

Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml (200mg/ml)/Cyclophosphamide Injection 500mg/2.5ml (200mg/ml)

Dr.Reddy's Laboratories Limited

Chemwatch: 5681-67

Version No: 3.1

Safety Data Sheet according to OSHA HazCom Standard (2012) requirements

Chemwatch Hazard Alert Code: 4

Issue Date: 17/06/2024

Print Date: 18/06/2024

L.GHS.USA.EN

SECTION 1 Identification

Product Identifier

Product name	Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml (200mg/ml)/Cyclophosphamide Injection 500mg/2.5ml (200mg/ml)
Chemical Name	Not Applicable
Synonyms	Not Available
Proper shipping name	Flammable liquids, n.o.s. (contains ethanol)
Chemical formula	Not Applicable
Other means of identification	Not Available

Recommended use of the chemical and restrictions on use

Relevant identified uses	Use according to manufacturer's directions.
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Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

Registered company name	Dr.Reddy's Laboratories Limited
Address	8-2-337, Road No 3, Banjara Hills, Hyderabad Telangana 500034 India
Telephone	Not Available
Fax	+91 40 4900 2999
Website	www.drreddys.com
Email	Not Available

Emergency phone number

Association / Organisation	Dr.Reddy's Laboratories Limited	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone numbers	+91 40 4900 2900	+1 855-237-5573
Other emergency telephone numbers	Not Available	+61 3 9573 3188

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SECTION 2 Hazard(s) identification

Classification of the substance or mixture

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification	Flammable Liquids Category 2, Acute Toxicity (Oral) Category 4, Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 1, Carcinogenicity Category 1A, Reproductive Toxicity Category 1B, Specific Target Organ Toxicity - Repeated Exposure Category 1
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Label elements

**Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml
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Hazard pictogram(s)	   
Signal word	Danger

Hazard statement(s)

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H350	May cause cancer.
H360	May damage fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.

Hazard(s) not otherwise classified

Not Applicable

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P260	Do not breathe mist/vapours/spray.

Precautionary statement(s) Response

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/ attention.
P310	Immediately call a POISON CENTER/doctor/physician/first aider.
P370+P378	In case of fire: Use alcohol resistant foam or normal protein foam to extinguish.

Precautionary statement(s) Storage

P403+P235	Store in a well-ventilated place. Keep cool.
P405	Store locked up.

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
64-17-5	>60	<u>ethanol</u>
6055-19-2	10-30	<u>cyclophosphamide</u>
Not Available	balance	Ingredients determined not to be hazardous

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 First-aid measures

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: ▶ Immediately hold eyelids apart and flush the eye continuously with running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▶ Transport to hospital or doctor without delay. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: ▶ Immediately flush body and clothes with large amounts of water, using safety shower if available. ▶ Quickly remove all contaminated clothing, including footwear. ▶ Wash skin and hair with running water. Continue flushing with water until advised to stop by the Poisons Information Centre.

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	▶ Transport to hospital, or doctor.
Inhalation	▶ If fumes or combustion products are inhaled remove from contaminated area. ▶ Lay patient down. Keep warm and rested. ▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▶ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ▶ Transport to hospital, or doctor, without delay.
Ingestion	▶ If swallowed do NOT induce vomiting. ▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▶ Observe the patient carefully. ▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. ▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▶ Seek medical advice.

Most important symptoms and effects, both acute and delayed

See Section 11

Indication of any immediate medical attention and special treatment needed

For employees potentially exposed to antineoplastic and/or cytotoxic agents on a regular basis, a preplacement physical examination and history (noting risk factors) is recommended. Periodic follow-up examinations should also be undertaken and should be overseen by a physician familiar with the toxic effects of the substance and full details of the nature of work undertaken by the employee.

Following administration of antineoplastics, control of nausea and vomiting may be attempted by giving phenothiazines such as perphenazine, prochlorperazine, promethazine or thiethylperazine. In bone-marrow depression, transfusion of blood or platelets reduces the risk of life-threatening haemorrhage. Granulocyte transfusions and injection of antibiotics may be necessary to combat infection in the neutropenic patient. Hyperuricaemia is avoided by the addition of allopurinol to treatment schedules and measures such as alkalisation of the urine and hydration may be adopted. MARTINDALE: The Extra Pharmacopoeia, 28th Edition.

