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

<table>
<thead>
<tr>
<th>Pfizer Global Manufacturing</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Inc</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, NY 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td></td>
<td>United Kingdom</td>
</tr>
<tr>
<td></td>
<td>+00 44 (0)1304 616161</td>
</tr>
</tbody>
</table>

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Epirubicin Hydrochloride Powder for Injection

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>Ellence, Farmorubicin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms:</td>
<td>Pharmorubicin Rapid Dissolution</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Anthracycline</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used as Antineoplastic</td>
</tr>
</tbody>
</table>

# 2. HAZARDS IDENTIFICATION

<table>
<thead>
<tr>
<th>Appearance:</th>
<th>Red freeze-dried powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Word:</td>
<td>WARNING</td>
</tr>
</tbody>
</table>

Statement of Hazard:
Harmful if swallowed.
Suspected of causing cancer.
Suspected of damaging fertility or the unborn child.
Suspected of causing genetic defects.

Additional Hazard Information:

**Short Term:**
Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

**Long Term:**
Repeat-dose studies in animals have shown a potential to cause adverse effects on testes the developing fetus.

Known Clinical Effects:
Adverse effects most commonly reported in clinical use include local irritation, nausea, vomiting, inflammation of the mouth (stomatitis), facial flushing, conjunctivitis of the eye, tearing (lachrymation), loss of hair, and discoloration of skin. Effects on blood and blood-forming organs have also occurred.

EU Indication of danger:
Harmful
Toxic to reproduction, Category 2
Carcinogenic: Category 2
Mutagenic: Category 2

EU Hazard Symbols:

![T Symbol]
2. HAZARDS IDENTIFICATION

EU Risk Phrases:
- R45 - May cause cancer.
- R46 - May cause heritable genetic damage.
- R60 - May impair fertility.
- R61 - May cause harm to the unborn child.
- R22 - Harmful if swallowed.

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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epirubicin Hydrochloride</td>
<td>56390-09-1</td>
<td>260-145-2</td>
<td>Xn;R22 Repr.Cat.2;R60-61 Muta.Cat.2;R46 Carc.Cat.2;R45</td>
<td>0.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: 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: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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: Restrict access to work area. Avoid breathing dust. Avoid contact with eyes, skin and clothing. 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.

Epirubicin Hydrochloride Pfizer OEL TWA-8 Hr: 0.6 µg/m³


Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section. It is recommended that all operations be fully enclosed and no air recirculated.

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: Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>Freeze-dried powder</th>
<th>Color:</th>
<th>Red</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

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
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)

Epirubicin Hydrochloride
- Rat Oral LD50 1350 mg/kg
- Rat Intravenous LD50 17mg/kg
- Mouse Oral LD50 > 2000mg/kg
- Mouse Intravenous LD50 3150mg/kg

Lactose Monohydrate
- Rat Oral LD50 29700 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.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Epirubicin Hydrochloride
- 6 Week(s) Rabbit Intravenous 1 mg/kg/day LOAEL Heart, Kidney
- 6 Week(s) Dog Intravenous 0.4 mg/kg/day LOAEL Kidney

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

Epirubicin Hydrochloride
- Reproductive & Fertility Rat Oral 0.3 mg/kg/day LOAEL Fertility
- Reproductive & Fertility Rat Oral 0.1 mg/kg/day NOAEL Fertility
- Embryo / Fetal Development Rat Intravenous 0.8 mg/kg/day LOAEL Fetotoxicity
- Embryo / Fetal Development Rat Intravenous 2 mg/kg/day LOAEL Teratogenic, Fetotoxicity
- Embryo / Fetal Development Rat Intravenous 0.2 mg/kg/day NOAEL Teratogenic, Fetotoxicity
11. TOXICOLOGICAL INFORMATION

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

Epirubicin Hydrochloride
Bacterial Mutagenicity (Ames) Positive
Mammalian Cell Mutagenicity HGPRT Positive
Chromosome Aberration Human Lymphocytes Positive
Chromosome Aberration Mouse Lymphoma Positive

Lactose Monohydrate
In Vitro Bacterial Mutagenicity (Ames) Negative

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

Epirubicin Hydrochloride
1 Year(s) Rat Intravenous 3.6 mg/kg LOAEL Tumors, Female reproductive system
18 Month(s) Rat Intravenous 0.5 mg/kg LOAEL Tumors

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Harmful
Toxic to reproduction, Category 2
Carcinogenic: Category 2
Mutagenic: Category 2

EU Risk Phrases:
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R22 - Harmful if swallowed.

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.
Suspected of causing cancer.
Suspected of damaging fertility or the unborn child.
Suspected of causing genetic defects.

Canada - WHMIS: Classifications
WHMIS hazard class:
D2a very toxic materials

Epirubicin Hydrochloride
EU EINECS/ELINCS List 260-145-2

Methylparaben
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-785-7

Lactose Monohydrate
Australia (AICS): Present
Text of R phrases mentioned in Section 3

R22 - Harmful 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: Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

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