

Busulfan SDS/MSDS (Safety Data Sheet)

1. PRODUCT AND COMPANY IDENTIFICATION

Product identifier

* Product Name: Busulfan

* Catalog Number: S1692

* CAS Number: 55-98-1

* IUPAC Name: 1,4-dimethanesulfonate-1,4-butanediol

Relevant identified uses and uses advised against

* Identified uses: For research and development use only; laboratory chemicals; manufacture of substances.

* Uses advised against: Not for pharmaceutical, household, or other unapproved uses.

Details of the supplier

* Company: Selleck Chemicals

* TollFree: +1 877 796-6397

* Tel: +1 832 582-8158

* Fax: +1 832 582-8590

Emergency telephone number

* Emergency phone #: +1 832 582-8158

2. HAZARDS IDENTIFICATION

2.1 GHS classification in accordance with 29 CFR 1910 (OSHA HCS):

Acute toxicity (oral): Category 1. H300

Acute toxicity (oral): Category 3. H301

Acute toxicity (dermal): Category 1. H310

Skin irritation: Category 2. H315

Serious eye irritation: Category 2. H319

Acute toxicity (inhalation): Category 1. H330

Specific target organ toxicity (single exposure): Category 3. H335

Germ cell mutagenicity: Category 1. H340

Carcinogenicity: Category 1. H350

Reproductive toxicity: Category 1. H360

Specific target organ toxicity (single exposure): Category 2. H371

Specific target organ toxicity (repeated exposure): Category 2. H373

2.2 GHS Label elements, including precautionary statements

Hazard Pictogram(s)



Signal Word

Danger

Hazard statement(s)	H300: Fatal if swallowed H301: Toxic if swallowed H310: Fatal in contact with skin H315: Causes skin irritation H319: Causes serious eye irritation H330: Fatal if inhaled H335: May cause respiratory irritation H340: May cause genetic defects H350: May cause cancer H360: May damage fertility or the unborn child H371: May cause damage to organs H373: May causes damage to organs through prolonged or repeated exposure
Precautionary statement(s)	None.
Prevention	P203: Obtain, read and follow all safety instructions before use. P260: Do not breathe dust/fume/gas/mist/vapors/spray. P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P262: Do not get in eyes, on skin, or on clothing. P264: Wash hands thoroughly after handling. P264+P265: Wash hands thoroughly after handling. Do not touch eyes. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P284: [In case of inadequate ventilation] Wear respiratory protection.
Response	P301+P316: IF SWALLOWED: Get emergency medical help immediately. P302+P352: IF ON SKIN: wash with plenty of water. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351: IF IN EYES: Rinse cautiously with water for several minutes. P308+P316: IF exposed or concerned: Get emergency medical help immediately. P316: Get emergency medical help immediately. P318: if exposed or concerned, get medical advice. P319: Get medical help if you feel unwell. P320: Specific treatment is urgent. P321: Specific treatment (see information on this label and safety datasheet)). P330: Rinse mouth. P332+P317: If skin irritation occurs: Get medical help. P337+P317: If eye irritation persists: Get medical help. P338: Remove contact lenses, if present and easy to do. Continue rinsing. P361+P364: Take off immediately all contaminated clothing and wash it before reuse. P362+P364: Take off contaminated clothing and wash it before reuse.
Storage	P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up.
Disposal	P501: P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Other hazards

None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Busulfan
 CAS Number: 55-98-1
 PubChem CID: 2478
 Molecular formula: C₆H₁₄O₆S₂
 Molecular weight: 246.3 g/mol
 IUPAC name: 4-methylsulfonyloxybutyl methanesulfonate

3.2 Mixtures

Not applicable (pure substance).

4. FIRST-AID MEASURES

4.1 Description of first aid measures

Inhalation: INHALATION: IMMEDIATELY leave the contaminated area; take deep breaths of fresh air. IMMEDIATELY call a physician and be prepared to transport the victim to a hospital even if no symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop. Provide proper respiratory protection to rescuers entering an unknown atmosphere. Whenever possible, Self-Contained Breathing Apparatus (SCBA) should be used; if not available, use a level of protection greater

Skin contact: SKIN: IMMEDIATELY flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. If symptoms such as redness or irritation develop, IMMEDIATELY call a physician and be prepared to transport the victim to a hospital for treatment.

Eye contact: EYES: First check the victim for contact lenses and remove if present. Flush victim's eyes with water or normal saline solution for 20 to 30 minutes while simultaneously calling a hospital or poison control center. Do not put any ointments, oils, or medication in the victim's eyes without specific instructions from a physician. IMMEDIATELY transport the victim after flushing eyes to a hospital even if no symptoms (such as redness or irritation) develop.

