

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>PALLADIA</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Toceranib Phosphate Tablets
<b>Recommended use</b>	Veterinary anti-neoplastic agent
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (USA)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison and Drug Center</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (CA)</b>	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	productsupport@zoetis.com
<b>Product Support</b>	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

**Supplier** Not available.

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Reproductive toxicity (the unborn child) Specific target organ toxicity following repeated exposure	Category 1B Category 1 (blood system, digestive organs)
<b>Environmental hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	May damage the unborn child. Causes damage to organs (blood system, digestive organs) through prolonged or repeated exposure.
<b>Precautionary statement</b>	
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	IF exposed or concerned: Get medical advice/attention.

<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Other hazards</b>	None known.
<b>Supplemental information</b>	None.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Magnesium stearate		557-04-0	*
Microcrystalline cellulose		9004-34-6	*
Silica, Amorphous, Fumed		7631-86-9	*
Toceranib Phosphate		874819-74-6	10, 15, or 50 mg***

**Composition comments**      \*\*\* per tablet/capsule/lozenge/suppository  
\* Non-hazardous Ingredients

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
<b>Skin contact</b>	Remove contaminated clothing. Wash off immediately with soap and plenty of water. Get medical advice/attention if you feel unwell. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
<b>Eye contact</b>	Do not rub eyes. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Call a physician or poison control centre immediately.
<b>Ingestion</b>	Rinse mouth. Call a physician or poison control centre 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.
<b>Most important symptoms/effects, acute and delayed</b>	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Prolonged exposure may cause chronic effects. May cause reproductive effects. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
<b>General information</b>	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. Show this safety data sheet to the doctor in attendance.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed. Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Ensure adequate ventilation. Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Do not get in eyes, on skin, or on clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. 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. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Avoid dust formation. Wear personal protective equipment. Prevent release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean contaminated surface thoroughly.

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

**Environmental precautions****7. Handling and storage****Precautions for safe handling**

Do not handle until all safety precautions have been read and understood. Use this product with adequate ventilation. Avoid dust formation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid contact with skin. Do not get this material on clothing. Do not taste or swallow. Wear appropriate personal protective equipment. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Wash contaminated clothing before reuse. Avoid release to the environment. Observe good industrial hygiene practices. Use care in handling/storage.

**Conditions for safe storage, including any incompatibilities**

Store locked up. Store in a well-ventilated place. Store in a cool, dry place out of direct sunlight. @ 15-30°C (59-86°F). Store in original tightly closed container. Keep away from heat, sparks and open flame. 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****Zoetis****Components****Type****Value**

Toceranib Phosphate (CAS 874819-74-6)

TWA

10 µg/m<sup>3</sup>

**US. ACGIH Threshold Limit Values****Components****Type****Value**

Magnesium stearate (CAS 557-04-0)

TWA

10 mg/m<sup>3</sup>

Microcrystalline cellulose (CAS 9004-34-6)

TWA

10 mg/m<sup>3</sup>

**Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)****Components****Type****Value**

Magnesium stearate (CAS 557-04-0)

TWA

10 mg/m<sup>3</sup>

Microcrystalline cellulose (CAS 9004-34-6)

TWA

10 mg/m<sup>3</sup>

**Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)****Components****Type****Value****Form**

Magnesium stearate (CAS 557-04-0)

TWA

10 mg/m<sup>3</sup>

Microcrystalline cellulose (CAS 9004-34-6)

TWA

3 mg/m<sup>3</sup>

Respirable fraction.

10 mg/m<sup>3</sup>

Total dust.

Silica, Amorphous, Fumed (CAS 7631-86-9)

TWA

4 mg/m<sup>3</sup>

Total

1.5 mg/m<sup>3</sup>

Respirable.

**Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)****Components****Type****Value**

Magnesium stearate (CAS 557-04-0)

TWA

10 mg/m<sup>3</sup>

Microcrystalline cellulose (CAS 9004-34-6)

TWA

10 mg/m<sup>3</sup>

**Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)**

Components	Type	Value
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m3
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3

**Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)**

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	Total dust.
Silica, Amorphous, Fumed (CAS 7631-86-9)	TWA	6 mg/m3	Respirable dust.

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Control banding approach</b>	Not available.
<b>Appropriate engineering controls</b>	Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves.
<b>Other</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	In case of insufficient ventilation, wear suitable respiratory equipment. Respirator must be worn if exposed to dust. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.
<b>Thermal hazards</b>	Not applicable.
<b>General hygiene considerations</b>	Observe any medical surveillance requirements. 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**

<b>Appearance</b>	Tablets
<b>Physical state</b>	Solid.
<b>Form</b>	Solid.
<b>Colour</b>	Orange. or Blue. or Red.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.

