

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Palladia 50MG/15MG/10MG</b>	
<b>Other means of identification</b>		
<b>Synonyms</b>	Toceranib Phosphate Tablets	
<b>Recommended use of the chemical and restrictions on use</b>		
<b>Recommended use</b>	Veterinary anti-neoplastic agent	
<b>Restrictions on use</b>	Not for human use	
<b>Details of manufacturer or importer</b>		
<b>Company Name (AU)</b>	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA	
<b>Tel</b>	1800 814 883	
<b>Fax</b>	(02) 8876 0444	
<b>Email</b>	australia.animalhealth@zoetis.com	
<b>Emergency Phone</b>	1800 814 883 (all hours)	
<b>Police and Fire Brigade</b>	Dial 000	
<b>If ineffective</b>	Dial Poisons Information Centre (13 1126 from anywhere in Australia)	

## 2. Hazard(s) identification

### Classification of the hazardous chemical

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

### Label elements, including precautionary statements

#### Hazard symbol(s)



Health hazard

#### Signal word

Danger

#### Hazard Statement(s)

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

#### Precautionary Statement(s)

##### 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/vapors/spray. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Use personal protective equipment as required.

##### Response

IF exposed or concerned: Get medical advice/attention.

##### Storage

Store locked up.

##### Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Other hazards which do not result in classification

None known.

#### Supplemental information

None.

### 3. Composition/information on ingredients

#### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Toceranib Phosphate	874819-74-6	11-13
Colloidal silicon dioxide	7631-86-9	*
Magnesium stearate	557-04-0	*
Microcrystalline cellulose	9004-34-6	*

**Composition comments** \*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

### 4. First-aid measures

#### Description of necessary first aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<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. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control centre immediately.

**Personal protection for first-aid responders** 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.

**Symptoms caused by exposure** 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.

**Medical attention and special treatment** Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

### 5. Fire-fighting measures

#### Extinguishing media

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**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. Fine particles (such as dust and mists) may fuel fires/explosions.

**Special protective equipment and precautions for fire fighters** 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.

**Hazchem Code** None.

**General fire hazards** No unusual fire or explosion hazards noted.

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

### 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

**For emergency responders** Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Ventilate the contaminated area. Avoid the generation of dusts during clean-up. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protection recommended in Section 8 of the SDS.

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

**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. 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.

**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. 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. Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. < 15-30°C (59-86°F). Store in a well-ventilated place. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Keep away from food, drink and animal feeding stuffs. Keep out of the reach of children.

**8. Exposure controls and personal protection****Control parameters**

Follow standard monitoring procedures.

**Occupational exposure limits****Zoetis****Components****Type****Value**

Toceranib Phosphate (CAS 874819-74-6)

TWA

10 µg/m<sup>3</sup>

**Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)****Components****Type****Value****Form**

Colloidal silicon dioxide (CAS 7631-86-9)

TWA

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

Respirable dust.

Magnesium stearate (CAS 557-04-0)

TWA

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

Inhalable dust.

Microcrystalline cellulose (CAS 9004-34-6)

TWA

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

Inhalable fibers.

**Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)****Components****Type****Value****Form**

Colloidal silicon dioxide (CAS 7631-86-9)

TWA

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

Respirable fraction.

Magnesium stearate (CAS 557-04-0)

TWA

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

Inspirable dust.

Microcrystalline cellulose (CAS 9004-34-6)

TWA

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

Inspirable dust.

**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>

**UK. EH40 Workplace Exposure Limits (WELs)****Components****Type****Value****Form**

Colloidal silicon dioxide (CAS 7631-86-9)

TWA

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

Inhalable dust.

Microcrystalline cellulose (CAS 9004-34-6)

STEL

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

Respirable dust.

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

Inhalable dust.

**UK. EH40 Workplace Exposure Limits (WELs)**

Components	Type	Value	Form
	TWA	4 mg/m <sup>3</sup>	Respirable dust.
		10 mg/m <sup>3</sup>	Inhalable dust.

**Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)**

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	4 mg/m <sup>3</sup>	Inhalable fraction.

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Control banding approach** Not available.

**Appropriate engineering controls** 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.

**Individual protection measures, for example personal protective equipment (PPE)**

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended.

**Skin protection**

**Hand protection** Wear appropriate chemical resistant gloves.

**Other**

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

**Respiratory protection**

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.

**Thermal hazards**

Not applicable.

**Hygiene measures**

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, 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 physical and chemical parameters</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. Hydrogen fluoride. Carbon oxides. Nitrogen oxides (NOx). Oxides of phosphorus.

## 11. Toxicological information

### Information on possible 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 of large amounts may produce gastrointestinal disturbances including irritation, nausea, and diarrhoea. However, ingestion is not likely to be a primary route of occupational exposure.	
<b>Symptoms related to exposure</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.	

### Acute toxicity

Components	Species	Test results
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

Components	Species	Test results
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/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>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	
	In Vivo Micronucleus Result: negative Species: Rat	
<b>Carcinogenicity</b>	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.

### 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 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

#### Bioaccumulative potential

No data available.

#### Mobility in soil

No data available for this product.

#### 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 methods

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. Contract with a disposal operator licensed by the Law on Disposal and Cleaning.

#### Residual waste

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. Empty containers should be taken to an approved waste handling site for recycling or disposal.

## 14. Transport information

#### ADG

Not regulated as dangerous goods.

#### RID

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

### Safety, health and environmental regulations

**National regulations**

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA No. 64615, 64616, 64617

Poison Schedule (Product) - Schedule 4

This SDS replaces version: Issued October 2015

**High Volume Industrial Chemicals (HVIC)**

Colloidal silicon dioxide (CAS 7631-86-9) 10000 - 99999 TONNES See the regulation for additional information.

**Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)**

Not listed.

**National Pollutant Inventory (NPI) substance reporting list**

Not listed.

**Prohibited Carcinogenic Substances**

Not regulated.

**Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)**

Not listed.

**Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)**

Not listed.

**Restricted Carcinogenic Substances**

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** 14-November-2016



**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