This SDS packet was issued with item:

078057148

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 078926029 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).

078057155 078856641 078856658



Revision date: 14-Mar-2007

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IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health

Pfizer Inc

235 East 42nd Street New York, NY 10017

Poison Control Center Phone: 1-866-531-8896 Technical Services Phone: 1-800-366-5288

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Pfizer Ltd.

Kent

CT13 9NJ

United Kingdom

+00 44 (0)1304 616161

Emergency telephone number:

ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Pyrantel Pamoate Tablets

Trade Name: **Chemical Family:** PYR-A-PAM; NEMEX; CANEX

Mixture

Intended Use:

Veterinary product used as anti-worm agent (anthelmintic)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Pyrantel pamoate	22204-24-6	244-837-1	78
Sodium lauryl sulfate	151-21-3	205-788-1	*
Magnesium Stearate	557-04-0	209-150-3	*
Corn Starch	9005-25-8	232-679-6	*

Ingredient	CAS Number	EU EINECS List	%
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	*
Alginic acid	9005-32-7	232-680-1	*

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety.

3. HAZARDS IDENTIFICATION

Appearance:

Round, convex orange tablet

Statement of Hazard:

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

Additional Hazard Information:

Short Term:

An Occupational Exposure Limit has been established for one or more of the ingredients (see

Section 8).

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

Material Name: Pyrantel Pamoate Tablets

Revision date: 14-Mar-2007 Version: 1.1

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.

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4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get

medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs

or persists, get 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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other

sulfur-containing compounds.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn

out gear. Evacuate area and fight fire from a safe distance.

Fire / Explosion Hazards: Not applicable

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 spilled material by a method that

controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of

dry solids. 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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with

eyes, skin, and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Pyrantel pamoate

Material Name: Pyrantel Pamoate Tablets

Revision date: 14-Mar-2007

Pfizer OEL TWA-8 Hr:

0.3 mg/m3

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr:

0.3 mg/m³

Pfizer STEL

0.75 mg/m³

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)

= 10 mg/m3 TWA

except stearates of toxic metals

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Australia TWA

= 10 mg/m3 TWA

Corn Starch

OSHA - Final PELS - TWAs:

 $= 15 \text{ mg/m}^3 \text{ TWA}$ total

 $= 5 \text{ mg/m}^3 \text{ TWA}$

ACGIH Threshold Limit Value (TWA)

= 10 mg/m3 TWA

Australia TWA

= 10 mg/m3 TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Local and

general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment:

Hands:

Not required for the normal use of this product. Wear protective gloves when working with

large quantities.

Eyes:

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is

possible.

Skin:

Not required for the normal use of this product. Wear protective clothing when working with

large quantities.

Respiratory protection:

Not required for the normal use of this product. 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:

Tablets

Color:

Orange

Molecular Formula:

Mixture

Molecular Weight:

Mixture

10. STABILITY AND REACTIVITY

Stability:

Stable under normal conditions of use.

Conditions to Avoid:

None known

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

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

Pyrantel pamoate

Mouse Oral LD50 > 24 g/kg

Material Name: Pyrantel Pamoate Tablets

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Rat Oral LD50 > 24 g/kg

Mouse Intraperitoneal LD50 620 mg/kg Rat Intraperitoneal LD50 535 mg/kg

Alginic acid

Rat Oral LD50 > 5 g/kg

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/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)

Sodium lauryl sulfate

Eye Irritation Rabbit Severe Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

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

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

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.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to

the environment should be avoided.

Material Name: Pyrantel Pamoate Tablets

Revision date: 14-Mar-2007

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13. DISPOSAL CONSIDERATIONS

Disposal Procedures:

Dispose of waste in accordance with all applicable laws and regulations.

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.

