

Issuing Date: 28-Jun-2021

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1. Identification**Product identifier**

SDS Number: 1093673
Product Name: Cyclophosphamide

Other means of identification

Synonyms: None

Recommended use of the chemical and restrictions on use

Product Use: Pharmaceutical.
Product Type: Regulated Prescription Drug
Uses advised against: No information available

Details of manufacturer or importer

Baxter Healthcare Pty. Ltd.
1 Baxter Drive
Old Toongabbie NSW 2146 Australia
Telephone : (02) 98481111

Emergency telephone number

Australia: 1 800 229 837 and Poison Information Centre 13 11 26
Verisk 3E Global Incident Response Hotline +1 760 476 3962; Access Code 335625

2. Hazard(s) identification**GHS Classification**

Acute toxicity - Oral	Category 4 - (H302)
Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 1 - (H318)
Skin sensitization	Category 1 - (H317)
Germ cell mutagenicity	Category 1A - (H340)
Carcinogenicity	Category 1A - (H350)
Reproductive toxicity	Category 1A - (H360)
Effects on or via lactation	Yes - (H362)
Specific target organ toxicity (repeated exposure)	Category 1 - (H372)

Label elements

Exclamation mark
Health hazard
Corrosion

**Signal word**

Danger

Hazard statements

H302 - Harmful if swallowed
 H315 - Causes skin irritation
 H317 - May cause an allergic skin reaction
 H318 - Causes serious eye damage
 H340 - May cause genetic defects
 H350 - May cause cancer
 H360 - May damage fertility or the unborn child
 H362 - May cause harm to breast-fed children
 H372 - Causes damage to organs through prolonged or repeated exposure

Precautionary Statements - Prevention

Obtain special instructions before use
 Do not handle until all safety precautions have been read and understood
 Use personal protective equipment as required
 Do not breathe dust/fume/gas/mist/vapors/spray
 Avoid contact during pregnancy/while nursing
 Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product
 Contaminated work clothing should not be allowed out of the workplace
 Wear protective gloves

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention
 Specific treatment (see supplemental first aid instructions on this label)
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 Immediately call a POISON CENTER or doctor/physician
 IF ON SKIN: Wash with plenty of soap and water
 Take off contaminated clothing and wash before reuse
 If skin irritation or rash occurs: Get medical advice/attention
 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other hazards which do not result in classification

General Hazards No information available

3. Composition/information on ingredients

Chemical Name	CAS No.	Weight-%
Cyclophosphamide 50-18-0	50-18-0	100

4. First-aid measures

Description of first aid measures**General Advice**

Treat symptomatically and supportively.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Eye contact:

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

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.

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.

Most important symptoms and effects, both acute and delayed

Irritating to eyes and skin. May cause sensitization by skin contact. Contains a known or suspected carcinogen. Contains a known or suspected mutagen. Contains a known or suspected reproductive toxin.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

Note to physicians May cause sensitization in susceptible persons. Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media

Use extinguishing media suitable for surrounding materials.

Specific hazards arising from the chemical

No information available

Special protective actions for fire-fighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions

See Section 12 for environmental precautions.

Methods and material for containment and cleaning up

Methods for Containment:

Place spilled material in an appropriate container for disposal. Prevent dust cloud. Clean up promptly by sweeping or vacuum.

Methods for cleaning up:

Place spilled material in an appropriate container for disposal.

Precautions to prevent secondary hazards

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

7. Handling and storage

Precautions for safe handling

Technical measures/precautions: Do not ingest. Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store at or below 25°C (77°F). Store in original container. Keep away from heat.

Incompatible materials: No information available

8. Exposure controls/personal protection

Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical Name	Australia nohsc :	ACGIH TLV
Cyclophosphamide - 50-18-0	-	-

Appropriate engineering controls

Engineering Measures Provide general or local exhaust ventilation. Open handling must be limited.

Individual protection measures, such as personal protective equipment

Eye/face protection Tight sealing safety goggles.

Skin and body protection Disposable close-front gown or coveralls.

Hand protection Latex gloves. Nitrile rubber.

Respiratory protection No personal respiratory protective equipment normally required. In the case of respirable dust and/or fumes, use a properly fitted air-purifying respirator.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: Solid.

