



MATERIAL SAFETY DATA SHEET

Revision date: 12-Mar-2010

Version: 1.1

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

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Material Name: Pyrantel Pamoate Suspension

Trade Name: COMBANTRIN
Chemical Family: Tetrahydropyrimidine
Intended Use: Pharmaceutical product used as anti-worm agent (anthelmintic)

2. HAZARDS IDENTIFICATION

Appearance: Liquid suspension

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Short Term: May cause mild eye irritation. (based on components) .
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on gastrointestinal system, liver.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including nausea, vomiting, abdominal cramps, anorexia, diarrhea, and constipation. Occasional, transient changes reported in liver function tests, but no liver damage seen.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Pyrantel pamoate	22204-24-6	244-837-1	Not Listed	5
Lecithin	8002-43-5	232-307-2	Not Listed	*
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Magnesium aluminum silicate	1327-43-1	215-478-8	Not Listed	*

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Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Citric acid monohydrate	5949-29-1	Not listed	Not Listed	*
Povidone	9003-39-8	Not listed	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	*
Sorbitol	6706-59-8	Not listed	Not Listed	*
Polysorbate 80	9005-65-6	Not listed	Not Listed	*
Flavor	NOT ASSIGNED	Not listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
Antifoam Emulsion	Mixture	Not listed	Not Listed	*

Additional Information:

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

4. FIRST AID MEASURES

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- 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.

5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

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.

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7. HANDLING AND STORAGE

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Pyrantel pamoate

Pfizer OEL TWA-8 Hr: 300µg/m³

Glycerin, USP

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	50 mg/m ³ MAK
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELs - TWAs:	15 mg/m ³ total 5 mg/m ³
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Magnesium aluminum silicate

Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed

Analytical Method:

Engineering Controls:

Environmental Exposure Controls:

Personal Protective Equipment:

Analytical method available for pyrantel pamoate. Contact Pfizer Inc for further information.

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 airborne contamination levels below the exposure limits listed above in this section.

Refer to specific Member State legislation for requirements under Community environmental legislation.

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:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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9. PHYSICAL AND CHEMICAL PROPERTIES

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

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

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)

Sodium benzoate

Rat	Oral	LD50	4,070 mg/kg
Mouse	Oral	LD50	1600 mg/kg

Glycerin, USP

Mouse	Oral	LD50	4090 mg/kg
Rat	Oral	LD50	12.6 g/kg
Rabbit	Dermal	LD50	> 10 g/kg
Rat	Inhalation	LC50 1hr	> 570 mg/m ³
Rat	Dermal	LD 50	>21.9 g/kg

Polysorbate 80

Rat	Oral	LD50	25 g/kg
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Lecithin

Rat	Oral	LD50	> 8 ml/kg
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Pyrantel pamoate

Mouse	Oral	LD50	> 24 g/kg
Rat	Oral	LD50	> 24 g/kg
Mouse	Intraperitoneal	LD50	620 mg/kg
Rat	Intraperitoneal	LD50	535 mg/kg

Povidone

Rat	Oral	LD50	100 g/kg
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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.

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11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

Glycerin, USP

Eye Irritation Rabbit Mild

Citric acid monohydrate

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

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

Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOEL Liver Kidney Blood Ureter Bladder

Pyrantel pamoate

1 Month(s) Rat Oral 500 mg/kg/day NOEL None identified
1 Month(s) Dog Oral 50 mg/kg/day LOEL Gastrointestinal system Liver
13 Week(s) Rat Oral 300 mg/kg/day NOEL None identified
13 Week(s) Dog Oral 100 mg/kg/day NOEL Gastrointestinal system Liver

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Sodium benzoate

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

Pyrantel pamoate

Reproductive & Fertility Rat Oral 250 mg/kg NOEL No effects at maximum dose
Prenatal & Postnatal Development Rat Oral 250 mg/kg NOEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 250 mg/kg NOEL Not Teratogenic
Embryo / Fetal Development Rabbit Oral 250 mg/kg NOEL Not Teratogenic

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

Pyrantel pamoate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Povidone

IARC: Group 3

12. ECOLOGICAL INFORMATION

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

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LD50 96 Hours 50 mg/L
Daphnia magna (Water Flea) EC50 24 Hours >500 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

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.

Pyrantel pamoate

Australia (AICS):	Listed
EU EINECS/ELINCS List	244-837-1

Citric acid monohydrate

Australia (AICS):	Listed
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Povidone

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

Lecithin

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

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15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-307-2
Sodium benzoate	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	208-534-8
Glycerin, USP	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-289-5
Magnesium aluminum silicate	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	215-478-8
Polysorbate 80	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Water, purified	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.
Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 7 - Handling and Storage.
Prepared by:	Toxicology and 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 warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet