1. PRODUCT AND COMPANY IDENTIFICATION

Product Identifier: 
Product Name: Cyclophosphamide for Injection, USP

Relevant identified uses of the substance or mixture and uses advised against
Product Use: Antineoplastic Agent.
Product Type: Regulated Prescription Drug
Uses advised against: No information available.

Details of the supplier of the safety data sheet
BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
(800) 422-9837 or (224) 948-4770

E-mail Address
onebaxter@baxter.com

Emergency telephone number
Carechem24 International
+44 (0) 1235 239 670

2. HAZARDS IDENTIFICATION
1118057 - Cyclophosphamide for Injection, USP

Revision Date: 11/08/2012

Label Elements

Signal Word
Warning

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

Classification of the substance or mixture
REGULATION (EC) No 1272/2008

<table>
<thead>
<tr>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Oral Toxicity</td>
</tr>
<tr>
<td>Skin Corrosion/Irritation</td>
</tr>
<tr>
<td>Serious Eye Damage/Eye Irritation</td>
</tr>
<tr>
<td>Skin Sensitization</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
</tr>
<tr>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>Reproductive Toxicity</td>
</tr>
<tr>
<td>Effects on or via lactation</td>
</tr>
<tr>
<td>Specific Target Organ Toxicity (Repeated Exposure)</td>
</tr>
<tr>
<td>Ozone</td>
</tr>
</tbody>
</table>

Classification according to EU Directives 67/548/EEC or 1999/45/EC
Precautionary Statements
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTRE or doctor/physician
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P321 - Specific treatment (see supplemental first aid instructions on this label)
P363 - Wash contaminated clothing before reuse
P263 - Avoid contact during pregnancy/while nursing
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical attention/advice if you feel unwell
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P501 - Dispose of contents/container to an approved waste disposal plant

Obligatory Precautionary Statements
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P321 - Specific treatment (see supplemental first aid instructions on this label)
P202 - Do not handle until all safety precautions have been read and understood
P263 - Avoid contact during pregnancy/while nursing
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P201 - Obtain special instructions before use
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention

Other Hazards
Indication of Danger: Xn - Harmful.

Risk Phrases:
R22 - Harmful if swallowed.
R41 - Risk of serious damage to eyes.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.

R48/23/24/25 - Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>EINECS-No.</th>
<th>CAS-No</th>
<th>Weight %</th>
<th>Classification</th>
<th>EU - GHS Substance Classification</th>
<th>REACH No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclophosphamide</td>
<td>200-015-4</td>
<td>50-18-0</td>
<td>100</td>
<td>Carc. 1; R45</td>
<td>Acute Tox. 4 (H302)</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mut. Cat. 2; R46</td>
<td>Mut. 1A (H360)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat. 1; R61 T; R48/23/24/25 Xi; R41 Xn R64</td>
<td>Repr. 1A (H360)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Xi; R41</td>
<td>Skin Irrit. 2 (H315)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Xn</td>
<td>Eye Dam. 1 (H318)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R41</td>
<td>Skin Sens. 1 (H317)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT RE 1 (H372)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lact. (H362)</td>
<td></td>
</tr>
</tbody>
</table>

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

### 4. FIRST AID MEASURES

**Description of first aid measures**

**General Advice:** Treat symptomatically and supportively.

**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.

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

**Most important symptoms and effects, both acute and delayed**
May be carcinogenic. See patient package insert in shipping carton for complete information.

**Indication of any immediate medical attention and special treatment needed**
Treat symptomatically. See patient package insert in shipping carton for complete information.
5. FIRE-FIGHTING MEASURES

Extinguishing media
Suitable extinguishing media: Use extinguishing media suitable for surrounding materials.
Extinguishing media which must not be used for safety reasons:
No information available.

Special hazards arising from the substance or mixture
No information available.

Advice 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. Follow all fire fighting procedures (Section 5). Use suitable protective equipment (Section 8).

Environmental precautions
Do not allow material to contaminate ground water system.

Methods and material for containment and cleaning up
Methods for Containment:
If emergency personnel are unavailable, contain spilled material. Absorb with vacuum cleaner approved for carcinogenic substances.
Methods for cleaning up:
Place spilled material in an appropriate container for disposal. Avoid production of dust. Clean contaminated surface thoroughly.

Reference to other sections
See Section 12 for additional information.

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

Incompatible products:
No special restrictions on storage with other products.

Specific End Uses
Other Guidelines: None

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.
Exposure controls
Engineering measures: Provide general or local exhaust ventilation. Open handling must be limited.

Personal protective equipment
Eye protection: Goggles, face shield, or other full-face protection if potential exists for direct exposure to dust.


Respiratory protection: No personal respiratory protective equipment normally required.

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

Environmental Exposure Controls:
Do not allow material to contaminate ground water system.

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.
P H: 4.0 - 6.0
Melting point/range: 49 - 53 °C
Boiling point/range: No information available.
Flash point: No information available.
Flammability (solid, gas): No information available.
Evaporation rate: 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
10. STABILITY AND REACTIVITY

Reactivity
No data available

Chemical Stability
Stable under recommended storage conditions.

Possibility of Hazardous Reactions
Polymerization: Not applicable
Hazardous Reactions: No information available

Conditions to Avoid
Keep away from heat.

Incompatible Materials

Hazardous Decomposition Products
Halogenated hydrocarbons. Organic compounds of phosphoric compounds. Organic nitrogenous products of decomposition.

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Component</th>
<th>LC50 Inhalation</th>
<th>LD50 Dermal</th>
<th>LD50 Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclophosphamide</td>
<td>-</td>
<td>-</td>
<td>342 mg/kg (rat)</td>
</tr>
<tr>
<td>50-18-0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Information on Toxicological Effects

Acute Toxicity
Inhalation: Toxic: 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. 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.

Irritation: Causes serious eye damage. Causes skin irritation.
Corrosivity: None.
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: No information available
12. ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Component</th>
<th>Ecotoxicity - Water Flea Data</th>
<th>Fish Species Ecotoxicity</th>
<th>Ecotoxicity - Freshwater Algae Data</th>
<th>Ecotoxicity - Microtox Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclophosphamide 50-18-0</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
</tbody>
</table>

Toxicity

Ecotoxicity Effects:

- NOEC (96 h): > 984 mg/l Salmo gairdneri;
- NOEC (48 h): > 987 mg/l Daphnia magna;
- EC 10 (16h): > 10000 mg/l Pseudomonas putida.

Persistence and degradability

Not readily biodegradable.

Bioaccumulative potential

No data available

Mobility in soil

High mobility in soil.

Results of PBT and vPvB assessment

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Other adverse effects

Endocrine Disruptor Information:

No information available

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

IMDG/IMO

Not regulated

RID

Not regulated

ICAO / IATA:

Not regulated
15. REGULATORY INFORMATION

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

International Inventories

EU EINECS List - This product complies with EINECS

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

Chemical Safety Assessment
No

16. OTHER INFORMATION

Full text of R-phrases referred to under Section 3:
R22 - Harmful if swallowed
R41 - Risk of serious damage to eyes
R45 - May cause cancer
R46 - May cause heritable genetic damage
R61 - May cause harm to the unborn child
R48/23/24/25 - Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed

Additional information:
NOEC = No observable effect concentration

Key literature references and sources for data:
www.ChemADVISOR.com/

Prepared by: Technology Resources, Baxter Healthcare Corporation
Revision Date: 11/08/2012

This data sheet contains changes from the previous version in section(s)?:
New GHS format.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of Safety Data Sheet