For acute or short term repeated exposures to ethanol:

- ▶ Acute ingestion in non-tolerant patients usually responds to supportive care with special attention to prevention of aspiration, replacement of fluid and correction of nutritional deficiencies (magnesium, thiamine pyridoxine, Vitamins C and K).
- ▶ Give 50% dextrose (50-100 ml) IV to obtunded patients following blood draw for glucose determination.
- ▶ Comatose patients should be treated with initial attention to airway, breathing, circulation and drugs of immediate importance (glucose, thiamine).
- ▶ Decontamination is probably unnecessary more than 1 hour after a single observed ingestion. Cathartics and charcoal may be given but are probably not effective in single ingestions.
- ▶ Fructose administration is contra-indicated due to side effects.

SECTION 5 Fire-fighting measures

Extinguishing media

- ▶ Alcohol stable foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Special protective equipment and precautions for fire-fighters

Fire Fighting	▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water course.
Fire/Explosion Hazard	▶ Liquid and vapour are highly flammable. ▶ Severe fire hazard when exposed to heat, flame and/or oxidisers. ▶ Vapour may travel a considerable distance to source of ignition. ▶ Heating may cause expansion or decomposition leading to violent rupture of containers. Combustion products include: carbon dioxide (CO₂) hydrogen chloride phosgene nitrogen oxides (NO_x) phosphorus oxides (PO_x) other pyrolysis products typical of burning organic material.

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	▶ Remove all ignition sources. ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. ▶ Control personal contact with the substance, by using protective equipment.
Major Spills	▶ Clean up all spills immediately. ▶ Avoid breathing dust and contact with skin and eyes.

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- ▶ Wear protective clothing, gloves, safety glasses and dust respirator.
- ▶ Wet residue with water to prevent dusting
- ▶ Sweep up, shovel up or
- ▶ Vacuum up (consider explosion-proof machines designed to be grounded during storage and use).
- ▶ Clear area of personnel and move upwind.
- ▶ Alert Fire Brigade and tell them location and nature of hazard.
- ▶ May be violently or explosively reactive.
- ▶ Wear breathing apparatus plus protective gloves.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	▶ Containers, even those that have been emptied, may contain explosive vapours. ▶ Do NOT cut, drill, grind, weld or perform similar operations on or near containers. ▶ DO NOT allow clothing wet with material to stay in contact with skin Australian Standard (AS2639) and the National Institute of Health (USA) recommends that the preparation of injectable antineoplastic drugs should be performed in a Class II laminar flow biological safety cabinet and that personnel preparing drugs of this class should wear appropriate personal protective gear. Emphasise controls on containment. ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps.
Other information	▶ Store in original containers in approved flame-proof area. ▶ No smoking, naked lights, heat or ignition sources. ▶ DO NOT store in pits, depression, basement or areas where vapours may be trapped. ▶ Keep containers securely sealed.

Conditions for safe storage, including any incompatibilities

Suitable container	▶ Glass container is suitable for laboratory quantities ▶ Packing as supplied by manufacturer. ▶ Plastic containers may only be used if approved for flammable liquid. ▶ Check that containers are clearly labelled and free from leaks. ▶ For low viscosity materials (i) : Drums and jerry cans must be of the non-removable head type. (ii) : Where a can is to be used as an inner package, the can must have a screwed enclosure. ▶ For materials with a viscosity of at least 2680 cSt. (23 deg. C) ▶ For manufactured product having a viscosity of at least 250 cSt.
Storage incompatibility	▶ Avoid strong acids, bases.