Ingestion: INGESTION: If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and IMMEDIATELY call a hospital or poison control center. Generally, the induction of vomiting is NOT recommended outside of a physician's care due to the risk of aspirating the chemical into the victim's lungs. However, if the victim is conscious and not convulsing and if medical help is not readily available, consider the risk of inducing vomiting because of the high toxicity of the ch

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 (Toxicological Information).

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically. Contact a poison control center or physician for severe exposure.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable: Water spray, dry chemical, carbon dioxide (CO₂), alcohol-resistant foam.
 Unsuitable: None known.

5.2 Specific hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Wear self-contained breathing apparatus (SCBA) and full protective clothing.

Fight fire from upwind. Cool containers with water spray until fire is extinguished.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear appropriate personal protective equipment (see Section 8).

Avoid breathing dust/vapor. Ensure adequate ventilation.

Evacuate personnel to safe areas. Keep people away from and upwind of spill.

WARNING: Highly toxic — only trained personnel should handle spills.

6.2 Environmental precautions

Prevent product from entering drains, waterways, or soil.

Contain spill with inert absorbent material.

6.3 Methods and materials for containment and cleaning up

Excerpt from ERG Guide 154 [Substances - Toxic and/or Corrosive (Non-Combustible)]:

IMMEDIATE PRECAUTIONARY MEASURE: Isolate spill or leak area in all directions for at least 50 meters (150 feet) for liquids and at least 25 meters (75 feet) for solids.

SPILL: Increase the immediate precautionary measure distance, in the downwind direction, as necessary.

FIRE: If tank, rail tank car or highway tank is involved in a fire, ISOLATE for 800 meters (1/2 mile) in all directions; also, consider initial evacuation for 800 meters (1/2 mile) in all directions. (ERG, 2024)

SRP: At the time of review, criteria for land treatment or burial (sanitary landfill) disposal practices are subject to significant revision. Prior to implementing land disposal of waste residue (including waste sludge), consult with environmental regulatory agencies for guidance on acceptable disposal practices.

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ All contaminated disposables should be contained in sealable bags for transfer to larger waste containers. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ All bottles must be discarded as contaminated waste after decontamination of the biohazard cabinet. All protective apparel (gown, gloves, goggles, and respirator) should be discarded as contaminated waste. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ The contaminated filters must be removed, bagged in thick plastic and prepared for disposal in a hazardous waste dump site or incinerator licensed by the Environmental Protection Agency (EPA). /Antineoplastic agents/

For more Disposal Methods (Complete) data for BUSULFAN (8 total), please visit the HSDB record page.

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Accidental contamination of the health-care environment, resulting in exposure of personnel, patients, visitors, and family members to hazardous substances, is prevented by maintaining the physical integrity and security of packages of hazardous drugs. 1. Access to all areas where hazardous drugs are stored is limited to specified authorized staff. 2. A method should be present for identifying to personnel those drugs that require special precautions (eg, cytotoxics). One way to accomplish this is to apply appropriate warning labels to all hazardous drug containers, shelves, and bins where the drug products are stored. ... 3. A method of identifying, for patients and family members, those drugs that require special precautions in the home should be in place. This may be accomplished in the health-care setting, by providing specific labeling for

discharge medications, along with written instructions. 4. Methods for identifying shipping cartons of hazardous drugs should be required from manufacturers and distributors of these drugs. 5. Written procedures for handling damaged packages of hazardous drugs should be maintained. Personnel involved in shipping and receiving hazardous drugs should be trained in these procedures, including the proper use of protective garments and equipment. Damaged shipping cartons of hazardous drugs should be received and opened in an isolated area (eg, in a laboratory fume hood, if available, not in a vertical laminar airflow biological safety cabinet used for preparing sterile products). /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Facilities (eg, shelves, carts, counters, and trays) for storing hazardous drugs are designed to prevent breakage and to limit contamination in the event of leakage. Bins, shelves with barriers at the front, or other design features that reduce the chance of drug containers falling to the floor should be used. Hazardous drugs requiring refrigeration should be stored separately from nonhazardous drugs in individual bins designed to prevent breakage and to contain leakage. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Until the reproductive risks (or lack thereof) associated with handling hazardous drugs within a safety program have been substantiated, staff who are pregnant or breast-feeding should be allowed to avoid contact with these drugs. Policies should be in effect that provide these individuals with alternative tasks or responsibilities if they so desire. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ The pharmacy should provide access to information on toxicity, treatment of acute exposure (if available), chemical inactivators, solubility and stability of hazardous drugs (including investigational agents) used in the workplace. /Antineoplastic agents/

For more Preventive Measures (Complete) data for BUSULFAN (20 total), please visit the HSDB record page.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

SMALL SPILLS AND LEAKAGE: If a spill of this chemical occurs, FIRST REMOVE ALL SOURCES OF IGNITION, then you should dampen the solid spill material with acetone and transfer the dampened material to a suitable container. Use absorbent paper dampened with acetone to pick up any remaining material. Seal your contaminated clothing and the absorbent paper in a vapor-tight plastic bag for eventual disposal. Solvent wash all contaminated surfaces with acetone followed by washing with a soap and water solution. Do not reenter the contaminated area until the Safety Officer (or other responsible person) has verified that the area has been properly cleaned.

