



# MATERIAL SAFETY DATA SHEET

Revision date: 13-Sep-2012

Version: 2.0

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

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### Material Name: Cyclophosphamide Tablets - 50mg

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

## 2. HAZARDS IDENTIFICATION

**Appearance:** Pink or White Tablets  
**Signal Word:** DANGER

**Statement of Hazard:** Toxic if swallowed.  
May cause cancer.  
May damage fertility or the unborn child.  
May cause genetic defects.

**Additional Hazard Information:**

<b>Short Term:</b>	Toxic if swallowed (based on animal data)
<b>Long Term:</b>	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:**

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### 2. HAZARDS IDENTIFICATION

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.  
Hazardous Substance. Non-Dangerous Goods.

#### Australian Hazard Classification (NOHSC):

**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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Cyclophosphamide	50-18-0	200-015-4	T;R25 Repr.Cat.1;R60-61 Carc. Cat.1;R45 Mut. Cat.1;R46	41.6
Sucrose	57-50-1	200-334-9	Not Listed	*
Calcium carbonate	471-34-1	207-439-9	Not Listed	*
Maize starch	9005-25-8	232-679-6	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

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

#### Additional Information:

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

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 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.

**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. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

#### Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
<b>Calcium carbonate</b>	
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Latvia OEL - TWA	6 mg/m <sup>3</sup>
Poland OEL - TWA	10 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
<b>Maize starch</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
<b>Magnesium stearate</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>
<b>Microcrystalline cellulose</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. All operations should be fully enclosed. No air recirculation permitted.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Wear impervious, disposable gloves as minimum protection (double recommended).

**Eyes:** Wear safety glasses as minimum protection.

**Skin:** Wear impervious protective clothing when handling this compound.

**Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

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

### 10. STABILITY AND REACTIVITY

**Chemical 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	Para-periosteal	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
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##### **Calcium carbonate**

Rat	Oral	LD50	6450 mg/kg
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##### **Magnesium stearate**

Rat	Oral	LD50	> 2000 mg/kg
Rat	Inhalation	LC50	> 2000 mg/m <sup>3</sup>

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### 11. TOXICOLOGICAL INFORMATION

#### 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

##### Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

#### 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 Human Carcinogen

**OSHA:** Listed

##### Povidone

**IARC:** Group 3 (Not Classifiable)

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### 12. ECOLOGICAL INFORMATION

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

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

**Cyclophosphamide**  
**RCRA - U Series Wastes** Listed

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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:**  
DANGER

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## 15. REGULATORY INFORMATION

Toxic if swallowed.  
May cause cancer.  
May damage fertility or the unborn child.  
May cause genetic defects.

### Canada - WHMIS: Classifications

#### 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  
4.54 kg  
carcinogen initial date 2/27/87  
developmental toxicity initial date 1/1/89  
female reproductive toxicity 1/1/89  
male reproductive toxicity initial date 1/1/89

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

Present  
Schedule 4  
200-015-4

### Sodium stearyl fumarate

EU EINECS/ELINCS List

223-781-1

### Gelatin

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
EU EINECS/ELINCS List

Present  
Present  
232-554-6

### Sucrose

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
REACH - Annex IV - Exemptions from the  
obligations of Register:  
EU EINECS/ELINCS List

Present  
Present  
Present  
200-334-9

### Povidone

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):

Present  
Present

### Calcium carbonate

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
EU EINECS/ELINCS List

Present  
Present  
207-439-9

### Maize starch

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### 15. REGULATORY INFORMATION

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>REACH - Annex IV - Exemptions from the obligations of Register:</b>	Present
<b>EU EINECS/ELINCS List</b>	232-679-6
<b>Carnauba wax</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	232-399-4
<b>Lactose</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>REACH - Annex IV - Exemptions from the obligations of Register:</b>	Present
<b>EU EINECS/ELINCS List</b>	200-559-2
<b>Magnesium stearate</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	209-150-3
<b>Microcrystalline cellulose</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	232-674-9

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

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.

#### **Data Sources:**

Pfizer proprietary drug development information. Safety data sheets for individual ingredients.  
Publicly available toxicity information.

#### **Reasons for Revision:**

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 8 - Exposure Controls / Personal Protection.

#### **Prepared by:**

Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**