

SAFETY DATA SHEET



Section 1 - Identification

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

Section 2 - Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Acute toxicity, dermal	Category 5
	Reproductive toxicity (the unborn child)	Category 1B
	Specific target organ toxicity following repeated exposure	Category 1 (blood system, digestive organs)

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard

Signal word

Danger

Hazard statement(s)

May be harmful in contact with skin. 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/vapours/spray. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

Response

IF ON SKIN: Call a POISON CENTER or doctor/physician if you feel unwell.

Storage

Store locked up.

Disposal

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

Supplemental information

None.

Other hazards which do not result in classification

May form combustible dust concentrations in air.

Section 3 - Composition and information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
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	*

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

Section 4 - First aid measures

Description of necessary 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	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.
Eye contact	Do not rub eyes. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Rinse with water. Continue rinsing. Call a physician or poison control centre immediately.
Ingestion	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.

Personal protection for first-aid responders 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. You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

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. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Medical attention and special treatment Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

Section 5 - Firefighting measures

Specific hazards arising from the chemical	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.
Extinguishing media	
Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

Section 6 - Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away.
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For emergency responders Keep unnecessary personnel away. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Do not breathe dust. Avoid the generation of dusts during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. 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 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.

Section 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 eyes, skin, and clothing. 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)..

Section 8 - Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components	Type	Value
Toceranib (as Toceranib phosphate) (CAS 874819-74-6)	TWA	10 µg/m ³

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 ³	Respirable dust.
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m ³	Inhalable dust.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	Inhalable fibers.

US. ACGIH Threshold Limit Values

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

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	STEL	20 mg/m ³	Inhalable dust.
		4 mg/m ³	Respirable dust.
		10 mg/m ³	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	0.5 mg/m ³	Respirable fraction.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	4 mg/m ³	Inhalable dust.

Biological limit values	No biological exposure limits noted for the ingredient(s).
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, 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	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection	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.
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.

Section 9 - Physical and chemical properties

Appearance	Tablets
Physical state	Solid.
Form	Solid.
Colour	Orange. or Blue. or Red.
Odour	Not available.
Odour 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	
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour 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 physical and chemical parameters

Explosive properties Not explosive.

Oxidising properties Not oxidising.

Section 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 Keep away from heat, spark, open flames and other sources of ignition. Protect from sunlight. Moisture. Contact with incompatible materials.

Incompatible materials Strong oxidising agents. Fluorine.

Hazardous decomposition products 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.

Section 11 - Toxicological information

Information on possible 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. May be harmful in contact with skin.

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 exposure 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.

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)		
Acute		
Oral		
LD50	Rat	> 22500 mg/kg
Magnesium stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2000 mg/m3
Oral		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
Microcrystalline cellulose (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Toceranib (as Toceranib phosphate) (CAS 874819-74-6)		
Acute		
Oral		
	Rat	2500 mg/kg (Minimum Lethal Dose)
Subacute		
Oral		
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/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		
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.	

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.

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

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

Section 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.

Section 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. APVMA No. 64615, 64616, 64617 Poison Schedule (Product) - Schedule 4
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High Volume Industrial Chemicals (HVIC)

Colloidal silicon dioxide (CAS 7631-86-9)

10000 - 99999 TONNES See the regulation for additional information.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10, as amended)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Colloidal silicon dioxide (CAS 7631-86-9)	2000 tonnes/yr Threshold Category: 2B 400 tonnes/yr Threshold Category: 2A
Microcrystalline cellulose (CAS 9004-34-6)	2000 tonnes/yr Threshold Category: 2B 400 tonnes/yr Threshold Category: 2A

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 Carcinogenic Substances

Not regulated.

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

Not listed.

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).

Section 16 - Any other relevant information

Issue date	14-November-2016
Revision date	13-April-2023
Key abbreviations or acronyms used	AICIS: Australian Inventory of Industrial Chemicals.

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