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): EU EINECS List Present 244-837-1

Sodium lauryl sulfate

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

Present Present 205-788-1

Australia (AICS): EU EINECS List

FD&C yellow No.6 aluminum lake

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

Present Present 239-888-1

Australia (AICS): EU EINECS List

Magnesium Stearate

Present

Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List

Present 209-150-3

Corn Starch

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

XU Present

Australia (AICS): EU EINECS List

232-679-6

Material Name: Pyrantel Pamoate Tablets

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Alginic acid

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

ΧU

Australia (AICS): EU EINECS List Present

232-680-1

16. OTHER INFORMATION

Prepared by:

Toxicology and Hazard Communication Pfizer Global Environment, Health, and Safety

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet



Revision date: 03-Jun-2014 Version: 2.1 Page 1 of 8

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

Product Identifier

Material Name: Pyrantel Pamoate Tablets

Trade Name: PYR-A-PAM; NEMEX; CANEX

Chemical Family: Mixture

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

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

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 Control 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: VMIPS records@zoetis.com

IPSrecords@zoetis.com

Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Round, convex orange tablet

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

Other Hazards

Short Term: May be harmful if swallowed. May produce allergic reactions following skin contact. **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.

Australian Hazard Classification

(NOHSC):

PZ00502

Non-Hazardous Substance. Non-Dangerous Goods.

Material Name: Pyrantel Pamoate Tablets

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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	EU Classification	GHS Classification	%
		List		Glassification	
Pyrantel pamoate	22204-24-6	244-837-1	Not Listed	Not Listed	78
Sodium Lauryl Sulfate	151-21-3	205-788-1	Xn R22	Acute Tox 4 (H302)	<1
			T R24	Acute Tox 3 (H311)	
Magnesium Stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	Not Listed	Not Listed	*
Alginic acid	9005-32-7	232-680-1	Not Listed	Not Listed	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get

medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs

or persists, get 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

Aggravated by Exposure:

No data available

Exposure:

Medical Conditions

None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

Material Name: Pyrantel Pamoate Tablets Page 3 of 8
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5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

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

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water

used to fight fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Avoid dust formation. 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 / Cor

Collecting:

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of

dry solids. 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 proper personal protective equipment as specified in Section 8. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. 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.

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

PZ00502

Zoetis OEL TWA 8-hr 300µg/m³

Sodium Lauryl Sulfate

Zoetis OEL TWA 8-hr 300µg/m³

Material Name: Pyrantel Pamoate Tablets Page 4 of 8
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium Stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Corn Starch

ACGIH Threshold Limit Value (TWA) 10 mg/m³ 10 mg/m³ **Australia TWA Belgium OEL - TWA** 10 mg/m³ 10.0 mg/m³ **Bulgaria OEL - TWA** 4.0 mg/m^{3} Czech Republic OEL - TWA **Greece OEL - TWA** 10 mg/m³ 5 mg/m^3 Ireland OEL - TWAs 10 mg/m³ 4 mg/m^3 **OSHA - Final PELS - TWAs:** 15 mg/m³

OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³

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.

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

Equipment: protective equipment (PPE).

Hands: Wear impervious gloves if skin contact is possible.

Eyes: Safety glasses or goggles

Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and

laboratory areas.

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: Tablets Color: Orange

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

Molecular Formula: Mixture Molecular Weight: Mixture

Solvent Solubility:
Water Solubility:
PH:
No data available
No data available
No data available.
No data available.
No data available.
No data available
No data available
Partition Coefficient: (Method, pH, Endpoint, Value)

Partition Coemcient: (wethod, pri, Endpoint, value)

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

No data available

No data available

Material Name: Pyrantel Pamoate Tablets Page 5 of 8
Revision date: 03-Jun-2014 Version: 2.1

Relative Density:

Viscosity:

No data available

No data available

Flammablity:

Autoignition Temperature (Solid) (°C):No data availableFlammability (Solids):No data availableFlash Point (Liquid) (°C):No data availableUpper Explosive Limits (Liquid) (% by Vol.):No data availableLower Explosive Limits (Liquid) (% by Vol.):No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

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 fully investigated. The information included in this section describes the potential hazards of the individual ingredients.

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

Pyrantel pamoate

Mouse Oral LD50 > 24 g/kg Rat Oral LD50 > 24g/kg

Mouse Intraperitoneal LD50 620mg/kg Rat Intraperitoneal LD50 535mg/kg

Alginic acid

Rat Oral LD50 > 5 g/kg

Sodium Lauryl Sulfate

Rat Oral LD50 977 mg/kg Rabbit Dermal LD50 580mg/kg Rat Inhalation LC50 > 3900mg/m³ 1 h

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.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

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

PZ00502

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Material Name: Pyrantel Pamoate Tablets

Revision date: 03-Jun-2014 Version: 2.1

11. TOXICOLOGICAL INFORMATION

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Pyrantel pamoate

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

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to

the environment should be avoided.

