SAFETY DATA SHEET

Zoetis New Zealand Limited

Section 1: Identification of the Substance and Supplier

Trade Name:	**APOQUEL®**
ACVM Registration No.:	A010963
Classification:	Restricted Veterinary Medicine (RVM)
Recommended Use:	For the treatment of pruritus associated with allergic dermatitis in dogs. For the treatment of clinical manifestations of atopic dermatitis in dogs.
Company Details:	Zoetis New Zealand Limited
Address:	Level 4, 8 Mahuhu Crescent Auckland Central Auckland 1010 New Zealand
Telephone No.:	0800 963 847 (Business Hours)
Emergency Telephone No.:	National Poisons Centre: 0800 POISON (0800 764 766) Emergency Services: In an emergency dial 111
Date of Preparation:	01 July 2019

Section 2: Hazards Identification

Hazard Classification:	6.1D, 6.9B, 8.3A	
Priority Identifier(s):	DANGER – KEEP OUT OF REACH OF CHILDREN	
Secondary Identifier(s):	6.1D	May be harmful if swallowed, inhaled or absorbed through the skin. Avoid skin contact.
	6.9B	May cause organ damage from repeated oral exposure at high doses.
	8.3A	May cause eye damage.

Section 3: Composition / Information on Ingredients

Chemical Identity of Ingredients

Ingredient	CAS No.	Concentration
Oclacitinib maleate	1208319-27-0	Variable
Magnesium stearate	557-04-0	Proprietary
Microcrystalline cellulose	9004-34-6	Proprietary
Lactose monohydrate	64044-51-5	Proprietary
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

Necessary First Aid Measures:	**For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately.** 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.
	Ingestion: 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.
	Eye Contact: 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.
	Skin Contact: Remove any contaminated clothing and wash the affected area immediately with soap and water. If symptoms develop seek medical advice immediately.
	Inhalation: Move the patient to fresh air. If symptoms develop seek medical advice immediately.
Poisoning Symptoms:	No information available.
Workplace Facilities:	No specific facilities required. Standard emergency equipment must be available.
Hygiene Practices:	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.
Notes for Medical Personnel:	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

Type of hazard:	This product is non-flammable, non-combustible and non-explosive
Fire Hazard Properties:	Formation of toxic gases is possible during heating or fire. Fine particles (such as dusts or mists) may fuel fires/explosions.
Regulatory Requirements:	Not applicable.
Extinguishing Media & Methods:	Use dry chemical, foam, carbon dioxide or water to extinguish fires involving this product.
Hazchem Code:	Not allocated.
Recommended Protective Clothing:	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

Personal Precautions:	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.
Environmental Precautions:	Prevent material from entering surface water drains or waterways. If a significant quantity of material enters drains, advise emergency services.
Procedure for Spills:	1. Non-essential personnel should be evacuated from the affected area. 2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage. 3. Collect the spilled material by a method that minimises dust generation. 4. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 5. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains.
Procedure for Disposal:	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

Precautions for Safe Handling:	Minimise dust generation and accumulation. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with the eyes, skin and clothing.
Regulatory Requirements:	Not required.
Handling Practices:	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.
Approved Handlers:	Approved handlers are not required for this product.

Storage

Conditions for Safe Storage:	Store below 25°C (Air Conditioning). Keep out of reach of children. Store in a well ventilated area in the original container, tightly closed, away from foodstuffs.
Store Site Requirements:	Not required.
Packaging:	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

Workplace Exposure Standards:	Oclacitinib maleate:	Zoetis OEL TWA 8-hr 15 µgm^3
	Magnesium stearate:	Sweden OEL TWAs 5 mg/m^3
	Microcrystaline cellulose:	Australia TWA 10 mg/m^3

Application in the Workplace: The nature of this product makes it unlikely that this level will be approached during normal handling.

Exposure Standards Outside the Workplace: None set.

Engineering Controls: 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.

Personal Protection: 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.

- **Hands:** Impervious gloves are recommended if skin contact is possible and for bulk processing operations.
- **Eyes:** It is always prudent to utilise protective eyewear.
- **Skin:** 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.
- **Respiratory:** Respiratory protection is not normally required; however, if necessary utilise an air-purifying respirator that complies with NZ standards.