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US OSHA Permissible Exposure Limits (PELs) Table Z-1	ethanol	Ethyl alcohol (Ethanol)	1000 ppm / 1900 mg/m ³	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)	ethanol	Ethyl alcohol	1000 ppm / 1900 mg/m ³	Not Available	Not Available	Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
ethanol	Not Available	Not Available	15000* ppm

Ingredient	Original IDLH	Revised IDLH
ethanol	3,300 ppm	Not Available
cyclophosphamide	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
cyclophosphamide	E	≤ 0.01 mg/m ³
Notes:	Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.	

MATERIAL DATA

Exposure controls

Appropriate engineering controls	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk.
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	Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.
Individual protection measures, such as personal protective equipment	
Eye and face protection	▶ Chemical protective goggles with full seal. [AS/NZS 1337.1, EN166 or national equivalent] ▶ Shielded mask (gas-type). ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.
Skin protection	See Hand protection below
Hands/feet protection	▶ Elbow length PVC gloves NOTE: ▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. ▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Personal hygiene is a key element of effective hand care. ▶ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. ▶ Double gloving should be considered. ▶ PVC gloves.
Body protection	See Other protection below
Other protection	▶ Employees working with confirmed human carcinogens should be provided with, and be required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), shoe covers and gloves prior to entering the regulated area. [AS/NZS ISO 6529:2006 or national equivalent] ▶ Employees engaged in handling operations involving carcinogens should be provided with, and required to wear and use half-face filter-type respirators with filters for dusts, mists and fumes, or air purifying canisters or cartridges. A respirator affording higher levels of protection may be substituted. [AS/NZS 1715 or national equivalent] ▶ Emergency deluge showers and eyewash fountains, supplied with potable water, should be located near, within sight of, and on the same level with locations where direct exposure is likely. ▶ Prior to each exit from an area containing confirmed human carcinogens, employees should be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers must be identified with suitable labels. For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood. ▶ Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood. ▶ When handling antineoplastic materials, it is recommended that a disposable work-uniform (such as Tyvek or closed front surgical-type gown with knit cuffs) is worn. ▶ Potentially contaminated bodily fluids should be handled in accordance with local standards or codes of practice (appendix 10 of 'Cytotoxic Drugs and Related Waste' - Workcover New South Wales, HSE Information Sheet MISC615, OSHA Technical Manual (OTM) Section VI: Chapter 2) ▶ Overalls. ▶ PVC Apron. ▶ PVC protective suit may be required if exposure severe. ▶ Eyewash unit. ▶ Some plastic personal protective equipment (PPE) (e.g. gloves, aprons, overshoes) are not recommended as they may produce static electricity. ▶ For large scale or continuous use wear tight-weave non-static clothing (no metallic fasteners, cuffs or pockets). ▶ Non sparking safety or conductive footwear should be considered. Conductive footwear describes a boot or shoe with a sole made from a conductive compound chemically bound to the bottom components, for permanent control to electrically ground the foot and shall dissipate static electricity from the body to reduce the possibility of ignition of volatile compounds.

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

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Material	CPI
PE/EVAL/PE	A
BUTYL	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NITRILE	C
NITRILE+PVC	C
PVC	C

* CPI - Chemwatch Performance Index

Respiratory protection

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required.

Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 5 x ES	Air-line*	A-2 P2	A-PAPR-2 P2 ^
up to 10 x ES	-	A-3 P2	-
10+ x ES	-	Air-line**	-

* - Continuous Flow; ** - Continuous-flow or positive pressure demand

^ - Full-face

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

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A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Ansell Glove Selection

Glove — In order of recommendation

AlphaTec® Solvex® 37-185

AlphaTec® 58-008

AlphaTec® 79-700

AlphaTec® Solvex® 37-675

TouchNTuff® 83-500

DermaShield™ 73-711

MICROFLEX® 93-260

MICROFLEX® NeoPro® NPG-888

TouchNTuff® 73-500

TouchNTuff® DermaShield™ 73-701

The suggested gloves for use should be confirmed with the glove supplier.