STORAGE PRECAUTIONS: You should store this material at ambient temperatures and protect from moisture. (NTP, 1992)

Commercially available busulfan for injection concentrate should be stored in unopened ampules at 2-8 °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 °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 °C for up to 12 hours, during which time the infusion must be completed.

Commercially available busulfan tablets should be stored in well-closed containers at 25 °C but may be exposed to temperatures ranging from 15-30 °C.

7.2 Conditions for safe storage, including any incompatibilities

Commercially available busulfan for injection concentrate should be stored in unopened ampules at 2-8 °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 °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 °C for up to 12 hours, during which time the infusion must be completed.

Commercially available busulfan tablets should be stored in well-closed containers at 25 °C but may be exposed to temperatures ranging from 15-30 °C.

Store away from incompatible materials (see Section 10).

[Note: Specific storage temperature not available in public databases. Refer to supplier Certificate of Analysis (COA) for exact storage conditions.]

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure controls

8.1.1 Occupational exposure limits (OEL)

OSHA PEL: Not established.

ACGIH TLV: Not established.

NIOSH REL: Not established.

No occupational exposure limit values are established for this substance.

Use the lowest feasible exposure level (ALARA principle).

8.1.2 Appropriate engineering controls

Use only in a chemical fume hood or with local exhaust ventilation.

Ensure adequate ventilation to keep airborne concentrations below exposure limits.

8.2 Individual protection measures

8.2.1 Eye/face protection

Wear chemical safety goggles.

8.2.2 Skin protection

Wear protective gloves. Recommended material: Nitrile rubber.

Wear suitable protective clothing (lab coat).

8.2.3 Respiratory protection

Wear NIOSH-approved respirator with appropriate cartridges. SCBA for high concentrations.

8.2.4 Thermal hazards

Not applicable.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance: Myleran appears as white crystals or powder. (NTP, 1992)

b) Odor: No data available

c) Odor threshold: No data available

d) pH: No data available

e) Melting point/freezing point: 237 to 244 °F (NTP, 1992)

f) Initial boiling point and boiling range: No data available

g) Flash point: No data available

h) Evaporation rate: No data available

i) Flammability (solid, gas): No data available

j) Upper/lower flammability or explosive limits: No data available

k) Vapor pressure: No data available

- l) Vapor density: No data available
- m) Relative density: No data available
- n) Water solubility: Decomposes (NTP, 1992)
- o) Partition coefficient: n-octanol/water: Log P (n-octanol/water): -0.5
- p) Auto-ignition temperature: No data available
- q) Decomposition temperature: No data available
- r) Viscosity: No data available
- s) Explosive properties: No data available
- t) Oxidizing properties: No data available

9.2 Other information

Topological Polar Surface Area (TPSA): 104 Å²
Complexity: 293

10. STABILITY AND REACTIVITY

10.1 Reactivity

No specific reactivity hazards identified under normal handling conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions under normal conditions.

10.4 Conditions to avoid

Avoid heat, sparks, open flames, direct sunlight, and moisture.
Avoid strong oxidizing agents, strong acids, and strong bases.

10.5 Incompatible materials

Strong oxidizing agents, strong acids, strong bases.

10.6 Hazardous decomposition products

Thermal decomposition may produce: Carbon monoxide (CO), Carbon dioxide (CO₂), Sulfur oxides (SO_x).
See also Section 5 (Fire-fighting measures) for combustion products.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

No acute toxicity data available.

Skin corrosion/irritation:

Causes skin irritation (H315).

Serious eye damage/eye irritation:

Causes serious eye irritation (H319).

Respiratory or skin sensitization:

No data available.

Germ cell mutagenicity:

May cause genetic defects (H340).

Carcinogenicity:

May cause cancer (H350).

Reproductive toxicity:

May damage fertility or the unborn child (H360).

Specific target organ toxicity (single exposure):

H371, H373

Specific target organ toxicity (repeated exposure):

No data available.

Aspiration hazard:

No data available.

