

# SAFETY DATA SHEET



Revision date: 11-Apr-2014

Version: 3.0

Page 1 of 10

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

### Product Identifier

**Material Name:** Pyrantel Pamoate, Oxantel Pamoate and Praziquantel Tablets

**Trade Name:** CAZITEL

**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:** Pale yellow round 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:** Toxicity following ingestion is not expected. However, ingestion should be avoided.  
**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. Central nervous system effects such as dizziness, headache, insomnia, irritability and weakness have also been reported.

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**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.

## SAFETY DATA SHEET

Material Name: Pyrantel Pamoate, Oxantel Pamoate and Praziquantel Tablets  
Revision date: 11-Apr-2014

Page 2 of 10

Version: 3.0

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Febantel	58306-30-2	261-205-0	Not Listed	Not Listed	*
Pyrantel pamoate	22204-24-6	244-837-1	Not Listed	Not Listed	*
Praziquantel	55268-74-1	259-559-6	Not Listed	Acute Tox 5 (H303)	*
Sodium Lauryl Sulfate	151-21-3	205-788-1	Xn R22 T R24	Acute Tox 4 (H302) Acute Tox 3 (H311)	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
Flavor	NOT ASSIGNED	Not Listed	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:** 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

## SAFETY DATA SHEET

Material Name: Pyrantel Pamoate, Oxantel Pamoate and  
Praziquantel Tablets  
Revision date: 11-Apr-2014

Page 3 of 10

Version: 3.0

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

**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 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**

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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**

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

**Sodium Lauryl Sulfate**

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

## SAFETY DATA SHEET

Material Name: Pyrantel Pamoate, Oxantel Pamoate and  
Praziquantel Tablets  
Revision date: 11-Apr-2014

Page 4 of 10

Version: 3.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Magnesium stearate**

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

**Colloidal silicon dioxide**

Australia TWA	2 mg/m <sup>3</sup>
Austria OEL - MAKs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.1 mg/m <sup>3</sup>
	4.0 mg/m <sup>3</sup>
Estonia OEL - TWA	2 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
Ireland OEL - TWAs	6 mg/m <sup>3</sup>
	2.4 mg/m <sup>3</sup>
Latvia OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m <sup>3</sup>
Switzerland OEL - TWAs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>

**Microcrystalline cellulose**

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
Vietnam OEL - TWAs	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

**Praziquantel**

**Zoetis OEB**

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

**Exposure Controls**

## SAFETY DATA SHEET

Material Name: Pyrantel Pamoate, Oxantel Pamoate and  
Praziquantel Tablets  
Revision date: 11-Apr-2014

Page 5 of 10

Version: 3.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits or within the OEB range.
<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>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Safety glasses or goggles
<b>Skin:</b>	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection:</b>	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. 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>	Tablet	<b>Color:</b>	Pale 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>	No data available.		
<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		

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers

## SAFETY DATA SHEET

Material Name: Pyrantel Pamoate, Oxantel Pamoate and  
Praziquantel Tablets  
Revision date: 11-Apr-2014

Page 6 of 10

Version: 3.0

### 10. STABILITY AND REACTIVITY

**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

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

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### Pyrantel pamoate

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

##### Praziquantel

Rat Oral LD50 2840 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)

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

#### 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

#### 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

## SAFETY DATA SHEET

Material Name: Pyrantel Pamoate, Oxantel Pamoate and  
Praziquantel Tablets  
Revision date: 11-Apr-2014

Page 7 of 10

Version: 3.0

### 11. TOXICOLOGICAL INFORMATION

Embryo / Fetal Development Rabbit Oral 250 mg/kg NOEL Not Teratogenic

#### Praziquantel

Prenatal & Postnatal Development Rat No route specified 300 mg/kg/day NOEL Not teratogenic  
Prenatal & Postnatal Development Rabbit No route specified 200 mg/kg/day NOEL Not Teratogenic  
Reproductive & Fertility Rat No route specified 8000 mg/kg/day NOEL No effects at maximum dose

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Pyrantel pamoate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

#### Praziquantel

Mammalian Cell Mutagenicity Not specified Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Praziquantel

2 Year(s) Rat No route specified Not carcinogenic  
2 Year(s) Hamster No route specified Not carcinogenic

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

#### Colloidal silicon dioxide

IARC: Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. 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.

## SAFETY DATA SHEET

Material Name: Pyrantel Pamoate, Oxantel Pamoate and  
Praziquantel Tablets  
Revision date: 11-Apr-2014

Page 8 of 10

Version: 3.0

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

None required

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

#### **Febantel**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 6
<b>EU EINECS/ELINCS List</b>	261-205-0

#### **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

#### **Praziquantel**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	259-559-6

#### **Sodium Lauryl Sulfate**

<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

## SAFETY DATA SHEET

Material Name: Pyrantel Pamoate, Oxantel Pamoate and  
Praziquantel Tablets  
Revision date: 11-Apr-2014

Page 9 of 10

Version: 3.0

### 15. REGULATORY INFORMATION

<b>Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS/ELINCS List</b>	Schedule 6  205-788-1
<b>Magnesium stearate</b>	
<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>	209-150-3
<b>Colloidal silicon dioxide</b>	
<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>	231-545-4
<b>Croscarmellose sodium</b>	
<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>	Not Listed
<b>Microcrystalline cellulose</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	carcinogen initial date 12/18/09
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</b>	Use restricted. See item 9[f]. powder
<b>EU EINECS/ELINCS List</b>	232-674-9
<b>Flavor</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed

### 16. OTHER INFORMATION

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

H302 - Harmful if swallowed  
H303 - May be harmful if swallowed  
H311 - Toxic in contact with skin

T - Toxic  
Xn - Harmful

## SAFETY DATA SHEET

**Material Name: Pyrantel Pamoate, Oxantel Pamoate and  
Praziquantel Tablets**  
**Revision date: 11-Apr-2014**

**Page 10 of 10**

**Version: 3.0**

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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 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**