

100-1125 - Busulfan

Revision Date 14-Dec-2022 Revision Number 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Busulfan

Other means of identification

Catalog Number 100-1125

UN/ID no. UN2811

Document Number 10000019312

Synonyms Busulphan; Mielosan; Mylecitan; Myeloleukon; Mylecytan; Myleran; NCI C01592; NSC 750;

1,4-dimethanesulfonate 1,4-butanediol;

Recommended use of the chemical and restrictions on use

Recommended Use Laboratory chemical

Details of the supplier of the safety data sheet

Manufacturer/Supplier

STEMCELL Technologies Canada Inc. Suite 500 - 1618 Station Street Vancouver, British Columbia V6A 1B6 Canada

Emergency telephone number

Emergency Telephone 1-800-667-0322

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral	Category 3
Acute toxicity - Dermal	Category 1
Acute toxicity - Inhalation (Dusts/Mists)	Category 1
Carcinogenicity	Category 1A

Hazards not otherwise classified (HNOC)

Not applicable



100-1125 - Busulfan

Revision Date 14-Dec-2022 Revision Number 1

Label elements

Danger

Hazard statements

Toxic if swallowed Fatal in contact with skin Fatal if inhaled May cause cancer



Appearance Crystalline

Physical state Solid

Odor No data available

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

Do not get in eyes, on skin, or on clothing

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Do not breathe dust/fume/gas/mist/vapors/spray

Use only outdoors or in a well-ventilated area

Wear respiratory protection

Precautionary statements - Response

IF exposed or concerned: Get medical advice/attention

IF ON SKIN: Wash with plenty of water and soap

Immediately call a POISON CENTER or doctor

Take off immediately all contaminated clothing and wash it before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing

Immediately call a POISON CENTER or doctor

IF SWALLOWED: Immediately call a POISON CENTER or doctor

Rinse mouth

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant



100-1125 - Busulfan

Revision Date 14-Dec-2022 **Revision Number** 1

Other Information

Not applicable

Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown toxicity

- 0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
- 0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Synonyms

Busulphan;. Mielosan;. Milecitan;. Myeloleukon;. Mylecytan;. Myleran;. NCI C01592;. NSC 750;. 1,4-dimethanesulfonate 1,4-butanediol;.

Chemical name	CAS No.	Weight-%
butane-1,4-diyl dimethanesulfonate	55-98-1	100

^{*}The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of first aid measures

General advice Immediate medical attention is required. Show this safety data sheet to the doctor in

attendance. IF exposed or concerned: Get medical advice/attention.

Inhalation If breathing has stopped, give artificial respiration. Get medical attention immediately.

Remove to fresh air. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is

difficult, (trained personnel should) give oxygen.

Eve contact Get immediate medical advice/attention. Rinse immediately with plenty of water, also under

the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.

Get immediate medical advice/attention. Wash off immediately with soap and plenty of Skin contact

water while removing all contaminated clothes and shoes.

Ingestion Get immediate medical advice/attention. Do NOT induce vomiting. Clean mouth with water

and drink afterwards plenty of water. Never give anything by mouth to an unconscious

person.



100-1125 - Busulfan

Revision Date 14-Dec-2022 Revision Number 1

Self-protection of the first aider

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Use personal protective equipment as required. See section 8 for more information.

Most important symptoms and effects, both acute and delayed

Symptoms Coughing and/ or wheezing. Difficulty in breathing.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

surrounding environment.

Unsuitable extinguishing media CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the No information available.

chemical

Explosion data

Sensitivity to Mechanical Impact None. Sensitivity to Static Discharge None.

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 Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid generation of

dust. Do not breathe dust. Use personal protective equipment as required. Evacuate

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

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental precautions



100-1125 - Busulfan

Environmental precautions

Revision Date 14-Dec-2022 Revision Number 1

Prevent further leakage or spillage if safe to do so. Should not be released into the environment. Do not allow to enter into soil/subsoil. Prevent product from entering drains.

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 Pick up and transfer to properly labeled containers.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Do not breathe dust. Avoid generation of dust. In case of insufficient ventilation, wear

suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Take off

contaminated clothing and wash before reuse. Handle in accordance with good industrial

hygiene and safety practice. Avoid contact with skin, eyes or clothing.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store in accordance with information listed on the Product Information Sheet (PIS). Store

locked up. Keep out of the reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure

limit applicable in the region for which this safety data sheet is intended or other

recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.



100-1125 - Busulfan

Revision Date 14-Dec-2022 Revision Number 1

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Impervious gloves. Wear suitable gloves.

Skin and body protection Impervious clothing. Long sleeved clothing. Chemical resistant apron. Wear suitable

protective clothing.

Respiratory protection When workers are facing concentrations above the exposure limit they must use

appropriate certified respirators.

