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

Product Identifier

Material Name: Pyrantel Pamoate Suspension

Trade Name: COMBANTRIN; VERMINTEL; QUANTREL; HELMEX

Chemical Family: Tetrahydropyrimidine

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

Intended Use: Pharmaceutical product used as anti-worm agent (anthelmintic)

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

EU Classification:
EU Indication of danger: Not classified

Label Elements

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

Other Hazards

No data available

Australian Hazard Classification (NOHSC):

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 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

PZ00929
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyrantel pamoate</td>
<td>22204-24-6</td>
<td>244-837-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>5</td>
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<tr>
<td>Lecithin</td>
<td>8002-43-5</td>
<td>232-307-2</td>
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<td>*</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
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<td>Not Listed</td>
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<tr>
<td>Magnesium aluminum silicate</td>
<td>1327-43-1</td>
<td>215-478-6</td>
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<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Citric acid monohydrate</td>
<td>5949-29-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
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<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sorbitol</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 80</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Flavor</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Antifoam Emulsion</td>
<td>Mixture</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.

4. FIRST AID MEASURES

Description of 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.

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:
Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards:
Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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). 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Pyrantel pamoate
Pfizer OEL TWA-8 Hr: 300µg/m³

Glycerin, USP
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Czech Republic OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
Finland OEL - TWA 20 mg/m³
France OEL - TWA 10 mg/m³
Germany (DFG) - MAK 50 mg/m³
Greece OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Poland OEL - TWA 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Analytical Method:
Analytical method available for Pyrantel pamoate. Contact Pfizer Inc for further information.

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

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:
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
Odor: No data available.
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Sodium benzoate
No data available
Sorbitol
No data available
Water, purified
No data available
Polysorbate 80
No data available
Pyrantel pamoate
No data available
Citric acid monohydrate
No data available
Povidone
No data available
Flavor
No data available
Antifoam Emulsion
No data available
Lecithin
No data available
## 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium aluminum silicate</td>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Flammability</td>
<td>Autoignition Temperature (Solid) (°C): No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flammability (Solids): No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flash Point (Liquid) (°C): No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Upper Explosive Limits (Liquid) (% by Vol.): No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lower Explosive Limits (Liquid) (% by Vol.): No data available</td>
</tr>
</tbody>
</table>

### Polymerization
Will not occur

## 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Reactivity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium aluminum silicate</td>
<td>Reactivity</td>
<td>No data available</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>Chemical Stability</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td></td>
<td>Possibility of Hazardous Reactions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oxidizing Properties</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Conditions to Avoid</td>
<td>Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.</td>
</tr>
<tr>
<td></td>
<td>Incompatible Materials</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td></td>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
</tr>
</tbody>
</table>

## 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:
May cause mild eye irritation. May cause slight skin 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.

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

#### Sodium benzoate
- **Rat** Oral LD50 4,070 mg/kg
- **Mouse** Oral LD50 1600mg/kg

#### Polysorbate 80
- **Rat** Oral LD50 25 g/kg
11. TOXICOLOGICAL INFORMATION

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

Povidone
Rat Oral LD50 100 g/kg

Lecithin
Rat Oral LD50 > 8 ml/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

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)

Citric acid monohydrate
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Glycerin, USP
Eye 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
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

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
11. TOXICOLOGICAL INFORMATION

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)  *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 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

Toxicity:
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.

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.

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:
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
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
EU EINECS/ELINCS List 244-837-1

Lecithin
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
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

Glycerin, USP
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex V - Exemptions from the obligations of Register: 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

Magnesium aluminum silicate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
### 15. REGULATORY INFORMATION

**Aussie (AICS):**

EU EINECS/ELINCS List: Present

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**Citric acid monohydrate**

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

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**Povidone**

- 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: Not Listed

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**Sodium benzoate**

- 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: 208-534-8

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**Sorbitol**

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

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**Polysorbate 80**

- 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: Not Listed

---

**Flavor**

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

---

**Water, purified**

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- 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: 231-791-2

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**Antifoam Emulsion**

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed
15. REGULATORY INFORMATION

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 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information.

Revision date: 06-Nov-2014

Prepared by: Product Stewardship Hazard Communication

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