SAFETY DATA SHEET

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 (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)

2. Hazard(s) 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 or doctor/physician.

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 known.

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

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.

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.

Eye contact Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention immediately.

Ingestion 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. Rinse mouth.

Personal protection for first-aid responders Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

Symptoms caused by exposure Dusts may irritate the respiratory tract, skin and eyes. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Difficulty in breathing. Prolonged exposure may cause chronic effects.

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

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.

General fire hazards May form combustible dust concentrations in air.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away.

For emergency responders Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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). Ensure adequate ventilation. Avoid dust formation. Avoid release to the environment. 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.

7. Handling and storage

Precautions for safe handling

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

Conditions for safe storage, including any incompatibilities

Keep tightly closed in a dry, cool and well-ventilated place. @ 20 - 25C / 68 - 77F. Keep away from heat, sparks and open flame. Keep out of the reach of children.

8. Exposure controls and 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

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.

US. ACGIH Threshold Limit Values

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. EH40 Workplace Exposure Limits (WELs)

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.

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
Microcrystalline cellulose (CAS 9004-34-6)	TWA	4 mg/m3	Inhalable dust.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

OEL Additional Information: Severe Eye Irritant

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. General ventilation normally adequate. 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. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
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.

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	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
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.
Molecular formula	Mixture
Molecular weight	Mixture
Oxidising properties	Not oxidising.

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	Contact with incompatible materials. Keep away from heat, spark, open flames and other sources of ignition.
Incompatible materials	Strong oxidising agents. Fluorine.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on possible routes of exposure

Inhalation	Dust may irritate respiratory system.	
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 exposure	Dusts may irritate the respiratory tract, skin and eyes. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Difficulty in breathing. Prolonged exposure may cause chronic effects.
Acute toxicity	Not acutely toxic

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

Components	Species	Test Results
Oclacitinib maleate (CAS 1208319-27-0)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg
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/irritation Causes serious eye damage.

Eye contact

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

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitizer.

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 Vitro Micronucleus Result: Positive with activation, without activation

Mutagenicity

Oclacitinib maleate	In Vitro Micronucleus Result: Positive without activation, aneugenic Species: Chinese Hamster Ovary (CHO) cells In Vivo Micronucleus Result: Negative Species: Rat Bone Marrow

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.

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

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

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

12. Ecological information

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

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 is available on the degradability of 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.

13. Disposal considerations

Disposal methods Avoid release to the environment. 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.

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.

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 (23/12/2011).

APVMA No. 68310

Poison Schedule (Product) - Schedule 4

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

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.

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

Not listed.

Restricted Carcinogenic Substances

Not regulated.

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).

16. Other information

Issue date	03-November-2016
Revision date	23-November-2021
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	This document has undergone significant changes and should be reviewed in its entirety.