Appearance: Crystalline

Color: White

Odor: Odorless

Odor Threshold: No information available

pH: 4.0 - 6.0

Melting point / melting range: 49 - 53 °C

Boiling point / boiling range: No information available

Flash point: No information available

Evaporation rate: No information available

Flammability (solid, gas): No information available

Flammable limits in air-upper (%): 3000 g/m³

Flammable limits in air-lower (%): 750 g/m³

Vapor pressure: 0.0000033 kPa

Vapor density: No information available

Density: No information available

Solubility: Soluble in water.

Partition coefficient (n-octanol/water): log Kow = 0.63

Autoignition temperature: No information available

Decomposition temperature: No information available

Viscosity: No information available

Explosive Properties: No information available

Oxidizing Properties: No information available

Other information

Molecular weight: 279.1

10. Stability and reactivity

Reactivity

No information available.

Chemical stability

Stable under recommended storage conditions

Possibility of hazardous reactions

None under normal use conditions

Conditions to Avoid

Do not freeze.

Incompatible materials

Acids. Alkali metals. Oxidizing agents.

Hazardous decomposition products

Halogenated hydrocarbons. Organic compounds of phosphoric compounds. Organic nitrogenous products of decomposition.

11. Toxicological information

Acute toxicity**Information on likely routes of exposure****Product Information**

Inhalation:	Harmful: danger of serious damage to health by prolonged exposure through inhalation Irritating to respiratory system.
Eye contact:	Risk of serious damage to eyes
Skin contact:	Toxic: danger of serious damage to health by prolonged exposure with skin.
Ingestion:	Harmful if swallowed. Toxic: danger of serious damage to health by prolonged exposure if swallowed. Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Dermatologic effects (may include exfoliative dermatitis, photosensitivity, rash, itching). Hair loss. Blood effects (may include anemia, neutropenia (decreased number of neutrophils), thrombocytopenia (decreased number of platelets), bone marrow depression). Immune system effects.

Symptoms: No information available**Numerical measures of toxicity - Product Information****The following values are calculated based on chapter 3.1 of the GHS document**

Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity
 0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
 100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
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Cyclophosphamide 50-18-0	342 mg/kg (rat)	-	-
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Delayed and immediate effects as well as chronic effects from short and long-term exposure

Corrosivity:	Not classified.
Irritation:	Causes serious eye damage. Causes skin irritation.
Sensitization:	May cause an allergic skin reaction.
Mutagenic effects:	Contains a known or suspected mutagen.
Carcinogenic effects:	Contains a known or suspected carcinogen.
Reproductive toxicity:	May impair fertility. May cause harm to the unborn child. May cause harm to breastfed babies.
STOT - single exposure:	Not classified.
STOT - repeated exposure:	Bladder. Bone marrow.
Aspiration Hazard:	Not classified.

12. Ecological information

Ecotoxicity

No information available

Unknown aquatic toxicity

0 % of the mixture consists of component(s) of unknown hazards to the aquatic environment.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Cyclophosphamide 50-18-0	-	-	-	-

Persistence and degradability

No information available.

Bioaccumulative potential

No information available.

Chemical Name	Partition coefficient
Cyclophosphamide 50-18-0	-

Mobility

No information available

Other adverse effects

This product does not contain any known or suspected endocrine disruptors.

Chemical Name	EU - Endocrine Disruptors Candidate List	EU - Endocrine Disruptors - Evaluated Substances	Endocrine disrupting potential
Cyclophosphamide 50-18-0	-	-	-

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products In accordance with local and national regulations

Contaminated Packaging In accordance with local and national regulations

14. Transport information

ADG Not regulated

IATA Not regulated

IMDG Not regulated

15. Regulatory information

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

National regulations

Australia

See section 8 for national exposure control parameters

Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

No poisons schedule number allocated

International Inventories

TSCA	Does not comply
DSL/NDL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply
NZIOC	Complies

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIOC - New Zealand Inventory of Chemicals and Chemical Substances

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

16. Other information

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Revision Note:
None

Key or legend to abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)
STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value
*	Skin designation
C	Carcinogen

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGl(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
RTECS (Registry of Toxic Effects of Chemical Substances)
World Health Organization

Disclaimer

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End of Safety Data Sheet