

# SAFETY DATA SHEET



## 1. Identification

**Product identifier** PALLADIA

**Other means of identification**

**Synonyms** Palladia 50MG/15MG/10MG \* Toceranib Phosphate Tablets

**Recommended use** Veterinary anti-neoplastic agent

**Recommended restrictions** Not for human use

### Manufacturer/Importer/Supplier/Distributor information

**Company Name (USA)** Zoetis Inc.  
10 Sylvan Way  
Parsippany, New Jersey 07054 (USA)

**Rocky Mountain Poison & Drug Safety** 1-866-531-8896

**Product Support/Technical Services** 1-888-963-8471

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

**Company Name (CA)** Zoetis Canada Inc.  
16740 Trans-Canada Highway  
Kirkland, Quebec, H9H 4M7

**Emergency telephone number** International CHEMTREC (24 hours): +1-703-527-3887

**Contact E-Mail** productsupport@zoetis.com

**Product Support** 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 identification

**Physical hazards** Not classified.

**Health hazards** Reproductive toxicity (the unborn child) Category 1B  
Specific target organ toxicity following repeated exposure Category 1 (blood system, digestive organs)

**Environmental hazards** Not classified.

### Label elements



**Signal word** Danger

**Hazard statement** May damage the unborn child. Causes damage to organs (blood system, digestive organs) through prolonged or repeated exposure.

### Precautionary statement

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapours/spray. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** IF exposed or concerned: Get medical advice/attention.

**Storage** Store locked up.

<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Supplemental information</b>	None.
<b>Other hazards</b>	May form combustible dust concentrations in air.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Toceranib ( as Toceranib phosphate)		874819-74-6	10, 15, or 50 mg***
Colloidal silicon dioxide		7631-86-9	*
Magnesium stearate		557-04-0	*
Microcrystalline cellulose		9004-34-6	*

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

**Composition comments**      \*\*\* per tablet/capsule/lozenge/suppository  
\* Non-hazardous Ingredients  
The full text for all H-statements is displayed in section 16.

### 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. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
<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. Symptoms may be delayed.
<b>General information</b>	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. For personal protection, see section 8 of the SDS.

### 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>	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>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. 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 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. Do not get in eyes, on skin, or on clothing.
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**Methods and materials for containment and cleaning up**

ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Avoid dust formation. Ensure adequate ventilation.

Large Spills: Stop the flow of material, if this is without risk. Clean surface thoroughly to remove residual contamination.

Small Spills: Clean surface thoroughly to remove residual contamination. 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. Wear personal protective equipment. Prevent release to the environment.

**Environmental precautions**

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

**7. Handling and storage**

**Precautions for safe handling**

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

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

Store locked up. Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store in tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). @ 15-30°C (59-86°F)..

**8. Exposure controls/personal protection**

**Occupational exposure limits**

**Zoetis**

**Components**

Toceranib ( as Toceranib phosphate) (CAS 874819-74-6)

**Type**

TWA

**Value**

10 µg/m<sup>3</sup>

**US. ACGIH Threshold Limit Values**

**Components**

Magnesium stearate (CAS 557-04-0)

**Type**

TWA

**Value**

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

**Form**

Respirable fraction.

Microcrystalline cellulose (CAS 9004-34-6)

TWA

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

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

Inhalable fraction.

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

**Components**

Colloidal silicon dioxide (CAS 7631-86-9)

**Type**

TWA

**Value**

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

**Form**

Respirable particles.

Magnesium stearate (CAS 557-04-0)

TWA

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

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

Total

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**

Colloidal silicon dioxide (CAS 7631-86-9)

**Type**

TWA

**Value**

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

**Form**

Respirable fraction.

Magnesium stearate (CAS 557-04-0)

TWA

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

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

Total dust.

Respirable.

Microcrystalline cellulose (CAS 9004-34-6)

TWA

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

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

Inhalable

Respirable fraction.

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

Components	Type	Value	Form
		10 mg/m3	Total dust.

