

Cyclophosphamide monohydrate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier

Product form : Substance
Substance name : Cyclophosphamide monohydrate
Product code : 201600245

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

1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.
Use of the substance/mixture : For professional use only
Function or use category : Laboratory chemicals

1.2.2. Uses advised against

Restrictions on use : Do not use : Ingestion, Inhalation, Dermal

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe 7, Allée Kastner, CS30026
F- 67081 Strasbourg
France
T +33(0)388412035 - F +33(0)388412771
sds@edqm.eu - www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 3	H301
Germ cell mutagenicity, Category 1A	H340
Carcinogenicity, Category 1A	H350
Reproductive toxicity, Category 1A	H360FD
Reproductive toxicity, Additional category, Effects on or via lactation	H362
Specific target organ toxicity – Repeated exposure, Category 1	H372

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

Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS06

GHS08

Signal word (CLP) : Danger
Hazard statements (CLP) : H301 - Toxic if swallowed.
H340 - May cause genetic defects.
H350 - May cause cancer.
H360FD - May damage fertility. May damage the unborn child.

Cyclophosphamide monohydrate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Precautionary statements (CLP)

- H362 - May cause harm to breast-fed children.
H372 - Causes damage to organs through prolonged or repeated exposure.
- : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P263 - Avoid contact during pregnancy and while nursing.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P314 - Get medical advice/attention if you feel unwell.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P330 - Rinse mouth.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP)



GHS06

GHS08

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Cyclophosphamide monohydrate	-	≤ 100	Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) Muta. 1A, H340 Carc. 1A, H350 Repr. 1A, H360FD Lact., H362 STOT RE 1, H372

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

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Move to fresh air. Allow affected person to breathe fresh air.
- First-aid measures after skin contact : Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent.
- First-aid measures after eye contact : Rinse with water while holding the eyes wide open.
- First-aid measures after ingestion : Rinse mouth. Immediately call a POISON CENTER/doctor. Specific medical surveillance. Prolonged medical observation may be indicated.

Cyclophosphamide monohydrate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

Symptoms/effects	: Delayed adverse effects possible.
Symptoms/effects after inhalation	: Insufficient data available.
Symptoms/effects after skin contact	: Insufficient data available.
Symptoms/effects after eye contact	: Insufficient data available.
Symptoms/effects after ingestion	: Symptoms may include dizziness, headache, nausea and loss of coordination.

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

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active substance. Pharmaceutical.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Extinguishing blanket.

5.2. Special hazards arising from the substance or mixture

Fire hazard : See Heading 2.2.

5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.

6.1.1. For non-emergency personnel

Emergency procedures : Wear suitable protective clothing, gloves and eye or face protection.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with : Sodium hypochlorite solution.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.

Precautions for safe handling : Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.

Storage conditions : Store locked up.

Cyclophosphamide monohydrate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses. DIN EN 166

8.2.2.2. Skin protection

Skin and body protection:

Use chemically protective clothing. DIN EN 13034

Hand protection:

Chemically resistant protective gloves. ISO 374-1

8.2.2.3. Respiratory protection

Respiratory protection:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Not available
Appearance	: Powder.
Odour	: Not applicable.
Odour threshold	: Not available
Melting point	: Not available

Cyclophosphamide monohydrate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 33,3 – 100 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Toxic if swallowed.
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)
Additional information	: Expert judgement and weight of evidence determination

Cyclophosphamide monohydrate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Cyclophosphamide monohydrate

LD50 oral rat

50 – 300

Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: May cause genetic defects.
Carcinogenicity	: May cause cancer.
Reproductive toxicity	: May damage fertility. May damage the unborn child. May cause harm to breast-fed children.
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Technical impossibility to obtain the data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Hazardous waste. Use suitable disposal containers.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Lack of data)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Lack of data)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: Dispose in a safe manner in accordance with local/national regulations.
Product/Packaging disposal recommendations	: Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.




SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

Cyclophosphamide monohydrate

Safety Data Sheet

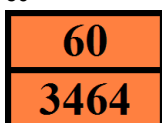
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 3464	UN 3464	UN 3464
14.2. UN proper shipping name		
ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S.	ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S.	Organophosphorus compound, solid, toxic, n.o.s.
Transport document description		
UN 3464 ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S., 6.1, III, (E)	UN 3464 ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S., 6.1, III	UN 3464 Organophosphorus compound, solid, toxic, n.o.s., 6.1, III
14.3. Transport hazard class(es)		
6.1	6.1	6.1
		
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR) : T2
Special provisions (ADR) : 43, 274
Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P002, IBC08, LP02, R001
Special packing provisions (ADR) : B3
Mixed packing provisions (ADR) : MP10
Portable tank and bulk container instructions (ADR) : T1
Portable tank and bulk container special provisions (ADR) : TP33
Tank code (ADR) : SGAH, L4BH
Tank special provisions (ADR) : TU15, TE19
Vehicle for tank carriage : AT
Transport category (ADR) : 2
Special provisions for carriage - Bulk (ADR) : VC1, VC2, AP7
Special provisions for carriage - Loading, unloading and handling (ADR) : CV13, CV28
Special provisions for carriage - Operation (ADR) : S9
Hazard identification number (Kemler No.) : 60
Orange plates :



Tunnel restriction code (ADR) : E

Transport by sea

Special provisions (IMDG) : 43, 223, 274

Cyclophosphamide monohydrate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: P002, LP02
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: T1
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-A
Stowage category (IMDG)	: A
Properties and observations (IMDG)	: Toxic if swallowed, by skin contact or by inhalation.

Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y645
PCA limited quantity max net quantity (IATA)	: 10kg
PCA packing instructions (IATA)	: 670
PCA max net quantity (IATA)	: 100kg
CAO packing instructions (IATA)	: 677
CAO max net quantity (IATA)	: 200kg
Special provisions (IATA)	: A3, A5, A6
ERG code (IATA)	: 6L

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

Cyclophosphamide monohydrate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 16: Other information

Indication of changes:

Classification of the substance or mixture.

Full text of H- and EUH-statements:	
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Carc. 1A	Carcinogenicity, Category 1A
H301	Toxic if swallowed.
H340	May cause genetic defects.
H350	May cause cancer.
H360FD	May damage fertility. May damage the unborn child.
H362	May cause harm to breast-fed children.
H372	Causes damage to organs through prolonged or repeated exposure.
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation
Muta. 1A	Germ cell mutagenicity, Category 1A
Repr. 1A	Reproductive toxicity, Category 1A
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.