11.2 Additional information

Carcinogen classification:

Busulfan

Group 1: Carcinogenic to humans

Volume 4: (1974) Some Aromatic Amines, Hydrazine and Related Substances, N-Nitroso Compounds and Miscellaneous Alkylating Agents

Volume Sup 7: Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42, 1987; 440 pages; ISBN 92-832-1411-0 (out of print)

Volume 100A: (2012) Pharmaceuticals

2012

2008

1, carcinogenic to humans. (L135)

Exposure routes:

Completely absorbed from the gastrointestinal tract. Busulfan is a small, highly lipophilic molecule that crosses the blood-brain-barrier. The absolute bioavailability, if a single 2 mg IV bolus injection is given to adult patients, is 80% $\pm$ 20%. In children (1.5 - 6 years old), the absolute bioavailability was 68% $\pm$ 31%. When a single oral dose is given to patients, the area under the curve (AUC) was 130 ng $\cdot$ y $\cdot$ hr/mL. The peak plasma concentration when given orally is 30 ng/mL (after dose norma

Signs and symptoms of exposure:

Signs of overdose include allergic reaction, unusual bleeding or bruising, sudden weakness or unusual fatigue, persistent cough, congestion, or shortness of breath; flank, stomach or joint pain; pronounced nausea, vomiting, diarrhea, dizziness, confusion, or darkening of the skin, chills, fever, collapse, and loss of consciousness.

Data source: Hazardous Substances Data Bank (HSDB) via PubChem.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

/AQUATIC SPECIES/ Tilapia mossambica (Peters) Teleostei, Cichlidae, is of commercial importance being farmed for human consumption. An effective means of sterilization would be of value since prolific breeding under farming conditions reduces growth rate. The possibility of using the antileukemic drug myleran as a chemosterilant has been investigated previously, however the present study indicated that it can induce dominant lethal mutations in this species.

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ ... exposure may be through inadvertent ingestion of the drug on foodstuffs (eg, workers' lunches), inhalation of drug dusts or droplets or direct skin contact. /Antineoplastic agents/

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

Log P (n-octanol/water): -0.5

Low potential for bioaccumulation (Log P < 3).

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available.

12.6 Other adverse effects

No other adverse ecological effects identified.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste Treatment Methods: Waste material must be disposed of in accordance with national and local regulations. Leave chemicals in original containers and do not mix with other waste. Handle uncleaned containers in the same manner as the product itself.

14. TRANSPORT INFORMATION

14.1 UN number

Not regulated as dangerous goods (research quantities typically exempt).

14.2 UN proper shipping name

Not subject to transport regulations (small quantities for research use).

14.3 Transport hazard class(es)

Not classified as dangerous goods for transport (research quantities).

DOT label: Poison

14.4 Packing group

Not applicable (not regulated as dangerous goods in typical research quantities).

14.5 Environmental hazards

Marine pollutant: No (not classified as environmentally hazardous per GHS).

14.6 Special precautions for user

Transport in original packaging. Ensure containers are tightly sealed.

For bulk or commercial quantities, consult applicable transport regulations (DOT, IATA, IMDG).

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

15. REGULATORY INFORMATION

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

US EPA / TSCA: Not available in public databases.

EU ECHA / REACH: Not available in public databases.

SARA 302 Components:

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards:

Acute (short-term) health hazard

Chronic (long-term) health hazard

Massachusetts Right To Know Components:

This material contains components subject to the Massachusetts Right to Know Act. See Section 2 for hazard classification.

Pennsylvania Right To Know Components:

This material contains components subject to the Pennsylvania Right to Know Act. See Section 2 for hazard classification.

New Jersey Right To Know Components:

This material contains components subject to the New Jersey Right to Know Act. See Section 2 for hazard classification.

California Prop. 65 Components:

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Other regulatory listings:

- California Safe Cosmetics Program (CSCP) Reportable Ingredient: Hazard Traits - Carcinogenicity; Developmental Toxicity Authoritative List - IARC Carcinogens - 1; NTP RoC - reasonable; Prop 65 Report - regardless of intended function of ingredient in the product
- FDA Requirements: The Approved Drug Products with Therapeutic Equivalence Evaluations List identifies currently marketed prescription drug products, incl busulfan, approved on the basis of safety and effectiveness by FDA under sections 505 of the Federal Food, Drug, and Cosmetic Act.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this substance.

For research-use-only compounds, no CSA is required under REACH Annex I.

16. OTHER INFORMATION

Revision Date: 2026/09/08

Further Information: The information provided is believed to be correct but is not exhaustive and should be used only as a guideline based on current knowledge. It does not represent a guarantee of the properties of the product.

Selleck Chemicals Corporation and its Affiliates shall not be held liable for any damage resulting from handling or contact with the product.