



SAFETY DATA SHEET

Revision date: 12-Apr-2015

Version: 1.3

Page 1 of 11

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

Product Identifier

Material Name: Oxamniquine Oral Suspension

Trade Name: MANSIL; VANSIL

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as Anthelmintic

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
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Emergency telephone number:

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4

EU Classification:

EU Indication of danger: Harmful

EU Risk Phrases:

R22 - Harmful if swallowed.

Label Elements

Signal Word: Warning

Hazard Statements: H302 - Harmful if swallowed

Precautionary Statements:

P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P501 - Dispose of contents/container in accordance with all local and national regulations

SAFETY DATA SHEET

Material Name: Oxamniquine Oral Suspension
Revision date: 12-Apr-2015

Page 2 of 11
Version: 1.3



Other Hazards

No data available

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Oxamniquine	21738-42-1	244-556-4	T;R25	Acute Tox.2 (H300)	5
Glycerol	56-81-5	200-289-5	Not Listed	Not Listed	*

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

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

SAFETY DATA SHEET

Material Name: Oxamniquine Oral Suspension
Revision date: 12-Apr-2015

Page 3 of 11
Version: 1.3

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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Not determined

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: None identified

Specific end use(s): Pharmaceutical product

SAFETY DATA SHEET

Material Name: Oxamniquine Oral Suspension
Revision date: 12-Apr-2015

Page 4 of 11
Version: 1.3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

SODIUM CHLORIDE

Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

Glycerol

Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Czech Republic OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
Finland OEL - TWA	20 mg/m ³
France OEL - TWA	10 mg/m ³
Germany (DFG) - MAK	50 mg/m ³
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL - TWAs	50 mg/m ³

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³

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): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls

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 air contamination levels below the exposure limits or within the OEB range listed above in this section.

SAFETY DATA SHEET

Material Name: Oxamniquine Oral Suspension
Revision date: 12-Apr-2015

Page 5 of 11
Version: 1.3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves 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 protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Suspension	Color:	Yellow
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	7.0-9.0
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	

Oxamniquine

No data available

Agar

No data available

Sorbitol solution

No data available

Sodium saccharin

No data available

SODIUM CHLORIDE

No data available

Polysorbate 80

No data available

Glycerol

No data available

Flavoring

No data available

Sucrose

No data available

Purified water

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available

SAFETY DATA SHEET

Material Name: Oxamniquine Oral Suspension
Revision date: 12-Apr-2015

Page 6 of 11
Version: 1.3

Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	None known
Incompatible Materials:	None identified
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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.

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.

Acute Toxicity: (Species, Route, End Point, Dose)

Oxamniquine

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

Sorbitol solution

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

Sodium saccharin

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

SODIUM CHLORIDE

Rat	Sub-tenon injection (eye)	LC50/1hr	> 42 g/m ³
Rat	Oral	LD 50	3g/kg
Mouse	Oral	LD 50	4g/kg
Rabbit	Dermal	LD 50	> 10g/kg

SAFETY DATA SHEET

Material Name: Oxamniquine Oral Suspension
Revision date: 12-Apr-2015

Page 7 of 11
Version: 1.3

11. TOXICOLOGICAL INFORMATION

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

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

SAFETY DATA SHEET

Material Name: Oxamniquine Oral Suspension
Revision date: 12-Apr-2015

Page 8 of 11
Version: 1.3

11. TOXICOLOGICAL INFORMATION

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

Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* 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 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

Toxicity:

No data available

Persistence and Degradability:

No data available

Bio-accumulative Potential:

No data available

Mobility in Soil:

No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

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

The following refers to all modes of transportation unless specified below.

MANSIL ORAL SUSPENSION

SAFETY DATA SHEET

Material Name: Oxamniquine Oral Suspension
Revision date: 12-Apr-2015

Page 9 of 11
Version: 1.3

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Oxamniquine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	244-556-4

Agar

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-658-1

SODIUM CHLORIDE

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Flavoring

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Glycerol

SAFETY DATA SHEET

Material Name: Oxamniquine Oral Suspension
Revision date: 12-Apr-2015

Page 10 of 11
Version: 1.3

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex V - Exemptions from the obligations of Register:	Not Listed Not Listed Present Present Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
EU EINECS/ELINCS List	200-289-5
Sodium saccharin	
CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List	Not Listed Not Listed Present Present 204-886-1
Sucrose	
CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List	Not Listed Not Listed Present Present Present 200-334-9
Sorbitol solution	
CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List	Not Listed Not Listed Present Present Present 200-061-5
Polysorbate 80	
CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List	Not Listed Not Listed Present Present Not Listed
Purified water	
CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS):	Not Listed Not Listed Present Present

SAFETY DATA SHEET

Material Name: Oxamniquine Oral Suspension
Revision date: 12-Apr-2015

Page 11 of 11
Version: 1.3

15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed

T - Toxic

R25 - Toxic if swallowed.

Data Sources:

Safety data sheets for individual ingredients. Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision:

Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

Revision date:

12-Apr-2015

Prepared by:

Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet