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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

Material Name: Oxamniquine Capsule

Trade Name: Mansil (R); Vansil (R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antischistosomal agent.

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxamniquine</td>
<td>21738-42-1</td>
<td>244-556-4</td>
<td>74</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Sodium Lauryl Sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose Monohydrate</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: hard gelatin, greenish/yellow capsules.

Signal Word: DANGER

Statement of Hazard: Fatal if swallowed.
Causes damage to central nervous system.

Additional Hazard Information:

Short Term: May cause skin irritation. Causes nose, throat and lung irritation.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on kidneys, liver, lungs, blood, central nervous system.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, drowsiness, headache, stomach pain, nausea, vomiting, diarrhea, loss of appetite and red discoloration of the urine. Fever, hallucination, excitement, skin rashes, insomnia, joint pain, temporary amnesia, chills and seizures, especially in persons with a history of epilepsy, have also been reported.

EU Indication of danger: Toxic
EU Hazard Symbols:

EU Risk Phrases:

R25 - Toxic if swallowed.

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: Wash skin with soap and water. Remove contaminated clothing and shoes. 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 immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

Fire / Explosion Hazards: Not determined

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: Avoid generating airborne dust. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Keep container tightly closed when not in use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Corn 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

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.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Oxamnique

Pfizer Occupational Exposure Band (OEB): OEB3 (control exposure to the range of >10ug/m³ to < 100ug/m³)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Hard-gelatin Capsule
Molecular Formula: Mixture
Color: greenish/yellow
Molecular Weight: Mixture
10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: None identified

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)

Oxamniquine
- Rat Oral LD50 30 mg/kg
- Mouse Oral LD50 1300 mg/kg
- Rat IM LD50 60 mg/kg
- Mouse IM LD50 2000 mg/kg
- Rat IP LD50 20 mg/kg

Magnesium Stearate
- 13 Week(s) Dog Intramuscular 30 mg/kg

Lactose Monohydrate
- Rat Oral LD 50 29700 mg/kg

Sodium Lauryl Sulfate
- Rat Oral LD 50 1288 mg/kg
- Rat Intraperitoneal LD 50 210 mg/kg

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

Oxamniquine
- Reproductive & Fertility Mouse Intramuscular 300 mg/kg LOAEL Fetotoxicity
- Embryo / Fetal Development Mouse Oral 200 mg/kg/day NOAEL Fetotoxicity
- Embryo / Fetal Development Mouse Intramuscular 300 mg/kg/day NOAEL Fetotoxicity
- Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOAEL Negative
- Embryo / Fetal Development Rabbit Intramuscular 400 mg/kg NOAEL Negative

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

Oxamniquine
- Bacterial Mutagenicity (Ames): Salmonella, E. coli Positive
- Direct DNA Damage: Bacteria Negative
In Vitro  Human Lymphocytes  Negative
In Vivo  Mouse Bone Marrow  Negative
Dominant Lethal Assay  Not specified  Negative

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

Oxamniquine
18 Month(s)  Mouse  Oral  150 mg/kg  NOAEL  Not carcinogenic
19 Month(s)  Hamster  Intramuscular  150 mg/kg  NOAEL  Not carcinogenic

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.

14. TRANSPORT INFORMATION

This material is regulated for transport under DOT, ADR, IMDG, and IATA regulations.

Proper shipping name:  Medicine, solid, toxic, n.o.s (Oxamniquine)
UN / ID No:  UN 3249
Hazard class:  6.1
Packing group:  II

If your commodity meets the definition of a limited quantity and is packaged for retail sale, it may be considered a consumer commodity and excepted from additional requirements as applicable.

15. REGULATORY INFORMATION

EU Symbol:  T
EU Indication of danger:  Toxic
EU Risk Phrases:  R25 - Toxic if swallowed.
EU Safety Phrases:  S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
OSHA Label:
DANGER
Fatal if swallowed.
Causes damage to central nervous system.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 1, Subdivision A

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Oxamniquine
EU EINECS List 244-556-4

Corn Starch
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS List 232-679-6

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

Lactose Monohydrate
Australia (AICS): Present

Sodium Lauryl Sulfate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 205-788-1

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16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

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

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End of Safety Data Sheet