

# SAFETY DATA SHEET



Revision date: 29-May-2015

Version: 4.4

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

### Product Identifier

**Material Name:** Pyrantel pamoate oral suspension

**Trade Name:** Nemex, Banminth, NEMEX-2 SUSPENSION, RFD LIQUID WORMER  
**Synonyms:** BANMINTH/NEMEX (PYRANTEL) SUSPENSION  
**Chemical Family:** Tetrahydropyrimidine

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

**Intended Use:** Veterinary product used as anti-worm agent (anthelmintic)  
**Restrictions on Use:** Not for human use

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

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

**Emergency telephone number:**  
International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Yellow suspension  
**Classification of the Substance or Mixture**  
**GHS - Classification** Not classified as hazardous

**EU Classification:**  
EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Not Classified  
**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

**Short Term:** May cause mild eye irritation. (based on components) .  
**Long Term:** May cause effects on gastrointestinal system, liver through prolonged or repeated exposure.  
**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.

### Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

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**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	%
Pyrantel pamoate	22204-24-6	244-837-1	Not Listed	Not Listed	</= 2.27
Magnesium aluminum silicate	1327-43-1	215-478-8	Not Listed	Not Listed	1
Glycerin, USP	56-81-5	200-289-5	Not Listed	Not Listed	1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sorbitol	6706-59-8	Not Listed	Not Listed	Not Listed	*
Lecithin	8002-43-5	232-307-2	Not Listed	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	*
Water, purified	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.

### 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

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### 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**

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

**Storage Temperature:** Store at or below 30°C (86°F).

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

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

**Pyrantel pamoate**

**Zoetis OEL TWA 8-hr** 300µg/m<sup>3</sup>

**Glycerin, USP**

**Australia TWA** 10 mg/m<sup>3</sup>

**Belgium OEL - TWA** 10 mg/m<sup>3</sup>

**Czech Republic OEL - TWA** 10 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Exposure Controls

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Suspension	<b>Color:</b>	Yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	4.5-6.0		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>	No data available		
<b>Flammability (Solids):</b>	No data available		
<b>Flash Point (Liquid) (°C):</b>	No data available		
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available		
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available		

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Polymerization: Will not occur

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** None  
**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  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.  
Routes of exposure: eye contact , skin contact

#### 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

##### **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<sup>3</sup>  
Rat Dermal LD 50 > 21.9 g/kg

##### **Pyrantel pamoate**

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

##### **Lecithin**

Rat Oral LD50 > 8 ml/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)

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### 11. TOXICOLOGICAL INFORMATION

#### Glycerin, USP

Eye Irritation Rabbit Mild

**Irritation / Sensitization Comments:** May cause mild eye irritation.

#### 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,
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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.

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### 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**

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LD50	96 Hours	50 mg/L
<i>Daphnia magna</i> (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

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### 15. REGULATORY INFORMATION

**WHMIS hazard class:**

Non-controlled

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

**Sorbitol**

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

**Pyrantel pamoate**

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

**Magnesium aluminum silicate**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	215-478-8

**Glycerin, USP**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present

<b>REACH - Annex V - Exemptions from the obligations of Register:</b>	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
<b>EU EINECS/ELINCS List</b>	200-289-5

**Lecithin**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>REACH - Annex IV - Exemptions from the obligations of Register:</b>	Present
<b>EU EINECS/ELINCS List</b>	232-307-2

**Sodium benzoate**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present

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### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8

#### 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

#### 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

### 16. OTHER INFORMATION

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**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.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this 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**