

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 (NZ) Zoetis New Zealand Limited
 Level 4, 8 Mahuhu Crescent
 Auckland Central
 Auckland 1010, New Zealand

Telephone No. 0800 963 847 (Business Hours)

Emergency No. (National Poisons Centre) 0800 POISON (0800 764 766)**Emergency No. (Emergency Services)** In an emergency dial 111**Section 2: Hazard identification****Classification of the hazardous chemical****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, 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/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.

Disposal

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

Other hazards which do not result in classification May form combustible dust concentrations in air.**Supplemental information** None.**Section 3: Composition/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

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. Wash contaminated clothing before reuse. Get medical attention if irritation develops and persists.
Eye contact	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.
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: Fire-fighting measures

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.

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.

Hazards from combustion products 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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away.
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. Wear personal protective equipment. Ensure adequate ventilation.

Large Spills: Stop the flow of material, if this is without risk. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with a damp cloth and place in container for disposal. 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. Prevent release to the environment.

Section 7: Handling and storage

Precautions for safe handling

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. When using, do not eat, drink or smoke. 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. Use care in handling/storage. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Conditions for safe storage, including any incompatibilities

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

Section 8: Exposure controls/personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components

Type	Value
TWA	10 µg/m ³

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

New Zealand. OELs (Workplace Exposure Standards and Biological Exposure Indices)

Components

Type	Value	Form
TWA	3 mg/m ³	Respirable dust.
	10 mg/m ³	Inhalable dust.
TWA	10 mg/m ³	
TWA	10 mg/m ³	Fiber.

Colloidal silicon dioxide (CAS 7631-86-9)

Magnesium stearate (CAS 557-04-0)

Microcrystalline cellulose (CAS 9004-34-6)

US. ACGIH Threshold Limit Values (TLV)

Components

Type	Value	Form
TWA	3 mg/m ³	Respirable fraction.
	10 mg/m ³	Inhalable fraction.
TWA	10 mg/m ³	

Magnesium stearate (CAS 557-04-0)

Microcrystalline cellulose (CAS 9004-34-6)

UK. OELs. Workplace Exposure Limits (WELs) (EH40/2005 (Fourth Edition 2020)), Table 1

Components

Type	Value	Form
STEL	20 mg/m ³	Inhalable dust.
TWA	4 mg/m ³	Respirable dust.
	10 mg/m ³	Inhalable dust.

Microcrystalline cellulose (CAS 9004-34-6)

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components

Type	Value	Form
TWA	2 mg/m ³	Respirable dust.

Colloidal silicon dioxide (CAS 7631-86-9)

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m3	Inhalable dust.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	Inhalable fibers.
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, 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. 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. If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL (occupational exposure limit), suitable respiratory protection must be worn. 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.		
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.
Kinematic 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. Avoid conditions which create dust. 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 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)		
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)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Toceranib (as Toceranib phosphate) (CAS 874819-74-6)		
<u>Acute</u>		
Oral		
	Rat	2500 mg/kg (Minimum Lethal Dose)
<u>Subacute</u>		
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/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 irritation	Not available.	
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.
Narcotic effects	Due to lack of data the classification is not possible.
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. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.
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. 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.
Special precautions to be taken during disposal	Dispose in accordance with all applicable regulations.
Method of disposal that should not be used	None known.

Section 14: Transport information

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

Applicable regulations	Registered pursuant to the ACVM Act 1997, No. A10834. See www.foodsafety.govt.nz for registration conditions. Approved pursuant to the HSNO Act 1996, Code No. HSR100757. See www.epa.govt.nz for approval controls.
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New Zealand Inventory of Chemicals (NZIoC): Registration status

Colloidal silicon dioxide (CAS 7631-86-9)	Does not have individual approval but may be used under an appropriate group standard
Magnesium stearate (CAS 557-04-0)	Does not have individual approval but may be used under an appropriate group standard
Microcrystalline cellulose (CAS 9004-34-6)	Does not have individual approval but may be used under an appropriate group standard
Toceranib (as Toceranib phosphate) (CAS 874819-74-6)	Does not have individual approval but may be used as a component in a product covered by a group standard. It is not approved for use as a chemical in its own right.

Section 16: Other information

Issue date	18-December-2024
Version No.	01
Key abbreviations or acronyms used	Not available.
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