



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Cyclophosphamide Tablets - 50mg

Trade Name: Cycloblastin; Cyclophar
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Cyclophosphamide	50-18-0	200-015-4	41.6
Maize starch	9005-25-8	232-679-6	*
Sucrose	57-50-1	200-334-9	*
Calcium carbonate	471-34-1	207-439-9	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Sodium stearyl fumarate	4070-80-8	223-781-1	*
Gelatin	9000-70-8	232-554-6	*
Macrogol 6000	Not assigned	Not listed	*
Opalux brown AS-9486	Not assigned	Not listed	*
Povidone	9003-39-8	Not listed	*
Starch pregelatinised maize	Not assigned	Not listed	*
Carnauba wax	8015-86-9	232-399-4	*
Lactose	63-42-3	200-559-2	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Pink or White Tablets
Signal Word: WARNING

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Statement of Hazard:	Harmful if swallowed. May cause adverse effects on blood forming organs. May cause harm to the unborn child. May cause reproductive system effects. Carcinogen Mutagen
Additional Hazard Information:	
Short Term:	Harmful if swallowed (based on animal data)
Long Term:	The use of this drug during pregnancy has resulted in birth defects. Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.
Known Clinical Effects:	Effects on blood and blood-forming organs have also occurred.
EU Indication of danger:	Toxic Toxic to reproduction: Category 1 Carcinogenic: Category 1 Mutagenic Category 1

EU Hazard Symbols:



EU Risk Phrases:

R25 - Toxic if swallowed.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin Contact:	Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
Ingestion:	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation:	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.

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Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use with adequate ventilation.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Maize starch

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Sucrose

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Calcium carbonate

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA particulate matter containing no asbestos and <1% crystalline silica
ACGIH OELs - Notice of Intended Changes Listed
Australia TWA = 10 mg/m³ TWA

Microcrystalline cellulose

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

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Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals

Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system.

Personal Protective Equipment:

Hands: Rubber gloves

Eyes: Safety glasses or goggles

Skin: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.

Respiratory protection: Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablets	Color:	Pink / White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Cyclophosphamide

Rat Oral LD 50 160 mg/kg

Rat Intravenous LD 50 148 mg/kg

Mouse Oral LD 50 137 mg/kg

Mouse Intravenous LD 50 140 mg/kg

Sucrose

Rat Oral LD50 29.7 g/kg

Calcium carbonate

Rat Oral LD50 6450 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

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Lactose

Rat Oral LD50 > 10 g/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Cyclophosphamide

Embryo / Fetal Development	Rat	Intraperitoneal	10 mg/kg	LOAEL	Teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	30 mg/kg	LOAEL	Fetotoxicity
Embryo / Fetal Development	Mouse	Intravenous	10 mg/kg	LOAEL	Teratogenic
Embryo / Fetal Development	Mouse	Intraperitoneal	5 mg/kg	LOAEL	Fetotoxicity, Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Cyclophosphamide

In Vivo Micronucleus Rodent Positive

In Vivo Chromosome Aberration Rodent Positive

In Vivo Sister Chromatid Exchange Rodent Positive

In Vitro Chromosome Aberration Human Lymphocytes Positive

Dominant Lethal Assay *Drosophila* Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Cyclophosphamide

2 Year(s) Rat Intravenous Benign tumors, Malignant tumors

2 Year(s) Rat Intraperitoneal Benign tumors, Malignant tumors, Female reproductive system

2 Year(s) Mouse Intraperitoneal Benign tumors, Malignant tumors

Carcinogen Status: See below

Cyclophosphamide

IARC: Group 1 - Carcinogenic to Humans

NTP: Known Carcinogen

OSHA: Present

Povidone

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

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13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

Cyclophosphamide
RCRA - U Series Wastes

Waste Number U058

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic
Toxic to reproduction: Category 1
Carcinogenic: Category 1
Mutagenic Category 1

EU Risk Phrases:
R25 - Toxic if swallowed.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Harmful if swallowed.
May cause adverse effects on blood forming organs.
May cause harm to the unborn child.
May cause reproductive system effects.
Carcinogen
Mutagen

Canada - WHMIS: Classifications

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WHMIS hazard class:

Class D, Division 1, Subdivision B
Class D, Division 2, Subdivision A



Cyclophosphamide

CERCLA/SARA Hazardous Substances
and their Reportable Quantities:
California Proposition 65

= 10 lb final RQ
= 4.54 kg final RQ
carcinogen, initial date 2/27/87
developmental toxicity, initial date 1/1/89
female reproductive toxicity, initial date 1/1/89
male reproductive toxicity, initial date 1/1/89

Australia (AICS):
Standard for the Uniform Scheduling
for Drugs and Poisons:
EU EINECS List

Present
Schedule 4

200-015-4

Sodium stearyl fumarate

EU EINECS List

223-781-1

Maize starch

Inventory - United States TSCA - Sect. 8(b)

XU

Australia (AICS):

Present

EU EINECS List

232-679-6

Gelatin

Inventory - United States TSCA - Sect. 8(b)

XU

Australia (AICS):

Present

EU EINECS List

232-554-6

Sucrose

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS List

200-334-9

Povidone

Inventory - United States TSCA - Sect. 8(b)

XU

Australia (AICS):

Present

Calcium carbonate

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS List

207-439-9

Carnauba wax

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS List

232-399-4

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)

XU

Australia (AICS):

Present

EU EINECS List

232-674-9

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Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 14 - Transport Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet