

Cyclophosphamide Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Cyclophosphamide Injection
Other means of identification : 500 mg per 2.5 mL vial, carton of 1 NDC 55150-270-99
1 g per 5 mL vial, carton of 1 NDC 55150-271-99
2 g per 10 mL vial, carton of 1 NDC 55150-272-01

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Eugia US LLC
279 Princeton Hightstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Flam. Liq. 3 H226
Acute Tox. 4 (Oral) H302
Muta. 1B H340
Carc. 1A H350
Repr. 1B H360

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

H226 - Flammable liquid and vapor
H302 - Harmful if swallowed
H340 - May cause genetic defects
H350 - May cause cancer
H360 - May damage fertility or the unborn child

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed.
P240 - Ground/Bond container and receiving equipment.
P241 - Use explosion-proof electrical/ventilating/lighting equipment.
P242 - Use only non-sparking tools.
P243 - Take precautionary measures against static discharge.
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.
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.
P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P330 - Rinse mouth.
P370+P378 - In case of fire: Use media other than water to extinguish.
P403+P235 - Store in a well-ventilated place. Keep cool.

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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.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | % | GHS US classification |
|------------------------------|---------------------|-----|---|
| Ethyl alcohol | (CAS-No.) 64-17-5 | 76 | Flam. Liq. 2, H225 Carc. 1A, H350 |
| Cyclophosphamide monohydrate | (CAS-No.) 6055-19-2 | 20 | Acute Tox. 3 (Oral), H301 Muta. 1B, H340 Carc. 1A, H350 Repr. 1B, H360 |
| Citric acid | (CAS-No.) 77-92-9 | 0.4 | Eye Irrit. 2A, H319 |

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

First-aid measures after skin contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention.

First-aid measures after eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

First-aid measures after ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

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

Symptoms/effects after inhalation : May be irritating to respiratory system.

Symptoms/effects after skin contact : May cause skin irritation.

Symptoms/effects after eye contact : May cause eye irritation.

Symptoms/effects after ingestion : Harmful if swallowed.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Protection during firefighting : Firefighters should wear full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

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6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not ingest. Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store vials at 2° - 8° C (36° - 46° F).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Cyclophosphamide monohydrate (6055-19-2)

Not applicable

Citric acid (77-92-9)

Not applicable

Ethyl alcohol (64-17-5)

| | | |
|-------|-----------------|------------------------|
| ACGIH | ACGIH OEL STEL | 1000 ppm |
| OSHA | OSHA PEL TWA | 1900 mg/m ³ |
| OSHA | OSHA PEL TWA | 1000 ppm |
| IDLH | IDLH | 3300 ppm (10% LEL) |
| NIOSH | NIOSH REL (TWA) | 1900 mg/m ³ |
| NIOSH | NIOSH REL (TWA) | 1000 ppm |

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : Use latex or rubber gloves.
Eye protection : None required under normal product handling conditions.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Color : Slightly yellow
Odor : Odorless
Odor threshold : No data available
pH : No data available
Melting point : No data available
Freezing point : No data available
Boiling point : No data available
Flash point : < 40 °C
Relative evaporation rate (butyl acetate=1) : No data available
Flammability : No data available
Vapor pressure : No data available
Relative vapor density at 20°C : No data available
Relative density : No data available

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| | |
|---|---------------------|
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosion limits | : No data available |
| Explosive properties | : No data available |
| Oxidizing properties | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

| Cyclophosphamide Injection | |
|--|------------------------|
| ATE US (oral) | 500 mg/kg body weight |
| Cyclophosphamide monohydrate (6055-19-2) | |
| ATE US (oral) | 100 mg/kg body weight |
| Citric acid (77-92-9) | |
| LD50 oral rat | 3 g/kg |
| ATE US (oral) | 3000 mg/kg body weight |
| Ethyl alcohol (64-17-5) | |
| LD50 oral rat | 7060 mg/kg |
| LC50 Inhalation - Rat | 124.7 mg/l/4h |
| ATE US (oral) | 7060 mg/kg |

| | |
|-----------------------------------|---|
| Skin corrosion/irritation | : Not classified |
| Serious eye damage/irritation | : Not classified |
| Respiratory or skin sensitization | : Not classified |
| Germ cell mutagenicity | : May cause genetic defects. |
| Carcinogenicity | : May cause cancer. |
| Reproductive toxicity | : May damage fertility or the unborn child. |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |

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SECTION 12: Ecological information

12.1. Toxicity

| Citric acid (77-92-9) | |
|-------------------------|--|
| LC50 - Fish [1] | 1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static]) |
| Ethyl alcohol (64-17-5) | |
| LC50 - Fish [1] | 12 – 16 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |
| EC50 - Crustacea [1] | 9268 – 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna) |
| LC50 - Fish [2] | > 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static]) |
| EC50 - Crustacea [2] | 2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static]) |

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

| Citric acid (77-92-9) | |
|---|------------------|
| Partition coefficient n-octanol/water (Log Pow) | -1.72 (at 20 °C) |
| Ethyl alcohol (64-17-5) | |
| Partition coefficient n-octanol/water (Log Pow) | -0.32 |

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Transport document description (DOT) : UN3248 Medicine, liquid, flammable, toxic, n.o.s., 3 (6.1), III

UN-No.(DOT) : UN3248

Proper Shipping Name (DOT) : Medicine, liquid, flammable, toxic, n.o.s.

Class (DOT) : 3 - Class 3 - Flammable and combustible liquid 49 CFR 173.120

Packing group (DOT) : III - Minor Danger

Subsidiary risk (DOT) : 6.1 - Class 6.1 - Poisonous materials 49 CFR 173.132

Hazard labels (DOT) : 3 - Flammable liquid
6.1 - Poison



DOT Packaging Non Bulk (49 CFR 173.xxx) : 203

DOT Packaging Bulk (49 CFR 173.xxx) : 242

DOT Special Provisions (49 CFR 172.102) : IB3 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1 and 31HA2, 31HB2, 31HN2, 31HD2 and 31HH2). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized, except for UN2672 (also see Special Provision IP8 in Table 2 for UN2672).

DOT Packaging Exceptions (49 CFR 173.xxx) : 150

DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 60 L

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DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : 220 L

DOT Vessel Stowage Location : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.

Emergency Response Guide (ERG) Number : 131

Other information : No supplementary information available.

International Air Transport Association (IATA)

In accordance with IATA

UN-No. (IATA) : 3248

Proper Shipping Name (IATA) : Medicine, liquid, flammable, toxic, n.o.s.

Class (IATA) : 3 - Flammable Liquids

Packing group (IATA) : III - Low danger

Subsidiary hazards (IATA) : 6.1 - Toxic Substances

SECTION 15: Regulatory information

15.1. US Federal regulations

Citric acid (77-92-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Ethyl alcohol (64-17-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Ethyl alcohol (64-17-5)

| U.S. - California - Proposition 65 - Carcinogens List | U.S. - California - Proposition 65 - Developmental Toxicity | U.S. - California - Proposition 65 - Reproductive Toxicity - Female | U.S. - California - Proposition 65 - Reproductive Toxicity - Male | No significant risk level (NSRL) |
|---|---|---|---|----------------------------------|
| Yes | Yes | No | No | |

Ethyl alcohol (64-17-5)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

| | |
|---------------------|---|
| Acute Tox. 3 (Oral) | Acute toxicity (oral) Category 3 |
| Acute Tox. 4 (Oral) | Acute toxicity (oral) Category 4 |
| Carc. 1A | Carcinogenicity Category 1A |
| Eye Irrit. 2A | Serious eye damage/eye irritation Category 2A |
| Flam. Liq. 2 | Flammable liquids Category 2 |
| Flam. Liq. 3 | Flammable liquids Category 3 |
| Muta. 1B | Germ cell mutagenicity Category 1B |
| Repr. 1B | Reproductive toxicity Category 1B |
| H225 | Highly flammable liquid and vapor |
| H226 | Flammable liquid and vapor |
| H301 | Toxic if swallowed |
| H302 | Harmful if swallowed |
| H319 | Causes serious eye irritation |
| H340 | May cause genetic defects |
| H350 | May cause cancer |
| H360 | May damage fertility or the unborn child |

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.