- ▶ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- ▶ The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- ▶ Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Liquid		
Physical state	Liquid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	3-6.5	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	49-53	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	16.1	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	HIGHLY FLAMMABLE.	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

**Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml
(200mg/ml)/Cyclophosphamide Injection 500mg/2.5ml (200mg/ml)**

Inhaled	Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual. Acute effects from inhalation of high concentrations of vapour are pulmonary irritation, including coughing, with nausea; central nervous system depression - characterised by headache and dizziness, increased reaction time, fatigue and loss of co-ordination	
Ingestion	Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.	
Skin Contact	The material produces moderate skin irritation; evidence exists, or practical experience predicts, that the material either ▶ produces moderate inflammation of the skin in a substantial number of individuals following direct contact, and/or ▶ produces significant, but moderate, inflammation when applied to the healthy intact skin of animals (for up to four hours), such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.	
Eye	When applied to the eye(s) of animals, the material produces severe ocular lesions which are present twenty-four hours or more after instillation.	
Chronic	On the basis of epidemiological data, the material is regarded as carcinogenic to humans. There is sufficient data to establish a causal association between human exposure to the material and the development of cancer. There is sufficient evidence to provide a strong presumption that human exposure to the material may result in the development of heritable genetic damage, generally on the basis of - appropriate animal studies, - other relevant information Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed. Serious damage (clear functional disturbance or morphological change which may have toxicological significance) is likely to be caused by repeated or prolonged exposure. As a rule the material produces, or contains a substance which produces severe lesions. Such damage may become apparent following direct application in subchronic (90 day) toxicity studies or following sub-acute (28 day) or chronic (two-year) toxicity tests. There is sufficient evidence to provide a strong presumption that human exposure to the material may result in developmental toxicity, generally on the basis of: - clear results in appropriate animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not secondary non-specific consequences of the other toxic effects. Exposure to the material may cause concerns for human fertility, generally on the basis that results in animal studies provide sufficient evidence to cause a strong suspicion of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects, but which are not a secondary non-specific consequence of other toxic effects. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. There exists limited evidence that shows that skin contact with the material is capable either of inducing a sensitisation reaction in a significant number of individuals, and/or of producing positive response in experimental animals. Chronic exposure of workers to mustard gas has produced chronic bronchitis and cancers of the respiratory tract. The rate of detoxification is low and repeated exposures may produce significant cumulative effects. Workers exposed to mustard gas during its production between 1929 and 1945 in Japanese factory (estimated concentrations 0.005 to 0.007 mg/m³) for 7-9 years showed skin damage (blisters) and suffered from coughing and increased sputum production. Of 501 workers who were examined in 1963, 90.7% still suffered chronic bronchitis, had markedly more severe and more persistent cough with more sputum production whilst 54.8% had abnormal skin pigmentation. Long-term exposure to ethanol may result in progressive liver damage with fibrosis or may exacerbate liver injury caused by other agents. Repeated ingestion of ethanol by pregnant women may adversely affect the central nervous system of the developing foetus, producing effects collectively described as foetal alcohol syndrome. These include mental and physical retardation, learning disturbances, motor and language deficiency, behavioural disorders and reduced head size. Consumption of ethanol (in alcoholic beverages) may be linked to the development of Type I hypersensitivities in a small number of individuals. Delayed or long-term effects may result from the action of antineoplastic agents on rapidly dividing normal cells in the bone marrow, lymphoreticular tissue, gastrointestinal mucosa, skin, gonads and foetus. The most common of these is bone-marrow depression with leucopenia, anaemia, thrombocytopenia and bleeding. Immunosuppressant effects involve both antibody and cell-mediated immunity and may increase susceptibility to infection and increase the risk of haemorrhage, both potentially life-threatening. GI effects may include stomatitis, mouth ulcers, oesophagitis, abdominal pain, haemorrhage, diarrhoea and intestinal ulceration and perforation.	
Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml (200mg/ml)/Cyclophosphamide Injection 500mg/2.5ml (200mg/ml)	TOXICITY	IRRITATION
	Not Available	Not Available
ethanol	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: 17100 mg/kg ^[1]	Eye (rabbit): 500 mg SEVERE
	Inhalation (Rat) LC50: 64000 ppm4h ^[2]	Eye (rabbit):100mg/24hr-moderate
	Oral (Rat) LD50: 7060 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
		Eye: no adverse effect observed (not irritating) ^[1]
		Skin (rabbit):20 mg/24hr-moderate
cyclophosphamide	TOXICITY	IRRITATION
	Oral (Dog) LD50: 44 mg/kg ^[2]	Not Available

