This SDS packet was issued with item:

078926029

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078391483 078926030

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078057148 078057155 078856641 078856658



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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)

1930 Zaventem

1930 Zaventem

Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896 Belgium

Product Support/Technical Services Phone: 1-800-366-5288

Emergency telephone number: Emergency telephone number:

Contact E-Mail: VMIPSrecords@zoetis.com

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</td
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	EU Classification	GHS	%
		EINECS/ELINCS		Classification	
		List			
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.

None known

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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Exposure: Identification and/or Section 11 - Toxicological Information.

Medical Conditions

Aggravated by Exposure:

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 Formation of toxic gases is possible during heating or fire.

Products:

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

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill Measures for Cleaning /

area thoroughly. Collecting:

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

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

Store as directed by product packaging. **Storage Conditions:**

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

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/m³

Glycerin, USP

Australia TWA 10 mg/m³ 10 ma/m³ **Belgium OEL - TWA** 10 mg/m³ Czech Republic OEL - TWA

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA 10 mg/m³ **Finland OEL - TWA** 20 mg/m³ France OEL - TWA 10 mg/m³ 50 mg/m³ Germany (DFG) - MAK **Greece OEL - TWA** 10 mg/m³ 10 mg/m³ **Ireland OEL - TWAs OSHA - Final PELS - TWAs:** 15 mg/m³ Poland OEL - TWA 10 mg/m^3 10 mg/m³ Portugal OEL - TWA Spain OEL - TWA 10 mg/m³ Switzerland OEL -TWAs 50 mg/m³

Exposure Controls

Engineering controls should be used as the primary means to control exposures. Keep **Engineering Controls:**

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.

Personal Protective

Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE). **Equipment:**

Impervious gloves are recommended if skin contact with drug product is possible and for bulk Hands:

processing operations.

Wear safety glasses or goggles if eye contact is possible. Eyes:

Impervious protective clothing is recommended if skin contact with drug product is possible and Skin:

for bulk processing operations.

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate Respiratory protection:

respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Yellow **Physical State:** Suspension Color:

No data available. Odor: **Odor Threshold:** No data available.

Molecular Formula: Mixture **Molecular Weight:** Mixture

Solvent Solubility: No data available Water Solubility: No data available

4.5-6.0 pH:

Melting/Freezing Point (°C): No data available **Boiling Point (°C):** No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

No data available. **Decomposition Temperature (°C):**

Evaporation Rate (Gram/s): No data available Vapor Pressure (kPa): No data available No data available Vapor Density (g/ml): No data available **Relative Density:** No data available Viscosity:

Flammablity:

170

No data available Autoignition Temperature (Solid) (°C): Flammability (Solids): No data available Flash Point (Liquid) (°C): No data available Upper Explosive Limits (Liquid) (% by Vol.): No data available Lower Explosive Limits (Liquid) (% by Vol.): 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 No data available

Products:

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.

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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/m³
Rat Dermal LD 50 > 21.9 g/kg

Pyrantel pamoate

Mouse Oral LD50 > 24 g/kg Rat Oral LD50 > 24g/kg Mouse Intraperitoneal LD50 620n

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,

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.

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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

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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

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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

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Pyrantel pamoate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

244-837-1

Magnesium aluminum silicate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Present

215-478-8

Glycerin, USP

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

Present

REACH - Annex V - Exemptions from the obligations of Register:

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

Present if not chemically modified, except they meet the criteria for

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equivalent level of concern

EU EINECS/ELINCS List 200-289-5

Lecithin

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the

Not Listed

Not Listed

Not Listed

Not Listed

Present

obligations of Register:

EU EINECS/ELINCS List 232-307-2

Sodium benzoate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Not Listed
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

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Water, purified

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the obligations of Register:

EU EINECS/ELINCS List

Not Listed

Present

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