Safety data sheet

according to 1907/2006/EC, Article 31

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

· ***1.1 Product identifier***

· ***Product name:*** **Busulfan**

· ***Part number:*** *Cat 403*
· ***CAS Number:***
55-98-1
· ***EC number:***
200-250-2
· ***1.2 Relevant identified uses of the substance or mixture and uses advised against***
No further relevant information available.
· ***Application of the substance / the mixture*** *Reference material for laboratory use only*

· ***1.3 Details of the supplier of the safety data sheet***
· ***Manufacturer/Supplier:***
British Pharmacopoeia Commission
MHRA
10 South Colonnade
Canary Wharf
London E14 4PU
United Kingdom
Tel : +44 (0)20 3080 6561
eMail: bpcrs@mhra.gov.uk

· ***Further information obtainable from:*** *eMail: bpcrs@mhra.gov.uk*
· ***1.4 Emergency telephone number:*** *+44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)*

SECTION 2: Hazards identification

· ***2.1 Classification of the substance or mixture***
· ***Classification according to Regulation (EC) No 1272/2008***

skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.
Acute Tox. 3 H311 Toxic in contact with skin.
Acute Tox. 3 H331 Toxic if inhaled.

health hazard

Muta. 1B H340 May cause genetic defects.
Carc. 1A H350 May cause cancer.
Repr. 1A H360 May damage fertility or the unborn child.
STOT SE 2 H371 May cause damage to organs.

· ***2.2 Label elements***
· ***Labelling according to Regulation (EC) No 1272/2008***
The substance is classified and labelled according to the CLP regulation.

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· ***Hazard pictograms***

GHS06 GHS08

· ***Signal word*** *Danger*

· ***Hazard statements***

H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.
H340 May cause genetic defects.
H350 May cause cancer.
H360 May damage fertility or the unborn child.
H371 May cause damage to organs.

· ***Precautionary statements***

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P321 Specific treatment (see on this label).
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· ***Additional information:***

Restricted to professional users.

· ***2.3 Other hazards***

· ***Results of PBT and vPvB assessment***

· ***PBT:*** *Not applicable.*

· ***vPvB:*** *Not applicable.*

SECTION 3: Composition/information on ingredients

· ***3.1 Chemical characterisation: Substances***

· ***CAS No. Description***

55-98-1 Busulfan

· ***Identification number(s)*** *None*

· ***EC number:*** *200-250-2*

· ***RTECS:*** *EK1750000*

· ***Additional information:*** *For the wording of the listed hazard phrases refer to section 16.*

SECTION 4: First aid measures

· ***4.1 Description of first aid measures***

· ***General information:***

Immediately remove any clothing soiled by the product.
Remove breathing equipment only after contaminated clothing has been completely removed.
In case of irregular breathing or respiratory arrest provide artificial respiration.

· ***After inhalation:***

Supply fresh air or oxygen; call for doctor.
In case of unconsciousness place patient in recovery position for transport.
Seek immediate medical advice.

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· ***After skin contact:***
Immediately wash with water and soap and rinse thoroughly.
Seek immediate medical advice.
· ***After eye contact:*** *Rinse opened eye for several minutes under running water. Then consult a doctor.*
· ***After swallowing:***
Rinse mouth. Do not induce vomiting.
Call for a doctor immediately.
· ***4.2 Most important symptoms and effects, both acute and delayed*** *No further relevant information available.*
· ***4.3 Indication of any immediate medical attention and special treatment needed***
No further relevant information available.

SECTION 5: Firefighting measures

· ***5.1 Extinguishing media***
· ***Suitable extinguishing agents:*** *Use fire extinguishing methods suitable for surrounding conditions.*
· ***5.2 Special hazards arising from the substance or mixture***
Formation of toxic gases is possible during heating or in case of fire.
· ***5.3 Advice for firefighters***
· ***Protective equipment:***
Mouth respiratory protective device.
Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures*** *Avoid formation of dust.*
· ***6.2 Environmental precautions:*** *Do not allow to enter sewers/ surface or ground water.*
· ***6.3 Methods and material for containment and cleaning up:***
Dispose of contaminated material as waste according to item 13.
Ensure adequate ventilation.
· ***6.4 Reference to other sections***
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling***
Remove dust thoroughly.
Store in cool, dry place in tightly closed receptacles.
Ensure good ventilation/extraction at the workplace.
Open and handle receptacle with care.
· ***Information about fire - and explosion protection:*** *Keep respiratory protective device available.*

· ***7.2 Conditions for safe storage, including any incompatibilities***
· ***Storage:***
· ***Requirements to be met by storerooms and receptacles:***
Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
Store only in the original receptacle unless other advice is given on the CoA.
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
· ***Information about storage in one common storage facility:*** *Store away from foodstuffs.*

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· ***Further information about storage conditions:*** *Keep container tightly sealed.*
· ***7.3 Specific end use(s)*** *No further relevant information available.*

SECTION 8: Exposure controls/personal protection

· ***8.1 Control parameters***
· ***Additional information about design of technical facilities:*** *No further data; see item 7.*
· ***Ingredients with limit values that require monitoring at the workplace:*** *Not required.*
· ***Additional information:*** *Lists used were valid at the time of SDS preparation.*

· ***8.2 Exposure controls***
· ***Personal protective equipment:***
· ***General protective and hygienic measures:***
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Store protective clothing separately.
Avoid contact with the eyes and skin.
· ***Respiratory protection:***
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced
· ***Protection of hands:***
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374

Protective gloves

· ***Material of gloves*** *Butyl rubber, BR*
· ***Penetration time of glove material***
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· ***Eye protection:***

Tightly sealed goggles

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Powder
Colour:	White
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/freezing point:	117 °C
Initial boiling point and boiling range:	Not determined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gas):**	Not determined.
· **Ignition temperature:**	Not determined
· **Decomposition temperature:**	Not determined.
· **Auto-ignition temperature:**	Not determined.
· **Explosive properties:**	Not determined.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapour pressure:**	Not applicable.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with**	Acetonitrile, acetone
· **water:**	Not determined.
· **Partition coefficient: n-octanol/water:**	-0.52 Log P
· **Viscosity:**	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity**
Stable under normal conditions.
No further relevant information available.
· **10.2 Chemical stability** Stable under normal conditions.
· **Thermal decomposition / conditions to be avoided:**
Formation of toxic gases is possible during heating or in case of fire.

