

# SAFETY DATA SHEET

Zoetis New Zealand Limited



## Section 1: Identification of the Substance and Supplier

<b>Trade Name:</b>	<b>PALLADIA®</b>
<b>ACVM Registration No.:</b>	A010834
<b>Classification:</b>	Restricted Veterinary Medicine (RVM)
<b>Recommended Use:</b>	Oral anti-neoplastic for the treatment of Patnaik grade II or III recurrent, cutaneous mast cell tumours with or without regional lymph node involvement in dogs.
<b>Company Details:</b>	Zoetis New Zealand Limited
<b>Address:</b>	Level 4, 8 Mahuhu Crescent Auckland Central Auckland 1010 New Zealand
<b>Telephone No.:</b>	0800 963 847 (Business Hours)
<b>Emergency Telephone No.:</b>	National Poisons Centre: 0800 POISON (0800 764 766) Emergency Services: In an emergency dial 111
<b>Date of Preparation:</b>	1 July 2019

## Section 2: Hazards Identification

<b>Hazard Classification:</b>	6.1E, 6.4A, 6.8A, 6.9A
<b>Priority Identifier(s):</b>	WARNING – KEEP OUT OF REACH OF CHILDREN
<b>Secondary Identifier(s):</b>	6.1E May be harmful if swallowed, inhaled or absorbed through the skin. Avoid skin contact. 6.4A May cause eye irritation. Avoid contact with the eyes. 6.8A May damage fertility or the unborn child from repeated oral exposure. 6.9A May cause organ damage from repeated oral exposure at high doses

## Section 3: Composition / Information on Ingredients

### Chemical Identity of Ingredients

Ingredient	CAS No.	Concentration
Toceranib phosphate	874819-74-6	Variable
Other ingredients determined not to be hazardous.	-	-

This is a commercial product whose exact ratio of components may vary.  
Trace quantities of impurities are also likely.

#### Section 4: First Aid Measures

<b>Necessary First Aid Measures:</b>	<p><b>For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately.</b> If the patient is not breathing begin artificial respiration and seek medical advice immediately. Never give fluids or induce vomiting if a patient is unconscious or convulsing, regardless of injury.</p> <p><b>Ingestion:</b> DO NOT induce vomiting. If the patient is conscious wash mouth out with water. Do not give anything by mouth to an unconscious person. Seek medical advice immediately.</p> <p><b>Eye Contact:</b> Flush the eye(s) out with running water for at least 15 minutes. Removal of contact lenses should be done with caution within 5 minutes of exposure. If symptoms develop seek medical advice immediately.</p> <p><b>Skin Contact:</b> Remove any contaminated clothing and wash the affected area immediately with soap and water. If symptoms develop seek medical advice immediately.</p> <p><b>Inhalation:</b> Move the patient to fresh air. If symptoms develop seek medical advice immediately.</p>
<b>Poisoning Symptoms:</b>	No information available.
<b>Workplace Facilities:</b>	No specific facilities required. Standard emergency equipment must be available.
<b>Hygiene Practices:</b>	Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while using this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
<b>Notes for Medical Personnel:</b>	Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient. Note the nature of this product.

#### Section 5: Fire-Fighting Measures

<b>Type of hazard:</b>	This product is not explosive or flammable, however, fine particles (such as dust and mists) may fuel fires / explosions.
<b>Fire Hazard Properties:</b>	Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen and products of fluorine.
<b>Regulatory Requirements:</b>	Not applicable.
<b>Extinguishing Media &amp; Methods:</b>	Use carbon dioxide, dry chemical, foam or water spray to extinguish fires involving this product.
<b>Hazchem Code:</b>	Not allocated.
<b>Recommended Protective Clothing:</b>	During large-scale fire fighting operations wear approved positive pressure, self-contained breathing apparatus and full protective turn-out gear.

## Section 6: Accidental Release Measures

<b>Personal Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment to minimise exposure. This may include eye protection, chemically resistant gloves, boots and overalls.
<b>Environmental Precautions:</b>	Prevent material from entering surface water drains or waterways. If a significant quantity of material enters drains, advise emergency services.
<b>Procedure for Spills:</b>	<ol style="list-style-type: none"><li>1. Non-essential personnel should be evacuated from the affected area.</li><li>2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage.</li><li>3. Collect the spilled material into labelled containers for disposal, minimising dust generation.</li><li>4. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains.</li></ol>
<b>Procedure for Disposal:</b>	Contaminated material must be disposed of at an approved landfill or other approved facility in accordance with local, regional and national requirements. Avoid contamination of any water supply with product or empty container.

