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

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


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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>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>5</td>
</tr>
<tr>
<td>Lecithin</td>
<td>8002-43-5</td>
<td>232-307-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td>1327-43-1</td>
<td>215-478-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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.
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/m³ TWA
Australia TWA 10 mg/m³
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/m³ MAK
Greece OEL - TWA Listed
Ireland OEL - TWAs Listed
OSHA - Final PELS - TWAs: 15 mg/m³ total
Poland OEL - TWA Listed
Portugal OEL - TWA Listed
Spain OEL - TWA Listed

Magnesium aluminum silicate

Bulgaria OEL - TWA Listed
Czech Republic OEL - TWA Listed


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.

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.

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
Molecular Formula: Mixture
Color: No data available.
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/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.
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  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
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

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.
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.

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

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

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

Lecithin
Inventory - United States TSCA - Sect. 8(b): Listed
Australia (AICS): Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance/Preparation</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium benzoate</td>
<td>Listed</td>
<td>232-307-2</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>Listed</td>
<td>208-534-8</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td>Listed</td>
<td>200-289-5</td>
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<td>Polysorbate 80</td>
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</tr>
<tr>
<td>Water, purified</td>
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</tbody>
</table>

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

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End of Safety Data Sheet