

CYCLOPHOSPHAMIDE

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

1.1. Product identifier

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

Use of the substance/mixture

Finished medicinal product

1.3. Details of the supplier of the safety data sheet

Company name: SANDOZ Oncology Injectables
EBEWE Pharma Ges.m.b.H. Nfg.KG

Street: Mondseestrasse 11

Place: A-4866 Unterach

Telephone: +43 7665 8123 0

Telefax: +43 7665 8123 11

e-mail: ask.oncology@sandoz.com

Responsible for the safety data sheet: sds@gbk-ingelheim.de

Emergency CONTACT (24-Hour-Number)

GBK/Infotrac ID 103736: (USA domestic) 1 800 535 5053 or international (001)
352 323 3500

1.4. Emergency telephone number: +49 (0) 6132 / 84463 (GBK GmbH)

Further Information

As a drug, the product does not need to be labelled.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Indications of danger: C2 - Carc. Cat. 2, M2 - Muta. Cat. 2, R2 - Repr. Cat. 2, T - Toxic

R phrases:

May cause cancer.

May cause heritable genetic damage.

May cause harm to the unborn child.

Toxic if swallowed.

GHS classification

Hazard categories:

Carcinogenicity: Carc. 1B

Germ cell mutagenicity: Muta. 1B

Reproductive toxicity: Repr. 1B

Acute toxicity: Acute Tox. 3

Hazard Statements:

Toxic if swallowed.

May cause genetic defects.

May cause cancer.

May damage fertility or the unborn child.

2.2. Label elements

Hazardous components which must be listed on the label

Cyclophosphamide / (RS)-N,N-bis(2-chloroethyl)-1,3,2-oxazaphosphinan-2-amine 2-oxide

Signal word: Danger

Pictograms: GHS06-GHS08



Hazard statements

H301 Toxic if swallowed.

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H340 May cause genetic defects.
H350 May cause cancer.
H360 May damage fertility or the unborn child.

Precautionary statements

P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.

Additional advice on labelling

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

2.3. Other hazards

May be absorbed through the skin.

SECTION 3: Composition/information on ingredients

3.1. Substances

Chemical characterization

Antineoplastic agent for treating cancer. Immunosuppressant. Cytotoxic agent.

Sum formula: C₇H₁₇Cl₂N₂O₃P

Molecular weight: 279,10 g/mol

Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification	
Index No	GHS classification	
REACH No		
200-015-4	Cyclophosphamide / (RS)-N,N-bis(2-chloroethyl)-1,3,2-oxazaphosphinan-2-amine 2-oxide	
6055-19-2	Carc. Cat. 2, Muta. Cat. 2, Repr. Cat. 2, T - Toxic R45-46-61-25	100 %
	Carc. 1B, Muta. 1B, Repr. 1B, Acute Tox. 3; H350 H340 H360 H301	

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated soaked clothing immediately and dispose of safely.

Take away from danger area and lay down affected person.

If you feel unwell, seek medical advice.

After inhalation

In case of inhalation of mist seek medical advice. Information on label instructions.

Remove the casualty into fresh air and keep him immobile.

Medical treatment.

After contact with skin

May be absorbed through the skin.

Wash off immediately with soap and plenty of water. Call a physician immediately.

After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Seek medical treatment by eye specialist.

After ingestion

Causes damage to organs (CNS, Blood) if swallowed. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical treatment immediately.

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

Causes damage to organs through prolonged or repeated exposure. Causes serious eye damage. Harmful if swallowed.

Ingestion causes irritation of upper respiratory system and gastrointestinal disturbance. Prolonged skin contact may cause skin

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irritation and/or dermatitis. May cause liver injury and blood disorders.

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

See patient package insert in shipping carton for complete information.

This product is a cytostatic. In case of therapeutical use of the product, typical side effects are: Heart rhythm disturbances, Vomiting, Nausea.

Administration of activated charcoal.

Treat symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, dry chemical, carbon dioxide (CO₂), water-spray.

Fire-extinguishing activities according to surrounding.

Unsuitable extinguishing media

Full water jet.

5.2. Special hazards arising from the substance or mixture

In case of fire formation of dangerous gases possible.

Fire may produce: Carbon monoxide (CO), carbon dioxide (CO₂) and nitrogen oxides (NO_x).

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective suit.

