SAFETY DATA SHEET

Section 1: Identification

Product identifier **APOQUEL**

Other means of identification

Synonyms Oclacitinib Maleate Film Coated Tablets

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product

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	Serious eye damage/eye irritation	Category 1
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3

Label elements, including precautionary statements

Hazard symbol(s)

Corrosion

Signal word Danger

Hazard statement(s) Causes serious eye damage. Harmful to aquatic life.

Precautionary statement(s)

Prevention Avoid release to the environment. Wear eye protection/face protection.

Response IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTRE/doctor.

Storage Store away from incompatible materials.

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

Other hazards which do not result in classification None.

Supplemental information May form combustible dust concentrations in air. May cause slight skin irritation.

Section 3: Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Oclacitinib maleate	1208319-27-0	5
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.

Section 4: First-aid measures

Description of necessary first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. 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. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention 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 unconsious person.

Personal protection for first-aid responders Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. IF exposed or concerned: Get medical advice/attention. 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 Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Dusts may irritate the respiratory tract, skin and eyes. Difficulty in breathing. Prolonged exposure may cause chronic effects.

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 (CO2).

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.

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 May form combustible dust concentrations in air.

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. Ensure adequate ventilation. Do not breathe dust. 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 release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

Avoid release to the environment. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Avoid dust formation. Ensure adequate ventilation. Prevent entry into waterways, sewer, basements or confined areas.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.

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.

Section 7: Handling and storage

Precautions for safe handling

Minimise dust generation and accumulation. Do not breathe dust. Do not get this material in contact with eyes. Avoid contact with skin. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Wash contaminated clothing before reuse.

Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. Keep tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Storage Temperature: 20 - 25C / 68 - 77F.

Section 8: Exposure controls/personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components	Type	Value
Oclacitinib maleate (CAS 1208319-27-0)	TWA	15 µg/m³

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

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m3	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	Fiber.

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	

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

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	STEL	20 mg/m3	Inhalable dust.
	TWA	4 mg/m3	Respirable dust.
		10 mg/m3	Inhalable dust.

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).

Exposure guidelines

OEL Additional Information: Severe Eye Irritant

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. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Provide eyewash station.

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

Eye/face protection	If contact is likely, safety glasses with side shields are recommended. Industrial use: Wear safety glasses with side shields (or goggles) and a face shield.
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.
Other	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection	No personal respiratory protective equipment normally required. Respirator must be worn if exposed to dust. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.
Thermal hazards	Not applicable.
Hygiene measures	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	Film-coated tablets
Physical state	Solid.
Form	Solid.
Colour	White
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 flammable.
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.
Molecular formula	Mixture

Molecular weight	Mixture
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. Contact with incompatible materials.
Incompatible materials	Strong oxidising agents. Fluorine.
Hazardous decomposition products	No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system. Prolonged inhalation may be harmful.	
Skin contact	Prolonged skin contact may cause temporary irritation.	
Oclacitinib maleate		Species: Rabbit Severity: Minimal
Microcrystalline cellulose		Species: Rabbit Severity: Non-irritating
Eye contact	Causes serious eye damage.	
Microcrystalline cellulose		Species: Rabbit Severity: Non-irritating
Oclacitinib maleate		Species: Rabbit Severity: Severe
Ingestion	May cause discomfort if swallowed.	

Symptoms related to the physical, chemical and toxicological characteristics	Severe eye irritation. Dusts may irritate the respiratory tract, skin and eyes. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Difficulty in breathing. Permanent eye damage including blindness could result. Prolonged exposure may cause chronic effects.

Information on toxicological effects

Acute toxicity	May be harmful in contact with skin.

Components	**Species**	**Test Results**
Magnesium stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2000 mg/m3
Oral		
LD50	Rat	> 2000 mg/kg
Microcrystalline cellulose (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Oclacitinib maleate (CAS 1208319-27-0)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
Oral		
LD50	Rat	310 mg/kg
Subacute		
Oral		
LOAEL	Dog	18 mg/kg/day, 10 days (Target organ(s): Blood)
		1 mg/kg/day, 28 days (Target organ(s): Bone Marrow)
NOAEL	Rat	100 mg/kg/day, 7 days (Target organ(s): Blood, Spleen, Lymphoid tissue, Heart, Bone marrow, Thymus)
Subchronic		
Oral		
LOAEL	Dog	0.5 mg/kg/day, 90 days (Target organ(s): Blood, Bone Marrow, Spleen, Lymphoid tissue)

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

Oclacitinib maleate	Result: Minimal Species: Rabbit

Serious eye damage/eye irritation Causes serious eye damage.

Eye contact

Microcrystalline cellulose	Species: Rabbit Severity: Non-irritating
Oclacitinib maleate	Species: Rabbit Severity: Severe

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

Oclacitinib maleate	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

Oclacitinib maleate	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli In Vitro Chromosome Aberration Result: Negative with activation, without activation Species: Human lymphocytes In Vivo Micronucleus (1) Result: Negative Species: Rat In Vivo Micronucleus (2) 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

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Embryo/Fetal Development

Oclacitinib maleate

1 mg/kg/day OECD 414, [Fetal growth, not teratogenic]
Result: NOEL
Species: Rat

5 mg/kg/day OECD 414, [Maternal toxicity, embryo/fetal viability, not teratogenic]
Result: NOAEL
Species: Rabbit

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

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. May cause damage to organs through prolonged or repeated exposure.

Section 12: Ecological information

Ecotoxicity Avoid release to the environment. Harmful to aquatic life.

Components		Species	Test Results
Oclacitinib maleate (CAS 1208319-27-0)			
Aquatic			
Algae	EC50	Pseudokirchneriella subcapitata (Green Alga)	6.1 mg/l, 72 Hours
Crustacea	EC50	Daphnia magna (Water Flea)	18 mg/l, 48 Hours
Fish	LC50	Oncorhynchus mykiss (rainbow trout)	38 mg/l, 96 Hours

Persistence and degradability No data available for this product.

Bioaccumulative potential See below

Partition coefficient n-octanol / water (log Kow)

Oclacitinib maleate 1.18, Predicted Log D @ pH 7.4

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 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. A10963.
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.

New Zealand Inventory of Chemicals (NZIoC): Registration status

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

Section 16: Other information

Issue date	31-October-2024
Version No.	01
Key abbreviations or acronyms used	Not available.
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Revision information	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties GHS: Qualifiers