

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.04.2019

Revision: 22.04.2019

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

- **1.1 Product identifier**
- **Trade name:** Cyclophosphamide Monohydrate
- **Article number:** 150749
- **CAS Number:**
6055-19-2
- **EC number:**
200-015-4
- **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 Kaisersberg
Illkirch Cedex 67402
France
tel: +33 3.88.67.54.25
www.mpbio.com
- **Further information obtainable from:** Quality Control 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. 3 H301 Toxic if swallowed.



GHS08 health hazard

Carc. 1B H350 May cause cancer.

- **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-determining components of labelling:**
Cyclophosphamide Monohydrate

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· **Hazard statements***H301 Toxic if swallowed.**H350 May cause cancer.*· **Precautionary statements***P101 If medical advice is needed, have product container or label at hand.**P102 Keep out of reach of children.**P103 Read label before use.**P280 Wear protective gloves/protective clothing/eye protection/face protection.**P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.**P321 Specific treatment (see on this label).**P330 Rinse mouth.**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**

6055-19-2 Cyclophosphamide Monohydrate

· **Identification number(s)**· **EC number:** 200-015-4**SECTION 4: First aid measures**· **4.1 Description of first aid measures**· **General information:***Immediately remove any clothing soiled by the product.**In case of irregular breathing or respiratory arrest provide artificial respiration.*· **After inhalation:** *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:** *Use fire extinguishing methods suitable to surrounding conditions.*· **5.2 Special hazards arising from the substance or mixture** *No further relevant information available.*· **5.3 Advice for firefighters**· **Protective equipment:** *No special measures required.***SECTION 6: Accidental release measures**· **6.1 Personal precautions, protective equipment and emergency procedures** *Not required.*

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- **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 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:** 2-8°C
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Further information about storage conditions:**
- **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.
- **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: White

- **Odour:** Indeterminate

- **Odour threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Product is not flammable.

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Not determined.

- **Explosive properties:** 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:** -

Not determined.
Insoluble.

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

- **Viscosity:**

Dynamic: Not applicable.

Kinematic: Not applicable.

Solids content: 100.0 %

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· 9.2 Other information

No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **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.
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:**
Toxic if swallowed.

· LD/LC50 values relevant for classification:**ATE (Acute Toxicity Estimates)**

Oral	LD50	94 mg/kg (rat)
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Oral	LD50	94 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** Based on available data, the classification criteria are not met.
- **Carcinogenicity**
May cause cancer.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **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 3 (German Regulation) (Self-assessment): 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.

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

SECTION 14: Transport information

- | | |
|--|--|
| · 14.1 UN-Number | UN3464 |
| · ADR, IMDG, IATA | |
| · 14.2 UN proper shipping name | 3464 ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S. (Cyclophosphamide Monohydrate) |
| · ADR | |
| · IMDG, IATA | ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S. (Cyclophosphamide Monohydrate) |
| · 14.3 Transport hazard class(es) | |
| · ADR, IMDG, IATA | |
| |  |
| · Class | 6.1 Toxic substances. |
| · Label | 6.1 |
| · 14.4 Packing group | III |
| · ADR, IMDG, IATA | |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Warning: Toxic substances. |
| · 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 |

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· Tunnel restriction code	E
· IMDG	
· 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
· UN "Model Regulation":	UN 3464 ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S. (CYCLOPHOSPHAMIDE MONOHYDRATE), 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:**
- **Additional classification according to Decree on Hazardous Materials, Annex II:**
Carcinogenic hazardous material group I (extremely dangerous).
Carcinogenic hazardous material group II (very dangerous).
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 SDS:** Quality Control Dept.
- **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. 3: Acute toxicity – Category 3
Carc. 1B: Carcinogenicity – Category 1B