



MATERIAL SAFETY DATA SHEET

Revision date: 23-Jan-2007

Version: 1.2

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

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

Material Name: Oxamniquine Oral Suspension

Trade Name: MANSIL; VANSIL
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antihelmintic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS List | % |
|-------------|------------|----------------|---|
| Oxamniquine | 21738-42-1 | 244-556-4 | 5 |
| Glycerol | 56-81-5 | 200-289-5 | * |

| Ingredient | CAS Number | EU EINECS List | % |
|-------------------|--------------|----------------|---|
| Agar | 9002-18-0 | 232-658-1 | * |
| SODIUM CHLORIDE | 7647-14-5 | 231-598-3 | * |
| Flavoring | NOT ASSIGNED | Not listed | * |
| Sodium saccharin | 128-44-9 | 204-886-1 | * |
| Sucrose | 57-50-1 | 200-334-9 | * |
| Sorbitol solution | 50-70-4 | 200-061-5 | * |
| Polysorbate 80 | 9005-65-6 | Not listed | * |
| Purified water | 7732-18-5 | 231-791-2 | * |

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

3. HAZARDS IDENTIFICATION

Appearance: Bright yellow suspension
Signal Word: DANGER

Statement of Hazard: Harmful if swallowed.

Additional Hazard Information:

Short Term: Not a skin irritant ; Not an eye irritant (based on components) .
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on kidneys, liver, lungs, blood, central nervous system.

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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.

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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

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

Sucrose

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

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 >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: Rubber gloves
Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection: 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: Suspension
Color: Yellow
Molecular Formula: Mixture
Molecular Weight: Mixture
pH: 7.0-9.0

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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

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 LD 50 3 g/kg
Mouse Oral LD 50 4 g/kg
Rabbit Dermal LD 50 > 10 g/kg

Polysorbate 80

Rat Oral LD50 25 g/kg

Glycerol

Rat Oral LD 50 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

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Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

12. ECOLOGICAL INFORMATION

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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



Oxamniquine
EU EINECS List 244-556-4

Agar
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

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| | |
|---|-----------|
| EU EINECS List | 232-658-1 |
| SODIUM CHLORIDE | |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS List | 231-598-3 |
| Glycerol | |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS List | 200-289-5 |
| Sodium saccharin | |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS List | 204-886-1 |
| Sucrose | |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS List | 200-334-9 |
| Sorbitol solution | |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS List | 200-061-5 |
| Polysorbate 80 | |
| Inventory - United States TSCA - Sect. 8(b) | XU |
| Australia (AICS): | Present |
| Purified water | |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS List | 231-791-2 |

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