General hygiene considerations Remove and wash contaminated clothing and gloves, including the inside, before re-use.

Avoid contact with skin, eyes or clothing. Do not breathe dust. Wear suitable gloves and eye/face protection. Take off contaminated clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state Solid Appearance Crystalline

ColorNo information availableOdorNo data availableOdor thresholdNo data available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pH No data available None known

Melting point / freezing point 114–118 °C (237.2–244.4 °F)

Boiling point / boiling rangeNo data availableNone knownFlash pointNo data availableNone knownEvaporation rateNo data availableNone known

Flammability (solid, gas) Product is not flammable.

Flammability Limit in Air None known

Upper flammability limit: No data available Lower flammability limit: No data available

Vapor pressureNo data availableNone knownVapor densityNo data availableNone knownRelative densityNo data availableNone knownWater solubilityNo data availableNone known

Solubility in other solvents ~0.5 mg/mL in a 1:1 solution of

DMSO:PBS (pH 7.2); ~16.7 mg/mL in

DMSO & DMF



100-1125 - Busulfan

Revision Date 14-Dec-2022 Revision Number 1

Partition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

Explosive properties No data available Oxidizing properties No information available

Other Information

Softening point No information available

Molecular weight 246.3 Molecular formula C6H14O6S2

VOC Content (%)
Liquid Density
No information available
No information available
No information available

10. STABILITY AND REACTIVITY

Reactivity No information available.

Chemical stability Stable under recommended transport or storage conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid Excessive heat.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products Carbon oxides. Hydrogen sulfide.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. Fatal if inhaled. (based on

components).

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available. Fatal in contact with skin.

(based on components).

Ingestion Specific test data for the substance or mixture is not available. Toxic if swallowed. (based

on components).



100-1125 - Busulfan

Revision Date 14-Dec-2022 Revision Number 1

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Coughing and/ or wheezing. Difficulty in breathing.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 100.00 mg/kg
ATEmix (dermal) 5.00 mg/kg
ATEmix (inhalation-dust/mist) 0.005 mg/l

Unknown acute toxicity 0 % of the mixture consists of ingredient(s) of unknown toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

- 0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Product Information

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

Skin corrosion/irritation No information available.

Product Information

Serious eye damage/eye irritation No information available.

Product Information

Respiratory or skin sensitization No information available.

Product Information

Germ cell mutagenicity No information available.

Product Information

Carcinogenicity Classification based on data available for ingredients.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
butane-1,4-diyl	-	Group 1	Known	X
dimethanesulfonate				
55-98-1				

Reproductive toxicity No information available.

Product Information



100-1125 - Busulfan

STOT - single exposure

Revision Date 14-Dec-2022 Revision Number 1

No information available.

Product Information

STOT - repeated exposureNo information available.

Product Information

Aspiration hazard No information available.

RTECS # EK1750000

12. ECOLOGICAL INFORMATION

Ecotoxicity The environmental impact of this product has not been fully investigated.

Product Information

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Other adverse effects No information available.

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 Do not reuse empty containers.

14. TRANSPORT INFORMATION

Note: When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity

Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted

Quantity.

DOT

UN/ID no. UN2811

Proper shipping name Toxic solids, organic, n.o.s. (Busulfan)



100-1125 - Busulfan

Revision Date 14-Dec-2022 Revision Number 1

Hazard class 6.1 Toxic substances

Packing Group

TDG Not regulated

MEX Not regulated

ICAO (air) Not regulated

IATA

UN Number UN2811

UN proper shipping name Toxic solid, organic, n.o.s. (Busulfan)

Transport hazard class(es) 6.1 Toxic substances

Packing Group

IMDG

UN Number UN2811

UN proper shipping name TOXIC SOLID, ORGANIC, N.O.S. (Busulfan)

Transport hazard class(es) 6.1 Toxic substances

Packing Group

RID Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Does not comply
DSL/NDSL Complies
EINECS/ELINCS Complies
ENCS Complies
IECSC Complies
KECL Does not comply

KECLDoes not complyPICCSDoes not complyAICSDoes not comply

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances



100-1125 - Busulfan

Revision Date 14-Dec-2022 Revision Number 1

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals.

Chemical name	California Proposition 65
butane-1,4-diyl dimethanesulfonate - 55-98-1	Carcinogen
	Developmental

U.S. State Right-to-Know Regulations

US State Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
butane-1,4-diyl dimethanesulfonate	-	X	X
55-98-1			

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable



100-1125 - Busulfan

Revision Date 14-Dec-2022 Revision Number 1

16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OF THE LAST REVISION

Prepared By, Quality Control. STEMCELL Technologies Canada Inc.

Revision Date 14-Dec-2022

Revision NoteNo information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text. STEMCELL Technologies Inc. shall not be held liable for any damage resulting from handling or from contact with the product.

End of Safety Data Sheet