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· ***10.3 Possibility of hazardous reactions*** *No dangerous reactions known.*
· ***10.4 Conditions to avoid*** *Heat.*
· ***10.5 Incompatible materials:*** *Strong oxidizing agents.*
· ***10.6 Hazardous decomposition products:***
Formation of toxic gases is possible during heating or in case of fire.

SECTION 11: Toxicological information

· ***11.1 Information on toxicological effects***
· ***Acute toxicity***
Toxic if swallowed, in contact with skin or if inhaled.

· ***LD/LC50 values relevant for classification:***

Oral	*LD50*	*110 mg/kg (mouse)*

· ***Primary irritant effect:***
· ***Skin corrosion/irritation*** *Based on available data, the classification criteria are not met.*
· ***Serious eye damage/irritation*** *Based on available data, the classifcation criteria are not met.*
· ***Respiratory or skin sensitisation*** *Based on available data, the classification criteria are not met.*
· ***Additional toxicological information:***

· ***CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)***

Oral	*Reproductive*	*5 mg/kg (rat)*

Muta. 1B, Carc. 1A, Repr. 1A
· ***Germ cell mutagenicity***
May cause genetic defects.
· ***Carcinogenicity***
May cause cancer.
· ***Reproductive toxicity***
May damage fertility or the unborn child.
· ***STOT-single exposure***
May cause damage to organs.
· ***STOT-repeated exposure*** *Based on available data, the classification criteria are not met.*
· ***Aspiration hazard*** *Based on available data, the classification criteria are not met.*

SECTION 12: Ecological information

· ***12.1 Toxicity***
· ***Aquatic toxicity:*** *No further relevant information available.*
· ***12.2 Persistence and degradability*** *No further relevant information available.*
· ***12.3 Bioaccumulative potential*** *No further relevant information available.*
· ***12.4 Mobility in soil*** *No further relevant information available.*
· ***Additional ecological information:***
· ***General notes:***
Water hazard class 3 (German Regulation) (Assessment by list): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
· ***12.5 Results of PBT and vPvB assessment***
· ***PBT:*** *Not applicable.*
· ***vPvB:*** *Not applicable.*

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· ***12.6 Other adverse effects*** *No further relevant information available.*

SECTION 13: Disposal considerations

· ***13.1 Waste treatment methods***
· ***Recommendation***
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· ***Uncleaned packaging:***
· ***Recommendation:*** *Dispose of in accordance with national regulations.*

SECTION 14: Transport information

· ***14.1 UN-Number***	
· ***ADR, IMDG, IATA***	*UN2811*
· ***ADR***	*2811 TOXIC SOLID, ORGANIC, N.O.S. (Busulfan)*
· ***IMDG, IATA***	*TOXIC SOLID, ORGANIC, N.O.S. (Busulfan)*
· ***14.3 Transport hazard class(es)***	
· ***ADR, IMDG, IATA***	

· ***Class***	*6.1 Toxic substances.*
· ***Label***	*6.1*
· ***14.4 Packing group***	
· ***ADR, IMDG, IATA***	*III*
· ***14.5 Environmental hazards:***	*Not applicable.*
· ***14.6 Special precautions for user***	*Warning: Toxic substances.*
· ***Hazard identification number (Kemler code):***	*60*
· ***EMS Number:***	*F-A,S-A*
· ***Stowage Category***	*A*
· ***14.7 Transport in bulk according to Annex II of Marpol and the IBC Code***	*Not applicable.*
· ***Transport/Additional information:***	
· ***ADR***	
· ***Limited quantities (LQ)***	*5 kg*
· ***Excepted quantities (EQ)***	*Code: E1* *Maximum net quantity per inner packaging: 30 g* *Maximum net quantity per outer packaging: 1000 g*
· ***Transport category***	*2*
· ***Tunnel restriction code***	*E*

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· ***UN "Model Regulation":***	*UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (BUSULFAN), 6.1, III*

SECTION 15: Regulatory information

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

· ***Directive 2012/18/EU***
· ***Named dangerous substances - ANNEX I*** *Substance is not listed.*
· ***Seveso category*** *H2 ACUTE TOXIC*
· ***Qualifying quantity (tonnes) for the application of lower-tier requirements*** *50 t*
· ***Qualifying quantity (tonnes) for the application of upper-tier requirements*** *200 t*

· ***National regulations:***

· ***Information about limitation of use:***
Workers are not allowed to be exposed to this hazardous material. Exceptions can be made by the authorities in certain cases.
· ***15.2 Chemical safety assessment:*** *A Chemical Safety Assessment has not been carried out.*

SECTION 16: Other information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

· ***Abbreviations and acronyms:***
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 3: Acute toxicity – Category 3
Muta. 1B: Germ cell mutagenicity – Category 1B
Carc. 1A: Carcinogenicity – Category 1A
Repr. 1A: Reproductive toxicity – Category 1A
STOT SE 2: Specific target organ toxicity (single exposure) – Category 2
· ***Sources***
Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.
· ***Data compared to the previous version altered.*** *All sections have been updated.*