## Section 7: Handling and Storage

### Handling

<b>Precautions for Safe Handling:</b>	No special technical protective measures required. No special handling advice required.
<b>Regulatory Requirements:</b>	Not required.
<b>Handling Practices:</b>	Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
<b>Approved Handlers:</b>	Approved handlers are not required for this product.

### Storage

<b>Conditions for Safe Storage:</b>	Store below 30°C (Room Temperature). Protect from direct sunlight. Keep out of reach of children. Store in a well ventilated area in the original container, tightly closed, away from foodstuffs.
<b>Store Site Requirements:</b>	No additional requirements.
<b>Packaging:</b>	Store in the original container, away from foodstuffs.

## Section 8: Exposure Control / Personal Protection

Always Read and Follow the Label Instructions and Warnings

### Workplace Exposure Guidelines

<b>Workplace Exposure Standards:</b>	A time weighted average (TWA) concentration for an 8-hour day and a 5-day week has not been established by NOHSC Australia for any of the major ingredients in this product. There is a blanket limit of 10 mg/m <sup>3</sup> for dusts or mists when limits have not otherwise been established.
<b>Application in the Workplace:</b>	The nature of this product makes it unlikely that this level will be approached during normal handling.
<b>Exposure Standards Outside the Workplace:</b>	None set.
<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
<b>Personal Protection:</b>	<p>The following instructions are for those coming into frequent and / or lengthy contact with this product. For occasional handling employ precautions suitable for the conditions under which the product is being handled.</p> <p><b>Hands:</b> Impervious gloves are recommended if skin contact is possible and for bulk processing operations.</p> <p><b>Eyes:</b> It is always prudent to utilise protective eyewear.</p> <p><b>Skin:</b> When prolonged or frequently repeated contact could occur, utilise chemically protective clothing. Selection of specific items such as a face shield, gloves, boots, or overalls will depend on the situation.</p> <p><b>Respiratory:</b> Respiratory protection is not normally required; however, if necessary utilise an air-purifying respirator that complies with NZ standards.</p>
<b>General Hygiene:</b>	Change work clothes regularly. Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.

## Section 9: Physical and Chemical Properties

<b>Appearance:</b>	Coloured, round tablet.
<b>Odour:</b>	No data available.
<b>Specific Gravity / Density:</b>	Not applicable.
<b>Melting Point:</b>	256°C
<b>Boiling Point:</b>	No data available.
<b>pH:</b>	Not applicable.
<b>Solubility in Water:</b>	< 0.005 mg/mL
<b>Flashpoint:</b>	Not applicable. This product is not flammable.
<b>Oxidising Properties:</b>	Not applicable. This product is not an oxidiser.
<b>Corrosive Properties:</b>	Not applicable. This product is not corrosive.
<b>Vapour Pressure:</b>	Not applicable.

## Section 10: Stability and Reactivity

<b>Stability of the Substance:</b>	This product is stable under normal conditions of use.
<b>Conditions to Avoid:</b>	As a precautionary measure, keep away from heat sources and electrostatic discharge.
<b>Material to Avoid:</b>	As a precautionary measure, keep away from strong oxidisers.
<b>Hazardous Decomposition Products:</b>	Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen and products of fluorine.
<b>Hazardous Polymerisation:</b>	This product is unlikely to spontaneously polymerise.
<b>Specific Data:</b>	No specific data available.