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Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

ETHANOL	The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling the epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.
CYCLOPHOSPHAMIDE	Somnolence, ataxia, nausea and vomiting, urine volume increase, haemorrhage, maternal effects, foetotoxicity, specific developmental abnormalities (central nervous system, musculoskeletal system, cardiovascular system, blood and lymphatic systems, hepatobiliary system), effects on newborn recorded. Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. Alkylating agents may damage the stem cell which acts as the precursor to components of the blood. Loss of the stem cell may result in pancytopenia (a reduction in the number of red and white blood cells and platelets) with a latency period corresponding to the lifetime of the individual blood cells. Granulocytopenia (a reduction in granular leukocytes) develops within days and thrombocytopenia (a disorder involving platelets), within 1-2 weeks, whilst loss of erythrocytes (red blood cells) needs months to become clinically manifest. Aplastic anaemia develops due to complete destruction of the stem cells. WARNING: This substance has been classified by the IARC as Group 1: CARCINOGENIC TO HUMANS. Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA. Tenth Annual Report on Carcinogens: Substance known to be Carcinogenic [National Toxicology Program: U.S. Dep. of Health and Human Services 2002]

Acute Toxicity	✓	Carcinogenicity	✓
Skin Irritation/Corrosion	✓	Reproductivity	✓
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✗
Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✓
Mutagenicity	✗	Aspiration Hazard	✗

Legend: ✗ – Data either not available or does not fill the criteria for classification
✓ – Data available to make classification

SECTION 12 Ecological information

Toxicity

Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml (200mg/ml)/Cyclophosphamide Injection 500mg/2.5ml (200mg/ml)	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
ethanol	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96h	Fish	42mg/L	4
	EC50(ECx)	96h	Algae or other aquatic plants	<0.001mg/L	4
	EC50	72h	Algae or other aquatic plants	275mg/l	2
	EC50	96h	Algae or other aquatic plants	<0.001mg/L	4
	EC50	48h	Crustacea	2mg/L	4
cyclophosphamide	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	336h	Fish	0.003mg/L	4

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
ethanol	LOW (Half-life = 2.17 days)	LOW (Half-life = 5.08 days)
cyclophosphamide	LOW (Half-life = 40.67 days)	LOW (Half-life = 0.16 days)

Bioaccumulative potential

Ingredient	Bioaccumulation
ethanol	LOW (LogKOW = -0.31)
cyclophosphamide	LOW (LogKOW = 0.63)

Continued...

**Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml
(200mg/ml)/Cyclophosphamide Injection 500mg/2.5ml (200mg/ml)**

Mobility in soil

Ingredient	Mobility
ethanol	HIGH (Log KOC = 1)
cyclophosphamide	LOW (Log KOC = 317.7)

SECTION 13 Disposal considerations**Waste treatment methods**

Product / Packaging disposal	- Antineoplastic (cytotoxic) wastes must be packed directly, ready for incineration, into colour-coded, secure, labelled, leak-proof containers sufficiently robust to withstand handling without breaking, bursting or leaking. - Containers of special design are available for particular needs (such as disposal of sharps) and should be used. - Once filled and closed, such containers must never be re-opened. - Immediate containers must bear a nationally accepted symbol or device depicting cytotoxic substances and be labelled with the words: CYTOTOXIC WASTE - INCINERATE in a style of lettering approved by the national/ state authority. DO NOT allow wash water from cleaning or process equipment to enter drains. - It may be necessary to collect all wash water for treatment before disposal. - In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. - Where in doubt contact the responsible authority.
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SECTION 14 Transport information**Labels Required**

Marine Pollutant	NO

Shipping container, transport vehicle placarding, and labeling may vary from the below information. This depends on the quantity shipped, the applicability of excepted quantity requirements, limited quantity requirements, and/or special provisions according to US DOT, IATA and IMDG regulations. In case of reshipment, it is the responsibility of the shipper to determine the appropriate labels and markings in accordance with applicable transport regulations.

