

SAFETY DATA SHEET



1. Identification

Product identifier	Cestex® Tablets
Other means of identification	
Synonyms	Cestex® (epsiprantel) Tablets * Cestex® * Cestex * Epsiprantel Tablets
Recommended use	Veterinary anti-worm agent (anthelmintic)
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Epsiprantel		98123-83-2	12
Corn Starch		9005-25-8	<10

Chemical name	Common name and synonyms	CAS number	%
Colloidal silicon dioxide		7631-86-9	<1
Magnesium Stearate		557-04-0	<1
Sodium lauryl sulfate		151-21-3	<1

Composition comments 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

Inhalation Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

Skin contact Wash off with soap and water. Get medical advice/attention if you feel unwell. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Mild skin irritation.

Indication of immediate medical attention and special treatment needed Treat symptomatically.

General information For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use water spray to cool unopened containers.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Ensure adequate ventilation. Remove sources of ignition.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimize dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Keep tightly closed in a dry, cool and well-ventilated place. @ 15-30°C (59-86°F). Keep away from heat and sources of ignition. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis

Components

Type

Value

Sodium lauryl sulfate (CAS 151-21-3)

TWA

0.3 mg/m3

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components

Type

Value

Form

Corn Starch (CAS 9005-25-8)

PEL

5 mg/m3

Respirable fraction.

15 mg/m3

Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components

Type

Value

Colloidal silicon dioxide (CAS 7631-86-9)

TWA

0.8 mg/m3

20 mppcf

US. ACGIH Threshold Limit Values

Components

Type

Value

Corn Starch (CAS 9005-25-8)

TWA

10 mg/m3

Magnesium Stearate (CAS 557-04-0)

TWA

10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components

Type

Value

Form

Colloidal silicon dioxide (CAS 7631-86-9)

TWA

6 mg/m3

Corn Starch (CAS 9005-25-8)

TWA

5 mg/m3

Respirable.

10 mg/m3

Total

Biological limit values

No biological exposure limits noted for the ingredient(s).

Control banding approach

Epsiprantel: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)

Appropriate engineering controls

Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Wear protective gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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.

Thermal hazards	Not applicable.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Round tablet.
Physical state	Solid.
Form	Solid.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Avoid heat, sparks, open flames and other ignition sources. Protect from sunlight.
Incompatible materials	Strong oxidizing agents. Acids.
Hazardous decomposition products	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
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Skin contact Prolonged skin contact may cause temporary irritation. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.

Sodium lauryl sulfate Species: Rabbit
Severity: Mild Moderate

Eye contact Direct contact with eyes may cause temporary irritation.

Sodium lauryl sulfate Species: Rabbit
Severity: Moderate

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Mild skin irritation.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
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Epsiprantel (CAS 98123-83-2)

Subacute

Oral

NOAEL	Cat	110 mg/kg/day, 4 days (Target organs: None identified)
		14 mg/kg/day, 3 days (No effects at maximum dose)
	Dog	500 mg/kg/day, 14 days (No effects at maximum dose)

Magnesium Stearate (CAS 557-04-0)

Chronic

Oral

LOAEL	Rat	1092 g/kg, 13 weeks Liver
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Sodium lauryl sulfate (CAS 151-21-3)

Acute

Oral

LD50	Rat	1288 mg/kg
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Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye Contact

Sodium lauryl sulfate Species: Rabbit
Severity: Moderate

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Skin sensitization

Sodium lauryl sulfate Species: Guinea Pig
Severity: Negative

Species: Mouse
Severity: Negative

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Sodium lauryl sulfate Bacterial Mutagenicity (Ames)
Result: Negative
Species: Salmonella

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Colloidal silicon dioxide (CAS 7631-86-9) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components	Species	Test Results
Sodium lauryl sulfate (CAS 151-21-3)		
	LC50	Oncorhynchus mykiss (Rainbow Trout) 3.6 mg/L, 96 Hours
Aquatic		
Crustacea	EC50	Water flea (Daphnia obtusa) 9.2 - 10.4 mg/l, 48 hours
Fish	LC50	Carp, hawk fish (Cirrhinus mrigala) 1.36 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code None known.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT Not regulated as dangerous goods.

IATA Not regulated as dangerous goods.

IMDG Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 04-23-2017

Version # 01

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Revision information This document has undergone significant changes and should be reviewed in its entirety.