Decomposes (NTP, 1992)
Partition coefficient n-octanol/water	no data available
Vapour pressure	6.56X10-6 mm Hg at 25 deg C (est)

Density and/or relative density	1.35 g/cm3
Relative vapour density	no data available
Particle characteristics	no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

This compound is an alkylating agent which hydrolyzes in water. (NTP, 1992).

10.2 Chemical stability

Solutions of busulfan diluted in 0.9% sodium chloride injection also have been shown to be stable when refrigerated at 2-8 deg C for up to 12 hours, during which time the infusion must be completed.

10.3 Possibility of hazardous reactions

MYLERAN is an alkylating agent which hydrolyzes in water. (NTP, 1992). Strong reducers may yield hydrogen sulfide.

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

no data available

SECTION 11: Toxicological information

Acute toxicity

- Oral: LD50 Mouse oral 120 mg/kg
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

Classification of carcinogenicity: 1) evidence in humans: Sufficient; 2) evidence in animals: Limited. Overall summary evaluation of carcinogenic risk to humans is Group 1: The agent is carcinogenic to humans. From table

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

SECTION 12: Ecological information

12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

12.5 Other adverse effects

no data available

SECTION 13: Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

SECTION 14: Transport information

14.1 UN Number

ADR/RID: UN2811 (For reference only, please check.) IMDG: UN2811 (For reference only, please check.) IATA: UN2811 (For reference only, please check.)

14.2 UN Proper Shipping Name

ADR/RID: TOXIC SOLID, ORGANIC, N.O.S. (For reference only, please check.) IMDG: TOXIC SOLID, ORGANIC, N.O.S. (For reference only, please check.) IATA: TOXIC SOLID, ORGANIC, N.O.S. (For reference only, please check.)

14.3 Transport hazard class(es)

ADR/RID: 6.1 (For reference only, please check.) IMDG: 6.1 (For reference only, please check.) IATA: 6.1 (For reference only, please check.)

14.4 Packing group, if applicable

ADR/RID: I (For reference only, please check.) IMDG: I (For reference only, please check.) IATA: I (For reference only, please check.)

14.5 Environmental hazards

ADR/RID: No IMDG: No IATA: No

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to IMO instruments

no data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
Busulfan	Busulfan	55-98-1	200-250-2
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Not Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Inventory of Chemicals (NZIoC)			Not Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Not Listed.
Vietnam National Chemical Inventory			Not Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Listed.
Korea Existing Chemicals List (KECL)			Not Listed.

SECTION 16: Other information

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Information on revision

Creation Date	July 15, 2019
Revision Date	May 26, 2024

Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: http://www.ilo.org/dyn/icsc/showcard.home
- HSDB - Hazardous Substances Data Bank, website: https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm
- IARC - International Agency for Research on Cancer, website: http://www.iarc.fr/
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: http://cameochemicals.noaa.gov/search/simple
- ChemIDplus, website: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: http://www.phmsa.dot.gov/hazmat/library/erg
- Germany GESTIS-database on hazard substance, website: http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp
- ECHA - European Chemicals Agency, website: https://echa.europa.eu/

Any questions regarding this SDS, Please send your inquiry to info@cato-chem.com

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Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. We as supplier shall not be held liable for any damage resulting from handling or from contact with the above product.