Land transport (DOT)

14.1. UN number or ID number	1993				
14.2. UN proper shipping name	Flammable liquids, n.o.s. (contains ethanol)				
14.3. Transport hazard class(es)	<table> <tr> <td>Class</td><td>3</td></tr> <tr> <td>Subsidiary Hazard</td><td>Not Applicable</td></tr> </table>	Class	3	Subsidiary Hazard	Not Applicable
Class	3				
Subsidiary Hazard	Not Applicable				
14.4. Packing group	II				
14.5. Environmental hazard	Not Applicable				
14.6. Special precautions for user	<table> <tr> <td>Hazard Label</td><td>3</td></tr> <tr> <td>Special provisions</td><td>IB2, T7, TP1, TP8, TP28</td></tr> </table>	Hazard Label	3	Special provisions	IB2, T7, TP1, TP8, TP28
Hazard Label	3				
Special provisions	IB2, T7, TP1, TP8, TP28				

Air transport (ICAO-IATA / DGR)

14.1. UN number	1993														
14.2. UN proper shipping name	Flammable liquid, n.o.s. * (contains ethanol)														
14.3. Transport hazard class(es)	<table> <tr> <td>ICAO/IATA Class</td><td>3</td></tr> <tr> <td>ICAO / IATA Subsidiary Hazard</td><td>Not Applicable</td></tr> <tr> <td>ERG Code</td><td>3H</td></tr> </table>	ICAO/IATA Class	3	ICAO / IATA Subsidiary Hazard	Not Applicable	ERG Code	3H								
ICAO/IATA Class	3														
ICAO / IATA Subsidiary Hazard	Not Applicable														
ERG Code	3H														
14.4. Packing group	II														
14.5. Environmental hazard	Not Applicable														
14.6. Special precautions for user	<table> <tr> <td>Special provisions</td><td>A3</td></tr> <tr> <td>Cargo Only Packing Instructions</td><td>364</td></tr> <tr> <td>Cargo Only Maximum Qty / Pack</td><td>60 L</td></tr> <tr> <td>Passenger and Cargo Packing Instructions</td><td>353</td></tr> <tr> <td>Passenger and Cargo Maximum Qty / Pack</td><td>5 L</td></tr> <tr> <td>Passenger and Cargo Limited Quantity Packing Instructions</td><td>Y341</td></tr> <tr> <td>Passenger and Cargo Limited Maximum Qty / Pack</td><td>1 L</td></tr> </table>	Special provisions	A3	Cargo Only Packing Instructions	364	Cargo Only Maximum Qty / Pack	60 L	Passenger and Cargo Packing Instructions	353	Passenger and Cargo Maximum Qty / Pack	5 L	Passenger and Cargo Limited Quantity Packing Instructions	Y341	Passenger and Cargo Limited Maximum Qty / Pack	1 L
Special provisions	A3														
Cargo Only Packing Instructions	364														
Cargo Only Maximum Qty / Pack	60 L														
Passenger and Cargo Packing Instructions	353														
Passenger and Cargo Maximum Qty / Pack	5 L														
Passenger and Cargo Limited Quantity Packing Instructions	Y341														
Passenger and Cargo Limited Maximum Qty / Pack	1 L														

Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml (200mg/ml)/Cyclophosphamide Injection 500mg/2.5ml (200mg/ml)**Sea transport (IMDG-Code / GGVSee)**

14.1. UN number	1993	
14.2. UN proper shipping name	FLAMMABLE LIQUID, N.O.S. (contains ethanol)	
14.3. Transport hazard class(es)	IMDG Class	3
	IMDG Subsidiary Hazard	Not Applicable
14.4. Packing group	II	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	EMS Number	F-E , S-E
	Special provisions	274
	Limited Quantities	1 L