Toxicity: No data available

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.

Material Name: Pyrantel Pamoate Tablets Page 7 of 8
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Revision date: 03-Jun-2014 Version: 2.1

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

Sodium Lauryl Sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 6
for Drugs and Poisons:	

for Drugs and Poisons:

EU EINECS/ELINCS List 205-788-1

FD&C yellow No.6 aluminum lake

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	239-888-1

Magnesium Stearate

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	209-150-3

Corn Starch

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

PZ00502

Material Name: Pyrantel Pamoate Tablets Page 8 of 8
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15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the Present

obligations of Register: EU EINECS/ELINCS List

232-679-6

Alginic acid

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

232-680-1

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H302 - Harmful if swallowed H311 - Toxic in contact with skin

T - Toxic Xn - Harmful

R22 - Harmful if swallowed. R24 - Toxic in contact with skin.

Data Sources: The data contained in this MSDS 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 5 - Fire Fighting Measures. Updated Section 7 - Handling and

Storage. Updated Section 8 - Exposure Controls / Personal Protection.

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

PZ00502



Revision date: 03-Jun-2014 Version: 2.1 Page 1 of 8

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

Product Identifier

Material Name: Pyrantel Pamoate Tablets

PYR-A-PAM; NEMEX; CANEX **Trade Name:**

Chemical Family: Mixture

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

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

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 Control 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: Round, convex orange tablet

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

Other Hazards

Short Term: May be harmful if swallowed. May produce allergic reactions following skin contact. Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on

gastrointestinal system, liver,

Ingestion of this material may cause effects similar to those seen in clinical use including **Known Clinical Effects:**

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):

PZ00502

Non-Hazardous Substance. Non-Dangerous Goods.

Material Name: Pyrantel Pamoate Tablets

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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	EU Classification	GHS Classification	%
		List		Glassification	
Pyrantel pamoate	22204-24-6	244-837-1	Not Listed	Not Listed	78
Sodium Lauryl Sulfate	151-21-3	205-788-1	Xn R22	Acute Tox 4 (H302)	<1
			T R24	Acute Tox 3 (H311)	
Magnesium Stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	Not Listed	Not Listed	*
Alginic acid	9005-32-7	232-680-1	Not Listed	Not Listed	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get

medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs

or persists, get 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

Aggravated by Exposure:

No data available

Exposure:

Medical Conditions

None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

Material Name: Pyrantel Pamoate Tablets

Revision date: 03-Jun-2014 Version: 2.1

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

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

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water

used to fight fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Avoid dust formation. 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 / Contain

Collecting:

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of

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dry solids. 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 proper personal protective equipment as specified in Section 8. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. 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.

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

PZ00502

Zoetis OEL TWA 8-hr 300µg/m³

Sodium Lauryl Sulfate

Zoetis OEL TWA 8-hr 300µg/m³

Material Name: Pyrantel Pamoate Tablets Page 4 of 8
Revision date: 03-Jun-2014 Version: 2.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium Stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Corn Starch

ACGIH Threshold Limit Value (TWA) 10 mg/m³ 10 mg/m³ **Australia TWA Belgium OEL - TWA** 10 mg/m³ 10.0 mg/m³ **Bulgaria OEL - TWA** 4.0 mg/m^{3} Czech Republic OEL - TWA **Greece OEL - TWA** 10 mg/m³ 5 mg/m^3 Ireland OEL - TWAs 10 mg/m³ 4 mg/m^3 **OSHA - Final PELS - TWAs:** 15 mg/m³ 10 ma/m³ Portugal OEL - TWA

Exposure Controls

Slovakia OEL - TWA

Switzerland OEL -TWAs

Spain OEL - TWA

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

4 mg/m³ 10 mg/m³

 3 mg/m^3

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

Equipment: protective equipment (PPE).

Hands: Wear impervious gloves if skin contact is possible.

Eyes: Safety glasses or goggles

Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and

laboratory areas.

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: Tablets Color: Orange

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

Molecular Formula: Mixture Molecular Weight: Mixture

Solvent Solubility:

Water Solubility:

PH:

No data available

No data available.

