

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078934078

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

078934077 078934079 078934080 078934081 078934082 078934083 078934084

# SAFETY DATA SHEET



Revision date: 18-Oct-2013

Version: 3.0

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

### Product Identifier

**Material Name:** Epsiprantel Tablets

**Trade Name:** Cestex® Tablets  
**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, biconvex tablet  
**Classification of the Substance or Mixture**  
**GHS - Classification** Not classified as hazardous

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

### Label Elements

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

**Other Hazards**  
**Short Term:** No data available  
Toxicity is not expected following ingestion, based on animal studies. However, ingestion should be avoided.

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

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

| Ingredient                | CAS Number | EU<br>EINECS/ELINCS<br>List | EU Classification | GHS<br>Classification | % |
|---------------------------|------------|-----------------------------|-------------------|-----------------------|---|
| Colloidal silicon dioxide | 7631-86-9  | 231-545-4                   | Not Listed        | Not Listed            | * |
| Sodium Lauryl Sulfate     | 151-21-3   | 205-788-1                   | Not Listed        | Not Listed            | * |
| Corn Starch               | 9005-25-8  | 232-679-6                   | Not Listed        | Not Listed            | * |
| Magnesium Stearate        | 557-04-0   | 209-150-3                   | Not Listed        | Not Listed            | * |

| Ingredient   | CAS Number   | EU<br>EINECS/ELINCS<br>List | EU Classification | GHS<br>Classification | %  |
|--------------|--------------|-----------------------------|-------------------|-----------------------|----|
| Epsiprantel  | 98123-83-2   | Not Listed                  | Not Listed        | Not Listed            | 12 |
| Film coating | NOT ASSIGNED | Not Listed                  | Not Listed        | Not Listed            | *  |
| Lactose      | 63-42-3      | 200-559-2                   | Not Listed        | Not Listed            | *  |

#### Additional Information:

\* Proprietary

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

### 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

No data available

##### Exposure:

##### Medical Conditions

None known

##### Aggravated by Exposure:

#### Indication of the Immediate Medical Attention and Special Treatment Needed

##### Notes to Physician:

None

### 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:

Not applicable

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### 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

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

### 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.

#### 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> |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                       |  |
|-----------------------|--|
| Switzerland OEL -TWAs | 4 mg/m <sup>3</sup><br>0.3 mg/m <sup>3</sup> |
|-----------------------|--|

#### Corn Starch

|                                   |   |
|-----------------------------------|---|
| 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>                        |
| Bulgaria OEL - TWA                | 10.0 mg/m <sup>3</sup>                      |
| Czech Republic OEL - TWA          | 4.0 mg/m <sup>3</sup>                       |
| Greece OEL - TWA                  | 10 mg/m <sup>3</sup><br>5 mg/m <sup>3</sup> |
| Ireland OEL - TWAs                | 10 mg/m <sup>3</sup><br>4 mg/m <sup>3</sup> |
| OSHA - Final PELs - TWAs:         | 15 mg/m <sup>3</sup>                        |
| Portugal OEL - TWA                | 10 mg/m <sup>3</sup>                        |
| Slovakia OEL - TWA                | 4 mg/m <sup>3</sup>                         |
| Spain OEL - TWA                   | 10 mg/m <sup>3</sup>                        |
| Switzerland OEL -TWAs             | 3 mg/m <sup>3</sup>                         |

#### 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>  |

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.

#### Epsiprantel

|            |   |
|------------|---|
| Zoetis OEB | OEB 2 (control exposure to the range of 100ug/m <sup>3</sup> to < 1000ug/m <sup>3</sup> ) |
|------------|---|

#### Exposure Controls

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

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

|   |                    |                          |                    |
|---|--------------------|--------------------------|--------------------|
| <b>Physical State:</b>                                      | Tablet             | <b>Color:</b>            | No data available. |
| <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>               | None known   |
| <b>Incompatible Materials:</b>            | As a precautionary measure, keep away from strong oxidizers  |
| <b>Hazardous Decomposition Products:</b>  | Thermal decomposition products may include carbon monoxide, carbon dioxide and oxides of nitrogen. |

### 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)

##### Lactose

Rat Oral LD50 > 10 g/kg

##### Sodium Lauryl Sulfate

Rat Oral LD 50 1288 mg/kg

Rat Sub-tenon injection (eye) LD 50 210mg/kg

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### 11. TOXICOLOGICAL INFORMATION

**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)

##### **Epsiprantel**

|           |     |      |               |       |                            |
|-----------|-----|------|---------------|-------|----------------------------|
| 3 Day(s)  | Cat | Oral | 14 mg/kg/day  | NOAEL | No effects at maximum dose |
| 4 Day(s)  | Cat | Oral | 110 mg/kg/day | NOAEL | None identified            |
| 14 Day(s) | Dog | Oral | 500 mg/kg/day | NOAEL | No effects at maximum dose |

##### **Magnesium Stearate**

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

##### **Sodium Lauryl Sulfate**

|          |     |      |          |       |              |
|----------|-----|------|----------|-------|--------------|
| 3 Day(s) | Rat | Oral | 75 mg/kg | LOAEL | Liver, Blood |
|----------|-----|------|----------|-------|--------------|

**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:** The environmental characteristics of this mixture 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.

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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.

##### **Epsiprantel**

|                                    |            |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65          | Not Listed |
| EU EINECS/ELINCS List              | Not Listed |

##### **Film coating**

|                                    |            |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65          | Not Listed |
| EU EINECS/ELINCS List              | Not Listed |

##### **Colloidal silicon dioxide**

|   |            |
|---|------------|
| 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                       | 231-545-4  |

##### **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<br>for Drugs and Poisons: | Schedule 6 |
| EU EINECS/ELINCS List   | 205-788-1  |

##### **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    |



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### 15. REGULATORY INFORMATION

|   |           |
|---|-----------|
| REACH - Annex IV - Exemptions from the obligations of Register: | Present   |
| EU EINECS/ELINCS List   | 232-679-6 |

#### Lactose

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting                              | Not Listed |
| California Proposition 65                                       | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                     | Present    |
| Australia (AICS):   | Present    |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present    |
| EU EINECS/ELINCS List   | 200-559-2  |

#### 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  |

### 16. OTHER INFORMATION

**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 8 - Exposure Controls / Personal Protection.

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

Zoetis 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 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**