



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 14-Dec-2022

Revision Number 1

100-1125 - Busulfan

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Document Number 10000019312

Product Name Busulfan

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

Pure substance/mixture Substance

Contains butane-1,4-diyl dimethanesulfonate

Molecular weight 246.3

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Laboratory chemical

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

STEMCELL Technologies SARL
40 Rue des Berges, Miniparc Polytec, Bâtiment Sirocco, 38000 Grenoble, France
+33 (0) 4 76 04 75 30
STEMCELL Technologies Germany GmbH
Stolberger Str. 200, 50933, Köln, Germany
+33 (0) 4 76 04 75 30
STEMCELL Technologies UK Ltd.
Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL
+33 (0) 4 76 04 75 30

For further information, please contact

1.4. Emergency telephone number

Emergency Telephone No information available

Emergency Telephone - \$45 - (EC)1272/2008

Europe 112

Section 2: HAZARDS IDENTIFICATION



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2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 3 - (H301)
Acute toxicity - Dermal	Category 1 - (H310)
Acute toxicity - Inhalation (Dusts/Mists)	Category 1 - (H330)
Carcinogenicity	Category 1A - (H350)

2.2. Label elements

200-250-2

Contains butane-1,4-diyl dimethanesulfonate



Signal word

Danger

Hazard statements

Hazard statements

H301 - Toxic if swallowed

H310 - Fatal in contact with skin

H330 - Fatal if inhaled

H350 - May cause cancer

Precautionary Statements - EU (§28, 1272/2008)

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P280 - Wear eye protection/ face protection

P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)

P322 - Specific measures (see .? on this label)

P361 + P364 - Take off immediately all contaminated clothing and wash it before reuse

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P310 - Immediately call a POISON CENTER or doctor

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

P422 - Store contents under inert gas

P201 - Obtain special instructions before use

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P313 - IF exposed or concerned: Get medical advice/attention

Additional information

This product requires tactile warnings if supplied to the general public This product requires child resistant fastenings if supplied to the general public

2.3. Other hazards

No information available



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Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Synonyms

Chemical name	EC No.	CAS No.	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
butane-1,4-diyl dimethanesulfonate	200-250-2	55-98-1	100	Acute Tox. 3 (H301) Acute Tox. 1 (H310) Acute Tox. 1 (H330) Carc. 1 (H350)	No data available

Full text of H- and EUH-phrases: see section 16

Section 4: FIRST AID MEASURES

4.1. 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.
Eye 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.
Skin contact	Get immediate medical advice/attention. Wash off immediately with soap and plenty of 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.
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.



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4.2. Most important symptoms and effects, both acute and delayed

Symptoms Coughing and/ or wheezing. Difficulty in breathing.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical No information available.

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. 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.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions 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.

6.3. Methods and material for containment and cleaning up



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Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.
<u>6.4. Reference to other sections</u>	
Reference to other sections	See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. 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.
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.

7.2. 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.
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7.3. Specific end use(s)

Identified Uses	
Risk Management Methods (RMM)	The information required is contained in this Material Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
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Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

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.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state Solid
Appearance Crystalline
Color No information available
Odor No data available.
Odor threshold No data available

Property	Values	Remarks • Method
pH	No data available	None known
Melting point / freezing point	114–118 °C (237.2–244.4 °F)	



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Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None 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 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)	~0.5 mg/mL in a 1:1 solution of DMSO:PBS (pH 7.2); ~16.7 mg/mL in DMSO & DMF;	
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
Explosive properties	No information available	
Oxidizing properties	No information available	
9.2. Other information		
Softening point	No information available	
Molecular weight	246.3	
Molecular formula	C ₆ H ₁₄ O ₆ S ₂	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under recommended transport or storage conditions.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

10.3. Possibility of hazardous reactions



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Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid Excessive heat.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon oxides. Hydrogen sulfide.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

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).

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



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Unknown acute toxicity 100 % 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.
 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
 100 % 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.

Product Information

Reproductive toxicity No information available.

Product Information

STOT - single exposure No information available.

Product Information

STOT - repeated exposure No information available.

Product Information

Aspiration hazard No information available.

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

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

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.



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Product Information

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. 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.

Section 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.

IMDG

14.1 UN Number UN2811
14.2 UN proper shipping name TOXIC SOLID, ORGANIC, N.O.S. (Busulfan)



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14.3 Transport hazard class(es)	6.1 Toxic substances
14.4 Packing Group	I
14.5 Marine pollutant	Not applicable
14.6 Special Provisions	None
14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code	No information available

RID

14.1 UN Number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

ADR

14.1 UN Number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

IATA

14.1 UN Number	UN2811
14.2 UN proper shipping name	Toxic solid, organic, n.o.s. (Busulfan)
14.3 Transport hazard class(es)	6.1 Toxic substances
14.4 Packing Group	I
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

Section 15: REGULATORY INFORMATION

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

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)



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Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

H1 - ACUTE TOXIC

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

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

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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

Full text of H-Statements referred to under section 3

H301 - Toxic if swallowed
H310 - Fatal in contact with skin
H330 - Fatal if inhaled
H350 - May cause cancer

Legend

SVHC: Substances of Very High Concern for Authorization:



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Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

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