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

Material Name: Cyclophosphamide Tablets - 50mg

Trade Name: Cycloblastin; Cyclophar
Chemical Family: Mixture
Intended Use: 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:
Short Term: Toxic 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
Carcinogenic: Category 1
Mutagenic: Category 1

EU Hazard Symbols:
T

EU Risk Phrases:
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.

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

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

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

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.
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/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>Threshold Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Calcium carbonate</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Maize starch</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWAs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWAs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
<th>Color:</th>
<th>Pink / White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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

**Calcium carbonate**
- Rat Oral LD50 6450 mg/kg

**Magnesium stearate**
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³
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)
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
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
Australia (AICS):
Standard for the Uniform Scheduling for Drugs and Poisons:
EU EINECS/ELINCS List

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
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):
EU EINECS/ELINCS List
Present
Present
207-439-9

Maize starch
15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)        Present
Australia (AICS):                                Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List                            232-679-6

Carnauba wax

Inventory - United States TSCA - Sect. 8(b)        Present
Australia (AICS):                                Present
EU EINECS/ELINCS List                            232-399-4

Lactose

Inventory - United States TSCA - Sect. 8(b)        Present
Australia (AICS):                                Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List                            200-559-2

Magnesium stearate

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

Microcrystalline cellulose

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