

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

- **1.1 Product identifier**
- **Trade name:** Melphalan
- **Article number:** 155345
- **CAS Number:**
148-82-3
- **EC number:**
205-726-3
- **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** Research use only.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
MP Biomedicals Europe
Parc d'Innovation BP 50067
Rue Geiler de Kaysersberg
Illkirch Cedex 67402
France
tel: +33 3.88.67.54.25
www.mpbio.com
- **Further information obtainable from:** Product safety department
- **1.4 Emergency telephone number:**
:n° ORFILA" (01-45-42-59-59)
CHEMTREC: 1-800-424-9300 (1-703-527-3887)

SECTION 2: Hazards identification

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



GHS06 skull and crossbones

Acute Tox. 2 H300 Fatal if swallowed.
Acute Tox. 1 H310 Fatal in contact with skin.
Acute Tox. 1 H330 Fatal if inhaled.



GHS08 health hazard

Muta. 1A H340 May cause genetic defects.
Carc. 1A H350 May cause cancer.
Repr. 2 H361 Suspected of damaging fertility or the unborn child.

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



GHS06 GHS08

- **Signal word** *Danger*
- **Hazard statements**
H300+H310+H330 Fatal if swallowed, in contact with skin or if inhaled.
H340 May cause genetic defects.

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- H350 May cause cancer.
 H361 Suspected of damaging fertility or the unborn child.
- **Precautionary statements**
- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
 P284 [In case of inadequate ventilation] wear respiratory protection.
 P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
 P320 Specific treatment is urgent (see on this label).
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **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**
 148-82-3 Melphalan
- **Identification number(s)**
- **EC number:** 205-726-3

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 have 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 stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Do not induce vomiting; call for medical help 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:**
 CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture**
 During heating or in case of fire poisonous gases are produced.
- **5.3 Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
 Mount respiratory protective device.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

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- **6.3 Methods and material for containment and cleaning up:**
Dispose 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**
Thorough dedusting.
Ensure good ventilation/exhaustion 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:** 15 - 30 °C
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Protect from exposure to the light.
Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **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.
- **Protection of hands:**



Protective gloves

- The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

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- **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

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Powder
· Colour:	Indeterminate
· Odour:	Indeterminate
· Odour threshold:	Not determined.

· **pH-value:** Not applicable.

· Change in condition

· Melting point/Melting range:	175 - 185 °C
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Product is not flammable.

· Ignition temperature:

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Not determined.

· **Danger of explosion:** Product does not present an explosion hazard.

· 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** -
· **water at 22 °C:** < 0.1 g/l

· **Partition coefficient (n-octanol/water):** Not determined.

· Viscosity:

· **Dynamic:** Not applicable.

· **Kinematic:** Not applicable.

· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

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- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity

Fatal if swallowed, in contact with skin or if inhaled.

· LD/LC50 values relevant for classification:

Oral	LD50	11.2 mg/kg (rat)
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· 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 classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity**
May cause genetic defects.
- **Carcinogenicity**
May cause cancer.
- **Reproductive toxicity**
Suspected of damaging fertility or the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **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 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

· 12.5 Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· 12.6 Other adverse effects

No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number · ADR, IMDG, IATA	UN2811
· 14.2 UN proper shipping name · ADR · IMDG · IATA	2811 TOXIC SOLID, ORGANIC, N.O.S. (Melphalan) TOXIC SOLID, ORGANIC, N.O.S. (Melphalan) Toxic solids, organic, n.o.s. (Melphalan)
· 14.3 Transport hazard class(es) · ADR, IMDG, IATA	
	
· Class · Label	6.1 Toxic substances. 6.1
· 14.4 Packing group · ADR, IMDG, IATA	II
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user · EMS Number: · Stowage Category	Warning: Toxic substances. F-A,S-A B
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	500 g Code: E4 Maximum net quantity per inner packaging: 1 g Maximum net quantity per outer packaging: 500 g
· UN "Model Regulation":	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (MELPHALAN), 6.1, II

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 H1** ACUTE TOXIC
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 20 t
- **National regulations:**
- **Additional classification according to Decree on Hazardous Materials, Annex II:**
Carcinogenic hazardous material group I (extremely dangerous).
Carcinogenic hazardous material group II (very dangerous).

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Carcinogenic hazardous material group III (dangerous).

· **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

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS:** *Product safety department*

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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. 2: Acute toxicity, Hazard Category 2

Acute Tox. 1: Acute toxicity, Hazard Category 1

Muta. 1A: Germ cell mutagenicity, Hazard Category 1A

Carc. 1A: Carcinogenicity, Hazard Category 1A

Repr. 2: Reproductive toxicity, Hazard Category 2

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