

### 1. Identification

<b>Product identifier</b>	<b>Cyclophosphamide Capsules</b>
<b>Other means of identification</b>	
<b>Product code</b>	25 mg capsule, imprinted with "54 006" on cap and body, 50 mg capsule, imprinted with "54 881" on cap and body
<b>Recommended use</b>	Treatment of symptoms of malignant diseases
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company name</b>	Hikma Pharmaceuticals USA Inc.
<b>Address</b>	1809 Wilson Road Columbus, Ohio 43228
<b>Telephone</b>	(614) 276-4000
<b>Emergency phone number</b>	CHEMTREC, U.S.: 1-800-424-9300 International: +1-703-527-3887 24/7

### 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Carcinogenicity	Category 1A
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		
<b>Hazard symbol</b>	None.	
<b>Signal word</b>	Warning	
<b>Hazard statement</b>	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Observe good industrial hygiene practices.	
<b>Response</b>	Wash hands after handling.	
<b>Storage</b>	Store at 20 – 25 °C (68 - 77°F).	
<b>Disposal</b>	Incineration of waste at an approved USEPA incinerator is recommended.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.	

### 3. Composition/information on ingredients

#### Substances

Chemical name	Common name and synonyms	CAS number	%
2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate		50-18-0	25 - 50mg

### 4. First-aid measures

<b>Inhalation</b>	If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

<b>Most important symptoms/effects, acute and delayed</b>	Exposed individuals may experience vomiting, nausea, and diarrhea.
<b>Indication of immediate medical attention and special treatment needed</b>	Overdosage should be managed with supportive measures, including appropriate treatment for any concurrent infection, myelosuppression, or cardiac toxicity should it occur. No specific antidote is known. Treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).
<b>Methods and materials for containment and cleaning up</b>	Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended. Cyclophosphamide is a USEPA listed waste and is assigned a USEPA waste code of U058.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.
<b>Conditions for safe storage, including any incompatibilities</b>	Store away from incompatible materials (see Section 10 of the SDS). Store at 20 – 25 °C (68 - 77°F). This is an antineoplastic product. Follow special handling and disposal procedures

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Ventilation should be matched to conditions.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.
<b>Skin protection</b>	
<b>Hand protection</b>	For consumer use, no unusual precautions are necessary.
<b>Other</b>	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

**Respiratory protection** None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

**Appearance** Blue opaque capsules

**Physical state** Solid.

**Form** Capsule.

**Color** Blue

**Odor** None.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** 393.8 - 397.4 °F (201 - 203 °C)

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Explosive limit - lower (%)** Not available.

**Explosive limit - upper (%)** Not available.

**Vapor pressure** Not available.

**Vapor density** Not available.

**Relative density** Not available.

**Solubility(ies)**

**Solubility (water)** Very soluble

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

## 10. Stability and reactivity

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.
<b>Skin contact</b>	Not expected to be hazardous in final pharmaceutical form. Dust may irritate skin.
<b>Eye contact</b>	Not expected to be hazardous in final pharmaceutical form. Dust may irritate the eyes.
<b>Ingestion</b>	Ingestion may cause irritation and malaise.

**Symptoms related to the physical, chemical and toxicological characteristics** Exposed individuals may experience vomiting, nausea, and diarrhea.

### Information on toxicological effects

<b>Acute toxicity</b>	Not expected to be acutely toxic.
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.
<b>Serious eye damage/eye irritation</b>	Dust may irritate the eyes.

### Respiratory or skin sensitization

<b>Respiratory sensitization</b>	Not a respiratory sensitizer.
<b>Skin sensitization</b>	Skin rash occurs occasionally in patients receiving the drug. Pigmentation of the skin and changes in nails can occur

**Germ cell mutagenicity** Mutagenic and clastogenic in multiple in vitro and in vivo genetic toxicology studies.

**Carcinogenicity** Possible cancer hazard based on tests with laboratory animals.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate (CAS 50-18-0) 1 Carcinogenic to humans.

#### NTP Report on Carcinogens

2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate (CAS 50-18-0) Known To Be Human Carcinogen.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

**Reproductive toxicity** This product has been rated Pregnancy Category D-POSITIVE EVIDENCE OR RISK, There is a risk to fetus after drug is administered, but under certain circumstances (e.g., treatment of life threatening illnesses) the benefits can outweigh the risk. Animal reproduction studies have not been conducted with product  
Exposure during pregnancy may cause birth defects, miscarriage, fetal growth retardation, and fetotoxic effects in the newborn  
Drug is present in breast milk. A decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - repeated exposure** Not classified.

**Aspiration hazard** Due to the physical form of the product it is not an aspiration hazard.

**Further information** See package insert.

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

#### Partition coefficient n-octanol / water (log Kow)

2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate (CAS 50-18-0) 0.63

**Mobility in soil** No data available.

**Other adverse effects** None.

## 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	Cyclophosphamide is a USEPA listed waste and is assigned a USEPA waste code of U058.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.

## 15. Regulatory information

<b>US federal regulations</b>	This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.
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### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

### CERCLA Hazardous Substance List (40 CFR 302.4)

2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate (CAS 50-18-0) LISTED

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - No Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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### SARA 302 Extremely hazardous substance

Not listed.

<b>SARA 311/312 Hazardous chemical</b>	No
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### SARA 313 (TRI reporting)

Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

<b>Safe Drinking Water Act (SDWA)</b>	Not regulated.
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Not listed.

### US state regulations

#### US. Massachusetts RTK - Substance List

2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate (CAS 50-18-0)

#### US. New Jersey Worker and Community Right-to-Know Act

Not listed.

#### US. Pennsylvania Worker and Community Right-to-Know Law

2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate (CAS 50-18-0)

**US. Rhode Island RTK**

2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate (CAS 50-18-0)

**US. California Proposition 65**

WARNING: This product contains a chemical known to the State of California to cause cancer.

**US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance**

2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate (CAS 50-18-0)

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

<b>Revision date</b>	15-October-2018
<b>Version #</b>	2
<b>References</b>	1) Cyclophosphamide Capsules, 30mg, Package Insert, Hikma Pharmaceuticals USA Inc., Columbus, Ohio. 2) PDR – Physicians Desk Reference. 3) Ariel Webinsight. Regulatory and ChemExpert Database.

<b>Disclaimer</b>	Hikma Pharmaceuticals USA Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.
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