## Section 11: Toxicological Information

### HSNO Classifications

- 6.1E** May be harmful if swallowed, inhaled or absorbed through the skin. Avoid skin contact.
- 6.4A** May cause eye irritation. Avoid contact with the eyes.
- 6.8A** May damage fertility or the unborn child from repeated oral exposure.
- 6.9A** May cause organ damage from repeated oral exposure at high doses

### Acute Effects

<b>Acute toxicity:</b>	<b>Toceranib phosphate</b> (Species, Route, End Point, Dose) <ul style="list-style-type: none"><li>• Rat Oral Minimum Lethal Dose 2500 mg/kg</li></ul>
<b>Irritation / Sensitisation:</b>	<b>Toceranib phosphate</b> (Study Type, Species, Severity) <ul style="list-style-type: none"><li>• Eye Irritation Rabbit Minimal</li><li>• Skin Irritation Rabbit Non-irritating</li><li>• Skin Sensitisation – LLNA Mouse Negative</li></ul>
<b>Repeated Dose Toxicity:</b>	<b>Toceranib phosphate</b> (Duration, Species, Route, Dose, End Point, Target Organ) <ul style="list-style-type: none"><li>• 14 Day(s) Rat Oral 10 mg/kg/day LOAEL Liver, Lymphatic system, Pancreas, Adrenal gland</li><li>• 8 Day(s) Dog Oral &lt; 50 mg/kg/day NOAEL Gastrointestinal system, Pancreas</li><li>• 7 Day(s) Dog Oral 2.5 mg/kg/day LOAEL Gastrointestinal system</li></ul>
<b>Genetic Toxicity:</b>	<b>Toceranib phosphate</b> (Study Type, Cell Type / Organism, Result) <ul style="list-style-type: none"><li>• <i>In Vitro</i> Bacterial Mutagenicity (Ames) <i>Salmonella, E. coli</i> Negative</li><li>• <i>In Vitro</i> Chromosome Aberration Human lymphocytes Negative</li><li>• <i>In Vitro</i> Micronucleus Rat Negative</li></ul>

### Chronic / Long Term Effects

No data is available relating to the effects of chronic / long-term exposure to this product.

## Section 12: Ecotoxicity Information

### HSNO Classifications

Not applicable. This product is not classified as ecotoxic.

The environmental characteristics of this material have not been fully evaluated.  
Avoid contamination of any water supply with product or empty container.

### Ecotoxicity Effects

<b>Toxicity to Birds:</b>	Not applicable
<b>Acute Toxicity to Fish:</b>	Not applicable
<b>Toxicity to Algae:</b>	Not applicable
<b>Toxicity to Aquatic Invertebrates:</b>	Not applicable
<b>Toxicity to Soil Dwelling Organisms:</b>	Not applicable
<b>Acute Toxicity to Bees:</b>	Not applicable
<b>Partition Coefficient:</b>	Calculated Log Pow/Log Kow: 2.58 (Toceranib phosphate) Calculated pH 7.4 – Log D: 0.03 (Toceranib phosphate)

### Environmental Fate

No information available.

## Section 13: Disposal Considerations

<b>Product Disposal:</b>	Preferably dispose of product by use in accordance with label directions. Otherwise dispose of product at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with product.
<b>Container Disposal:</b>	Dispose of empty containers by wrapping in paper and putting in garbage for disposal at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with empty container.

## Section 14: Transport Information

### Dangerous Goods Classification

<b>UN No.:</b>	Not applicable. This product is not a dangerous good.
<b>Class:</b>	Not applicable. This product is not a dangerous good.
<b>Packing Group:</b>	Not applicable. This product is not a dangerous good.
<b>Proper Shipping Name:</b>	Not applicable. This product is not a dangerous good.

## Section 15: Regulatory Information

<b>HSNO Approval No.:</b>	HSR100757
<b>HSNO Controls:</b>	See <a href="http://www.epa.govt.nz">www.epa.govt.nz</a> for controls
<b>ACVM Registration No.:</b>	A010834
<b>ACVM Controls:</b>	See <a href="http://www.foodsafety.govt.nz">www.foodsafety.govt.nz</a> for registration conditions

## Section 16: Other Information

**Note:** This product is a veterinary medicine and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to the Government health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

<b>CONTACT POINT:</b>	<b>Zoetis New Zealand Limited:</b>	0800 963 847 (Business Hours)
	<b>National Poisons Centre:</b>	0800 POISON (0800 764 766)
	<b>Emergency Services:</b>	Dial 111

This Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products.

**PLEASE READ ALL LABELS CAREFULLY BEFORE USING PRODUCT.**

If clarification of further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

® Registered trademark  
© 2019 All rights reserved