



# MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.2

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

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CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

### 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

### Hazardous

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

Ingredient	CAS Number	EU EINECS List	%
Lactose Monohydrate	64044-51-5	Not listed	*

**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

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### 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.

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### 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/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

#### Magnesium Stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> 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.

#### Oxamniquine

Pfizer Occupational Exposure Band (OEB): OEB3 (control exposure to the range of >10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

**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

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### 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

##### **Lactose Monohydrate**

Rat	Oral	LD 50	29700 mg/kg
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##### **Sodium Lauryl Sulfate**

Rat	Oral	LD 50	1288 mg/kg
Rat	Intraperitoneal	LD 50	210 mg/kg

#### 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

##### **Magnesium Stearate**

13 Week(s)	Rat	Oral	1092 g/kg	LOAEL	Liver
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##### **Sodium Lauryl Sulfate**

3 Day(s)	Rat	Oral	75 mg/kg	LOAEL	Liver, Blood
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#### 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

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

##### **Oxamniquine**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Positive
Direct DNA Damage	Bacteria	Negative

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*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 exempted 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).

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## OSHA Label:

DANGER

Fatal if swallowed.

Causes damage to central nervous system.

## Canada - WHMIS: Classifications

### WHMIS hazard class:

Class D, Division 1, Subdivision A



### 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

## 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