General Hygiene: 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

Appearance:	White, film-coated tablets.
Odour:	No data available.
Specific Gravity / Density:	No data available.
Melting Point:	No data available.
Boiling Point:	Not applicable.
pH:	No data available.
Solubility in Water:	No data available.
Flashpoint:	Not applicable. This product is not flammable.
Oxidising Properties:	Not applicable. This product is not an oxidiser.
Corrosive Properties:	Not applicable. This product is not corrosive.
Vapour Pressure:	Not applicable.

Section 10: Stability and Reactivity

Stability of the Substance:	This product is stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Material to Avoid:	As a precautionary measure, keep away from strong oxidisers.
Hazardous Decomposition Products:	No data available.
Hazardous Polymerisation:	This product is unlikely to spontaneously polymerise.
Specific Data:	No specific data available.

Section 11: Toxicological Information

HSNO Classifications

6.1D	May be harmful if swallowed, inhaled or absorbed through the skin. Avoid skin contact.
6.9B	May cause organ damage from repeated oral exposure at high doses.
8.3A	May cause eye damage.

Acute Effects

The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Lactose Monohydrate:
- Rat Oral LD50 29700 mg/kg

Microcrystalline cellulose:
- Rat Oral LD50 >5000 mg/kg
- Rabbit Dermal LD50 >2000 mg/kg

Magnesium stearate:
- Rat Oral LD50 >2000 mg/kg
- Rat Inhalation LC50 >2000 mg/m^3

Oclacitinib maleate:
- Rat Oral LD50 310 mg/kg
- Rat Dermal LD50 >2000 mg/kg

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitisation: (Study Type, Species, Severity)

Microcrystalline cellulose:
- Skin Irritation Rabbit Non-irritating
- Eye Irritation Rabbit Non-irritating

Oclacitinib maleate:
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Minimal
- Skin Sensitisation – LLNA Mouse Negative

Repeated Dose Toxicity:	(Duration, Species, Route, Dose, End Point, Target Organ) Oclacitinib maleate: • 7 Day(s) Rat Oral 100 mg/kg/day NOAEL Blood, Spleen, Lymphoid tissue, Heart, Bone marrow, Thymus • 10 Day(s) Dog Oral 18 mg/kg/day LOAEL Blood • 28 Day(s) Dog Oral 1 mg/kg/day LOAEL Bone marrow • 90 Day(s) Dog Oral 0.5 mg/kg/day LOAEL Blood, Bone marrow, Spleen, Lymphoid tissue
Genetic Toxicity:	(Study Type, Cell Type/Organism, Result) Lactose monohydrate: • *In Vitro* bacterial Mutagenicity (Ames) Negative Oclacitinib maleate: • Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative • *In Vivo* Micronucleus Rat Bone Marrow Negative • *In Vitro* Micronucleus Positive with activation without activation • *In Vitro* Micronucleus Chinese Hamster Ovary (CHO) cells Positive without activation aneugenic • *In Vitro* Chromosome Aberration Human Lymphocytes Negative with activation without activation

Chronic / Long Term Effects

No additional information available.

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

Aquatic Toxicity:	(Species, Method, End Point, Duration, Result) Oclacitinib maleate: • *Daphnia magna* (Water Flea) EC50 48 Hours 18 mg/L • *Pseudokirchneriella subcapitata* (Green Alga) EC50 72 Hours 6.1 mg/L • *Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 38 mg/L
Persistence and Degradability:	No data available.
Bio-accumulative Potential:	Oclacitinib maleate: • Predicated 7.4 Log D 1.18
Mobility in Soil:	No data available.

Environmental Fate

No additional information available.

Section 13: Disposal Considerations

Product Disposal:	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.
Container Disposal:	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

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

Section 15: Regulatory Information

HSNO Approval No.:	HSR100757
HSNO Controls:	See www.epa.govt.nz for controls
ACVM Registration No.:	A010963
ACVM Controls:	See www.foodsafety.govt.nz 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.

CONTACT POINT:

Zoetis New Zealand Limited:	0800 963 847 (Business Hours)
National Poisons Centre:	0800 POISON (0800 764 766)
Emergency Services:	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.