# MATERIAL SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Material Name: Oxamniquine Oral Suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade Name:</strong></td>
</tr>
<tr>
<td><strong>Chemical Family:</strong></td>
</tr>
<tr>
<td><strong>Intended Use:</strong></td>
</tr>
</tbody>
</table>

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Pfizer Pharmaceuticals Group
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**Emergency telephone number:**
CHEMTREC (24 hours): 1-800-424-9300

**Material Name: Oxamniquine Oral Suspension**

<table>
<thead>
<tr>
<th>Hazardous</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ingredient</strong></td>
</tr>
<tr>
<td>Oxamniquine</td>
</tr>
<tr>
<td>Glycerol</td>
</tr>
</tbody>
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<tr>
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</tr>
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<tbody>
<tr>
<td><strong>CAS Number</strong></td>
</tr>
<tr>
<td>Agar</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
</tr>
<tr>
<td>Flavoring</td>
</tr>
<tr>
<td>Sodium saccharin</td>
</tr>
<tr>
<td>Sucrose</td>
</tr>
<tr>
<td>Sorbitol solution</td>
</tr>
<tr>
<td>Polysorbate 80</td>
</tr>
<tr>
<td>Purified water</td>
</tr>
</tbody>
</table>

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

**2. COMPOSITION/INFORMATION ON INGREDIENTS**

**3. HAZARDS IDENTIFICATION**

| **Appearance:** | Bright yellow suspension |
| **Signal Word:** | DANGER |
| **Statement of Hazard:** | Harmful if swallowed. |
| **Additional Hazard Information:** | Not a skin irritant; Not an eye irritant (based on components). |
| **Short 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: Harmful

EU Hazard Symbols: 

EU Risk Phrases: R22 - Harmful 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 spill with absorbent material. 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 breathing vapor or mist. Avoid prolonged or repeated contact with skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Glycerol

<table>
<thead>
<tr>
<th>Classification</th>
<th>Exposure Limit(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>= 15 mg/m³ TWA total</td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>= 5 mg/m³ TWA</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>= 10 mg/m³ TWA</td>
</tr>
</tbody>
</table>

Sucrose

<table>
<thead>
<tr>
<th>Classification</th>
<th>Exposure Limit(s)</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>Australia TWA</td>
<td>= 10 mg/m³ TWA</td>
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</tbody>
</table>

The exposure limit(s) listed for solid components are only relevant if dust or mist 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.

Oxamniquine

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Protective Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hands:</td>
<td>Rubber gloves</td>
</tr>
<tr>
<td>Eyes:</td>
<td>Safety glasses or goggles</td>
</tr>
<tr>
<td>Skin:</td>
<td>Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.</td>
</tr>
<tr>
<td>Respiratory protection:</td>
<td>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.</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Suspension</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Yellow</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>pH:</td>
<td>7.0-9.0</td>
</tr>
</tbody>
</table>
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

Sorbitol solution
- Rat Oral LD50 15,900 mg/kg
- Mouse Oral LD50 17,800 mg/kg

Sodium saccharin
- Mouse Oral LD50 17.5 g/kg
- Rat Oral LD50 14.2 - 17 g/kg
- Rat Intraperitoneal LD50 7100 mg/kg

SODIUM CHLORIDE
- Rat Inhalation LC50/1hr > 42 g/m³
- Rat Oral LD50 3 g/kg
- Mouse Oral LD50 4 g/kg
- Rabbit Dermal LD50 > 10 g/kg

Polysorbate 80
- Rat Oral LD50 25 g/kg

Glycerol
- Rat Oral LD50 12600 mg/kg

Sucrose
- Rat Oral LD50 29.7 g/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)

SODIUM CHLORIDE
- Skin Irritation Rabbit Mild
- Eye Irritation Rabbit Mild

Glycerol
**Material Name:** Oxamniquine Oral Suspension  
**Revision date:** 23-Jan-2007  
**Version:** 1.2

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

**Oxamniquine**
- 4 Week(s) Mouse Oral 120 mg/kg NOAEL Blood, Central nervous system, Kidney, Liver, Lungs
- 4 Week(s) Dog Oral 20 mg/kg/day NOAEL Central Nervous System, Kidney, Liver, Lungs
- 11 Month(s) Dog Oral 20 mg/kg/day LOAEL Central Nervous System
- 13 Month(s) Dog Intramuscular 30 mg/kg NOAEL No effects at maximum dose
- 14 Month(s) Dog Oral 30 mg/kg LOAEL Central Nervous System

**Sodium saccharin**
- 36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder
- 54 Day(s) Rat Oral 32400 mg/kg LOAEL Immune system

**Glycerol**
- 28 Day(s) Rat Oral 16800 mg/kg LOAEL Endocrine system

**Reproduction & 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 Negative
- Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOAEL Negative
- Embryo / Fetal Development Rabbit Intramuscular 400 mg/kg NOAEL Negative

**Glycerol**
- Reproductive & Fertility-Males Rat Oral 100 mg/kg LOEL Fertility

**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.

**Sodium saccharin**
- IARC: Group 3

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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

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful

EU Risk Phrases: R22 - Harmful if swallowed.

EU Safety Phrases: S46 - If swallowed, seek medical advice immediately and show this container or label.

OSHA Label:
DANGER
Harmful if swallowed.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B
16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

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

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End of Safety Data Sheet