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

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	

**Canada. New Brunswick OELs: Threshold Limit Values (TLVs) Based on the 1991 and 1997 ACGIH TLVs and BEIs Publication (New Brunswick Regulation 91-191)**

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	3 mg/m3	Respirable.
		10 mg/m3	Inhalable
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m3	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	

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

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	

**Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety)**

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	10 mg/m3	Total dust.
Magnesium stearate (CAS 557-04-0)	TWA	10 ppm	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	Total dust.

**Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)**

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	15 minute	6 mg/m3	Respirable fraction.
		20 mg/m3	Inhalable fraction.
Magnesium stearate (CAS 557-04-0)	15 minute	20 mg/m3	
Microcrystalline cellulose (CAS 9004-34-6)	15 minute	20 mg/m3	Fiber.

**Biological limit values**

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

**Control banding approach**

Not available.

**Appropriate engineering controls**

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. Ensure adequate ventilation, especially in confined areas.

**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 appropriate chemical resistant gloves.

<b>Other</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection</b>	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 the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL (occupational exposure limit), suitable respiratory protection must be worn.
<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>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>	Keep away from heat, spark, open flames and other sources of ignition. Protect from sunlight. Moisture. Contact with incompatible materials.
<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

**Inhalation** Prolonged inhalation may be harmful. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin contact** Prolonged skin contact may cause temporary irritation.

Microcrystalline cellulose Species: Rabbit  
Severity: Non-irritating

Toceranib ( as Toceranib phosphate) Species: Rabbit  
Severity: Non-irritating

**Eye contact** Direct contact with eyes may cause temporary irritation.

Toceranib ( as Toceranib phosphate) Species: Rabbit  
Severity: Minimal

Microcrystalline cellulose Species: Rabbit  
Severity: Non-irritating

**Ingestion** 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.

**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. May cause reproductive effects. Prolonged exposure may cause chronic effects. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

### Information on toxicological effects

**Acute toxicity** May be harmful in contact with skin. May be harmful if swallowed.

Components	Species	Test Results
Colloidal silicon dioxide (CAS 7631-86-9)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	> 22500 mg/kg
Magnesium stearate (CAS 557-04-0)		
<b>Acute</b>		
<b>Inhalation</b>		
LC50	Rat	> 2000 mg/m3
<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 ( as 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)

**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.

**Corrosivity**

Toceranib ( as Toceranib phosphate)

Species: Rabbit  
Severity: Non-irritating

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

**Eye contact**

Toceranib ( as Toceranib phosphate)

Species: Rabbit  
Severity: Minimal

Microcrystalline cellulose

Species: Rabbit  
Severity: Non-irritating

**Respiratory or skin sensitisation**

**Canada - Alberta OELs: Irritant**

Colloidal silicon dioxide (CAS 7631-86-9)

Irritant

Magnesium stearate (CAS 557-04-0)

Irritant

Microcrystalline cellulose (CAS 9004-34-6)

Irritant

**Respiratory sensitisation** Not a respiratory sensitiser.

**Skin sensitisation** This product is not expected to cause skin sensitisation.

**Skin Sensitisation**

Toceranib ( as Toceranib phosphate)

LLNA  
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**

Toceranib ( as Toceranib phosphate)

In Vitro Bacterial Mutagenicity (Ames)  
Result: Negative  
Species: Salmonella , E. coli  
  
In Vitro Chromosome Aberration  
Result: Negative  
Species: Human lymphocytes  
  
In Vivo Micronucleus  
Result: Negative  
Species: Rat

**Carcinogenicity** Due to partial or complete lack of data the classification is not possible.

**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**

Colloidal silicon dioxide (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 inhalation may be harmful. Causes damage to organs through prolonged or repeated exposure.

**12. Ecological information**

**Ecotoxicity** Avoid release to the environment. 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.

<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	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

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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.
<b>Contaminated packaging</b>	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 Industrial Chemicals (AICIS)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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

**Revision date** 13-April-2023

**Version No.** 02

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