<b>Explosive limit – upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidising properties</b>	Not oxidising.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Moisture. Keep away from heat, spark, open flames and other sources of ignition. Protect from sunlight.
<b>Incompatible materials</b>	Strong oxidising agents. Fluorine.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Carbon oxides. Nitrogen oxides (NOx). Oxides of phosphorus. Hydrogen fluoride.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation.
Microcrystalline cellulose	Species: Rabbit Severity: Non-irritating

Toceranib Phosphate	Species: Rabbit Severity: Non-irritating
---------------------	---

<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
Toceranib Phosphate	Species: Rabbit Severity: Minimal

Microcrystalline cellulose	Species: Rabbit Severity: Non-irritating
----------------------------	---

<b>Ingestion</b>	Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. However, ingestion is not likely to be a primary route of occupational exposure.
------------------	---

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Prolonged exposure may cause chronic effects. May cause reproductive effects. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.
---	--

### Information on toxicological effects

<b>Acute toxicity</b>	May be harmful in contact with skin. May be harmful if swallowed.
-----------------------	---

Components	Species	Test results
------------	---------	--------------

Magnesium stearate (CAS 557-04-0)

#### Acute

#### **Inhalation**

LC50	Rat	> 2000 mg/m3
------	-----	--------------

Components	Species	Test results
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg
Microcrystalline cellulose (CAS 9004-34-6)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	> 2000 mg/kg
<b>Oral</b>		
LD50	Rat	> 5000 mg/kg
Toceranib Phosphate (CAS 874819-74-6)		
<b>Acute</b>		
<b>Oral</b>		
	Rat	2500 mg/kg (Minimum Lethal Dose)
<b>Subacute</b>		
<b>Oral</b>		
LOAEL	Dog	2.5 mg/kg/day, 7 days (Target organ(s): Gastrointestinal system)
	Rat	10 mg/kg/day, 14 days (Target organ(s): Liver, Lymphatic system, Pancreas, Adrenal gland)
NOAEL	Dog	< 50 mg/kg/day, 8 days (Target organ(s): Gastrointestinal system, Pancreas)
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Corrosivity</b>		
Toceranib Phosphate	Species: Rabbit Severity: Non-irritating	
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye contact</b>		
Toceranib Phosphate	Species: Rabbit Severity: Minimal	
Microcrystalline cellulose	Species: Rabbit Severity: Non-irritating	
<b>Respiratory or skin sensitisation</b>		
<b>Canada - Alberta OELs: Irritant</b>		
Magnesium stearate (CAS 557-04-0)	Irritant	
Microcrystalline cellulose (CAS 9004-34-6)	Irritant	
<b>Respiratory sensitisation</b>	Not a respiratory sensitizer.	
<b>Skin sensitisation</b>	This product is not expected to cause skin sensitisation.	
<b>Skin sensitisation</b>		
Toceranib Phosphate	LLNA Species: Mouse Severity: negative	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Mutagenicity</b>		
Toceranib Phosphate	In Vitro Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella , E. coli	
	In Vitro Chromosome Aberration Result: negative Species: Human lymphocytes	

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

**ACGIH Carcinogens**

Magnesium stearate (CAS 557-04-0)

A4 Not classifiable as a human carcinogen.

**Canada - Manitoba OELs: carcinogenicity**

Magnesium stearate (CAS 557-04-0)

Not classifiable as a human carcinogen.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Silica, Amorphous, Fumed (CAS 7631-86-9)

3 Not classifiable as to carcinogenicity to humans.

**Reproductive toxicity** May damage the unborn child.

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - repeated exposure** Causes damage to organs (blood system, digestive organs) through prolonged or repeated exposure.

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** Prolonged exposure may cause chronic effects.

## 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.

**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 discharge into drains, water courses or onto the ground. 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** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**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

**TDG**  
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

### Canadian regulations

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

#### Controlled Drugs and Substances Act

Not regulated.

#### Export Control List (CEPA 1999, Schedule 3)

Not listed.

#### Greenhouse Gases

Not listed.

#### Precursor Control Regulations

Not regulated.

### International regulations

#### Stockholm Convention

Not applicable.

#### Rotterdam Convention

Not applicable.

#### Kyoto protocol

Not applicable.

#### Montreal Protocol

Not applicable.

#### Basel Convention

Not applicable.

### 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

**Issue date** 24-May-2017

**Version No.** 01

**Disclaimer** 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. The information in the sheet was written based on the best knowledge and experience currently available.

**Revision information** Product and Company Identification: Synonyms  
Composition / Information on Ingredients: Ingredients  
GHS: Qualifiers