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

No data available

No data available

PZ00502

Material Name: Pyrantel Pamoate Tablets Page 5 of 8
Revision date: 03-Jun-2014 Version: 2.1

Relative Density:

Viscosity:

No data available

No data available

Flammablity:

Autoignition Temperature (Solid) (°C):No data availableFlammability (Solids):No data availableFlash Point (Liquid) (°C):No data availableUpper Explosive Limits (Liquid) (% by Vol.):No data availableLower Explosive Limits (Liquid) (% by Vol.):No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

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 fully investigated. The information

included in this section describes the potential hazards of the individual ingredients.

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

Pyrantel pamoate

Mouse Oral LD50 > 24 g/kg Rat Oral LD50 > 24g/kg

Mouse Intraperitoneal LD50 620mg/kg Rat Intraperitoneal LD50 535mg/kg

Alginic acid

Rat Oral LD50 > 5 g/kg

Sodium Lauryl Sulfate

Rat Oral LD50 977 mg/kg Rabbit Dermal LD50 580mg/kg Rat Inhalation LC50 > 3900mg/m³ 1 h

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.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Pyrantel pamoate

PZ00502

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

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Material Name: Pyrantel Pamoate Tablets

Revision date: 03-Jun-2014 Version: 2.1

11. TOXICOLOGICAL INFORMATION

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Pyrantel pamoate

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

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to

the environment should be avoided.

Toxicity: No data available

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.

PZ00502

Material Name: Pyrantel Pamoate Tablets Page 7 of 8 Revision date: 03-Jun-2014 Version: 2.1

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 244-837-1 **EU EINECS/ELINCS List**

Sodium Lauryl Sulfate

CERCLA/SARA 313 Emission reporting Not Listed **California Proposition 65** Not Listed Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present Standard for the Uniform Scheduling Schedule 6 for Drugs and Poisons:

205-788-1 **EU EINECS/ELINCS List**

FD&C yellow No.6 aluminum lake

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** 239-888-1

Magnesium Stearate

CERCLA/SARA 313 Emission reporting Not Listed **California Proposition 65** Not Listed Present Inventory - United States TSCA - Sect. 8(b) Australia (AICS): Present 209-150-3 **EU EINECS/ELINCS List**

Corn Starch

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

Material Name: Pyrantel Pamoate Tablets Page 8 of 8
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15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the

obligations of Register: EU EINECS/ELINCS List

232-679-6

Present

Alginic acid

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

232-680-1

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H302 - Harmful if swallowed H311 - Toxic in contact with skin

T - Toxic Xn - Harmful

R22 - Harmful if swallowed. R24 - Toxic in contact with skin.

Data Sources: The data contained in this MSDS 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 5 - Fire Fighting Measures. Updated Section 7 - Handling and

Storage. Updated Section 8 - Exposure Controls / Personal Protection.

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

PZ00502



Revision date: 29-May-2015 Version: 4.4 Page 1 of 9

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

Product Identifier

Material Name: Pyrantel pamoate oral suspension

Nemex, Banminth, NEMEX-2 SUSPENSION, RFD LIQUID WORMER **Trade Name:**

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 Belgium S.A. Zoetis Inc. 100 Campus Drive, P.O. Box 651 Mercuriusstraat 20 Florham Park, New Jersey 07932 (USA) 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:

CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887

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.

Material Name: Pyrantel pamoate oral suspension Page 2 of 9
Revision date: 29-May-2015 Version: 4.4

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</th
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.

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 None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

Material Name: Pyrantel pamoate oral suspension

Revision date: 29-May-2015 Version: 4.4

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

Material Name: Pyrantel pamoate oral suspension Page 4 of 9 Revision date: 29-May-2015 Version: 4.4

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:

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

Material Name: Pyrantel pamoate oral suspension

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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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Material Name: Pyrantel pamoate oral suspension

Revision date: 29-May-2015 Version: 4.4

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.

Material Name: Pyrantel pamoate oral suspension

Revision date: 29-May-2015 Version: 4.4

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

Page 7 of 9

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

Material Name: Pyrantel pamoate oral suspension

Revision date: 29-May-2015 Version: 4.4

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

Material Name: Pyrantel pamoate oral suspension Page 9 of 9
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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

Not Listed

Not Listed

Not Listed

Not Listed

Present

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