



MATERIAL SAFETY DATA SHEET

Revision date: 09-Jan-2009

Version: 1.0

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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: Veterinary 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

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Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
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	*

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	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
Flavor	NOT ASSIGNED	Not listed	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.

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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 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.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

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 TWA
Belgium 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	= 10 mg/m ³ TWA
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total = 5 mg/m ³ TWA
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: 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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

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

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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/m³
Rat Dermal LD 50 >21.9 g/kg

Polysorbate 80

Rat Oral LD50 25 g/kg

Lecithin

Rat Oral LD50 > 8 ml/kg

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

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)

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 LOAEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver Kidney Blood Ureter Bladder

Pyrantel pamoate

1 Month(s) Rat Oral 500 mg/kg/day NOAEL None identified
1 Month(s) Dog Oral 50 mg/kg/day LOAEL Gastrointestinal system Liver

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13 Week(s)	Rat	Oral	300 mg/kg/day	NOAEL	None identified
13 Week(s)	Dog	Oral	100 mg/kg/day	NOAEL	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
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Pyrantel pamoate

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

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

Pyrantel pamoate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
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Carcinogen Status:

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

Povidone

IARC: Group 3 (Not Classifiable)

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

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

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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):	Present
EU EINECS/ELINCS List	244-837-1

Citric acid monohydrate

Australia (AICS):	Present
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Povidone

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

Lecithin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
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)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8

Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-289-5

Magnesium aluminum silicate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-478-8

Polysorbate 80

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

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

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

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End of Safety Data Sheet