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
ethanol	Not Available
cyclophosphamide	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
ethanol	Not Available
cyclophosphamide	Not Available

SECTION 15 Regulatory information**Safety, health and environmental regulations / legislation specific for the substance or mixture****ethanol is found on the following regulatory lists**

US - Massachusetts - Right To Know Listed Chemicals
US DOE Temporary Emergency Exposure Limits (TEELs)
US NIOSH Recommended Exposure Limits (RELs)
US OSHA Permissible Exposure Limits (PELs) Table Z-1
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

cyclophosphamide is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 1: Carcinogenic to humans
US - California Proposition 65 - Carcinogens
US - California Proposition 65 - No Significant Risk Levels (NSRLs) for Carcinogens
US - California Proposition 65 - Reproductive Toxicity
US - California Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65 List
US - Massachusetts - Right To Know Listed Chemicals
US National Toxicology Program (NTP) 15th Report Part A Known to be Human Carcinogens

Additional Regulatory Information

Not Applicable

Federal Regulations**Superfund Amendments and Reauthorization Act of 1986 (SARA)****Section 311/312 hazard categories**

Flammable (Gases, Aerosols, Liquids, or Solids)	Yes
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No

Continued...

Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml (200mg/ml)/Cyclophosphamide Injection 500mg/2.5ml (200mg/ml)

In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	Yes
Acute toxicity (any route of exposure)	Yes
Reproductive toxicity	Yes
Skin Corrosion or Irritation	Yes
Respiratory or Skin Sensitization	No
Serious eye damage or eye irritation	Yes
Specific target organ toxicity (single or repeated exposure)	Yes
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

Name	Reportable Quantity in Pounds (lb)	Reportable Quantity in kg
cyclophosphamide	10	4.54

US. EPCRA Section 313 Toxic Release Inventory (TRI) (40 CFR 372)

None Reported

Additional Federal Regulatory Information

Not Applicable

State Regulations**US. California Proposition 65**

 **WARNING:** This product can expose you to chemicals including **cyclophosphamide**, which is known to the State of California to cause cancer, and **cyclophosphamide**, which is known to the State of California to cause birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov

Additional State Regulatory Information

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (ethanol; cyclophosphamide)
China - IECSC	No (cyclophosphamide)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	No (cyclophosphamide)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (cyclophosphamide)
USA - TSCA	No (cyclophosphamide)
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - FBEPH	Yes
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	17/06/2024
Initial Date	11/06/2024

SDS Version Summary

Version	Date of Update	Sections Updated
3.1	17/06/2024	Composition / information on ingredients - Ingredients

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

Continued...

**Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml
(200mg/ml)/Cyclophosphamide Injection 500mg/2.5ml (200mg/ml)**

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit,
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- OSF: Odour Safety Factor
- NOAEL: No Observed Adverse Effect Level
- LOAEL: Lowest Observed Adverse Effect Level
- TLV: Threshold Limit Value
- LOD: Limit Of Detection
- OTV: Odour Threshold Value
- BCF: BioConcentration Factors
- BEI: Biological Exposure Index
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration

- AIIC: Australian Inventory of Industrial Chemicals
- DSL: Domestic Substances List
- NDSL: Non-Domestic Substances List
- IECSC: Inventory of Existing Chemical Substance in China
- EINECS: European INventory of Existing Commercial chemical Substances
- ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ENCS: Existing and New Chemical Substances Inventory
- KECI: Korea Existing Chemicals Inventory
- NZIoC: New Zealand Inventory of Chemicals
- PICCS: Philippine Inventory of Chemicals and Chemical Substances
- TSCA: Toxic Substances Control Act
- TCSI: Taiwan Chemical Substance Inventory
- INSQ: Inventario Nacional de Sustancias Químicas
- NCI: National Chemical Inventory
- FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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**Cyclophosphamide Injection 1g/5ml (200mg/ml)/Cyclophosphamide Injection 2g/10ml
(200mg/ml)/Cyclophosphamide Injection 500mg/2.5ml (200mg/ml)**