Additional information

Cool containers at risk with water spray jet.

Collect contaminated firefighting water separately, must not be discharged into the drains.

Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Get unprotected persons to safety. Do not breathe vapours. Use personal protective clothing. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Keep away sources of ignition.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/ground water.

6.3. Methods and material for containment and cleaning up

Pick up mechanically, avoiding dust, and provide disposal in suitable recipients. Contaminated objects and floor clean thoroughly by consideration of environment regulations.

Wear complete protection equipment (P3-mask, safety goggles, protective gloves) when cleaning the area.

6.4. Reference to other sections

Observe protective instructions (see Sections 7 and 8).

Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid the formation and deposition of dust. Allow for sucking off.

Handle and open container with care.

Use personal protective clothing.

Advice on protection against fire and explosion

No specific precautions required.

Further information on handling

Take the usual precautions when handling with chemicals. At work do not eat, drink and smoke.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep only in original container. Keep container tightly closed in a dry, cool and well-ventilated place.

Store in a cool and shaded area.

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Advice on storage compatibility

Do not store together with oxidizing agents. Do not store with acids or alkalis.
Keep away from food, drink and animal feeding stuffs.

Further information on storage conditions

Protect against direct sun radiation.
Keep away from heat.

7.3. Specific end use(s)

Finished medicinal product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

Avoid explosion - before application obtain special instructions.
Handling should only be allowed by trained Personnel.

8.2. Exposure controls

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.
Avoid the formation and deposition of dust.
Provide emergency shower.
Provide eye bath.

Protective and hygiene measures

Wash hands before breaks and immediately after handling the product.
When using, do not eat, drink or smoke.
Avoid contact with skin, eyes and clothing.
Take off immediately all contaminated clothing.

Eye/face protection

Tightly fitting goggles (EN 166).

Hand protection

Chemical-resistant gloves (EN 374). (Latex gloves.)
Follow the recommendations of the glove manufacturer for breakthrough properties especially for workplace conditions involving mechanical stress and contact duration.

Skin protection

Protective suit.

Respiratory protection

No special protection is necessary when the product is handled inside a safety cabinet or an isolator.
Not required; except in case of aerosol formation.
Short term: filter apparatus, Filter P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Crystalline powder
Colour:	Whitish
Odour:	Almost odourless
pH-Value:	3,9 - 7,1
Melting point:	No data available.
Initial boiling point and boiling range:	48 - 51 °C
Softening point:	No data available.
Pour point:	No data available.
Flash point:	No data available.
Lower explosion limits:	No data available.
Upper explosion limits:	No data available.
Vapour pressure: (at 20 °C)	No data available.



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Density (at 20 °C):	No data available.
Water solubility: (at 20 °C)	Soluble
Solubility in other solvents:	Soluble in alcohols
Partition coefficient:	0,6 (20°C)
Ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity / dynamic:	No data available.
Viscosity / kinematic:	No data available.
Explosive properties:	No data available.

9.2. Other information

No data available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored and applied as directed.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Stable under normal conditions.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat. Sensitive to light.

10.5. Incompatible materials

Strong oxidizing agents. Strong acids and strong bases..

10.6. Hazardous decomposition products

No decomposition if stored and applied as directed.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicokinetics, metabolism and distribution

Cytotoxic agent.

The route of exposure: inhalation, ingestion.

Acute toxicity

Cyclophosphamide / (RS)-N,N-bis(2-chloroethyl)-1,3,2-oxazaphosphinan-2-amine 2-oxide:

LD50/oral/rat: 94 mg/kg

LDLo/oral/mouse: 350 mg/kg

LDLo/oral/dog: 44 mg/kg

LD50/intravenous/Guinea pig : 400 mg/kg

LD50/intravenous/mouse: 275 mg/kg

LD50/intravenous/Rabbit: 130 mg/kg

LD50/intravenous/dog : 40 mg/kg

LD50/intraperitoneal/Rat: 121 mg/kg

Irritation and corrosivity

Causes serious eye damage.

Ingestion causes irritation of upper respiratory system and gastrointestinal disturbance.

Prolonged skin contact may cause skin irritation and/or dermatitis.

May cause liver injury and blood disorders.

Severe effects after repeated or prolonged exposure

Causes damage to organs through prolonged or repeated exposure.

Harmful if swallowed.

May be absorbed through the skin.

Carcinogenic/mutagenic/toxic effects for reproduction

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Carcinogenicity: 1B
Mutagenicity: 1B
Reproductive toxicity: 1B

Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

SECTION 12: Ecological information

12.1. Toxicity

Do not discharge into the drains/surface waters/ground water.

12.2. Persistence and degradability

Not readily biodegradable. (28 days < 1%, OECD 301E)

12.3. Bioaccumulative potential

Low potential to bioaccumulation.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

ÖNORM S 2104 (BGBl II, Nr. 262, 21.07.2008): SN 53510 g 77

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

Waste disposal number of waste from residues/unused products

180108 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care); wastes from natal care, diagnosis, treatment or prevention of disease in humans; cytotoxic and cytostatic medicines
Classified as hazardous waste.

Contaminated packaging

ÖNORM S 2100: SN 53502

Empty containers should be taken for local recycling, recovery or waste disposal.

Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.

Packaging that cannot be cleaned should be disposed of like the product.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:

UN 3249

14.2. UN proper shipping name:

MEDICINE, SOLID, TOXIC, N.O.S.

14.3. Transport hazard class(es):

6.1

14.4. Packing group:

III

Hazard label:

6.1



Classification code:

T2

Special Provisions:

221 601

Limited quantity:

5 kg

Transport category:

2

Hazard No:

60

Tunnel restriction code:

E

Other applicable information (land transport)

SP 601: Pharmaceutical products (medicines) ready for use, which are substances manufactured and

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packaged for retail sale or distribution for personal or household consumption are not subject to the requirements of ADR/RID.

Inland waterways transport (ADN)

14.1. UN number:	UN 3249
14.2. UN proper shipping name:	MEDICINE, SOLID, TOXIC, N.O.S.
14.3. Transport hazard class(es):	6.1
14.4. Packing group:	III
Hazard label:	6.1



Classification code:	T2
Special Provisions:	221 601 802
Limited quantity:	5 kg

Other applicable information (inland waterways transport)

SP 601: Pharmaceutical products (medicines) ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption are not subject to the requirements of ADN.

Marine transport (IMDG)

14.1. UN number:	UN 3249
14.2. UN proper shipping name:	MEDICINE, SOLID, TOXIC, N.O.S.
14.3. Transport hazard class(es):	6.1
14.4. Packing group:	III
Hazard label:	6.1



Special Provisions:	221, 223
Limited quantity:	5 kg
EmS:	F-A, S-A

Air transport (ICAO)

14.1. UN number:	ID8000
14.2. UN proper shipping name:	CONSUMER COMMODITY - Containers, empty or re-used, not containing dangerous goods residue
14.3. Transport hazard class(es):	9
14.4. Packing group:	-
Hazard label:	9



Special Provisions:	A112
Limited quantity Passenger:	30 kg G
IATA-packing instructions - Passenger:	Y963
IATA-max. quantity - Passenger:	30 kg G
IATA-packing instructions - Cargo:	Y963
IATA-max. quantity - Cargo:	30 kg G

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

Handle in accordance with good industrial hygiene and safety practices.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

The transport takes place only in approved and appropriate packaging.

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SECTION 15: Regulatory information

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

EU regulatory information

Additional information

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

National regulatory information

Employment restrictions: Observe employment restrictions for young people. Observe employment restrictions for child bearing mothers and nursing. Observe employment restrictions for women of child-bearing age.

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

IMDG = International Maritime Code for Dangerous Goods

IATA/ICAO = International Air Transport Association / International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

IBC = Code International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH = Registration, Evaluation, Authorization and Restriction of Chemicals

CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization

DIN = Deutsche Industrie Norm

PBT = Persistent Bioaccumulative and Toxic

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

Relevant R-phrases (Number and full text)

- | | |
|----|-------------------------------------|
| 25 | Toxic if swallowed. |
| 45 | May cause cancer. |
| 46 | May cause heritable genetic damage. |
| 61 | May cause harm to the unborn child. |

Relevant H- and EUH-phrases (Number and full text)

- | | |
|------|-------------------------------------------|
| H301 | Toxic if swallowed. |
| H340 | May cause genetic defects. |
| H350 | May cause cancer. |
| H360 | May damage fertility or the unborn child. |

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

(n.a. = not applicable; n.d. = not determined)