

SAFETY DATA SHEET



1. Identification

Product identifier	APOQUEL
Other means of identification	
Synonyms	Oclacitinib Maleate Film Coated Tablets
Recommended use	Veterinary product
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 1
	Specific target organ toxicity following repeated exposure	Category 2 (blood, bone marrow, lymphatic system, spleen)
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3

Label elements



Signal word	Danger
Hazard statement	Causes serious eye damage. May cause damage to organs (blood, bone marrow, lymphatic system, spleen) through prolonged or repeated exposure. Harmful to aquatic life.
Precautionary statement	
Prevention	Do not breathe dust/fume/gas/mist/vapours/spray. Avoid release to the environment. Wear eye protection/face protection.

Response	Get medical advice/attention if you feel unwell. 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.
Supplemental information	May form combustible dust concentrations in air. May cause slight skin irritation.
Other hazards	None known.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Oclacitinib maleate		1208319-27-0	5
Magnesium stearate		557-04-0	*
Microcrystalline cellulose		9004-34-6	*

All concentrations are in percent by weight (kg) unless ingredient is a gas. Gas concentrations are in percent by volume (l).

Composition comments * This material is not considered to be hazardous according to regulatory guidelines (see Section 15).

4. 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	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.
Most important symptoms/effects, acute and delayed	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.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

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	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	May form combustible dust concentrations in air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. 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. Local authorities should be advised if significant spillages cannot be contained.
----------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

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.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

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. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection**Occupational exposure limits****Zoetis**

Components	Type	Value
Oclacitinib maleate (CAS 1208319-27-0)	TWA	15 µg/m ³

US. ACGIH Threshold Limit Values

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

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m ³
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

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

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

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

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

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

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	Total dust.

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	15 minute	20 mg/m ³	
	8 hour	10 mg/m ³	
Microcrystalline cellulose (CAS 9004-34-6)	15 minute	20 mg/m ³	Fiber.
	8 hour	10 mg/m ³	Fiber.

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. General ventilation normally adequate. Provide eyewash station.
Individual protection measures, such as personal protective equipment	
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.
General hygiene considerations	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	
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 information	
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 likely 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 the physical, chemical and toxicological characteristics

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.

Information on toxicological 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
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/eye irritation Causes serious eye damage.

Eye contact

Microcrystalline cellulose Species: Rabbit
Severity: Non-irritating

Oclacitinib maleate Species: Rabbit
Severity: Severe

Respiratory or skin sensitisation

Canada - Alberta OELs: Irritant

Magnesium stearate (CAS 557-04-0) Irritant

Microcrystalline cellulose (CAS 9004-34-6) Irritant

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 Vitro Micronucleus
Result: Positive with activation, without activation

In Vitro Micronucleus
Result: Positive without activation, aneugenic
Species: Chinese Hamster Ovary (CHO) cells

In Vivo Micronucleus
Result: Negative
Species: Rat Bone Marrow

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

ACGIH Carcinogens

Magnesium stearate (CAS 557-04-0) A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Magnesium stearate (CAS 557-04-0) 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 May cause damage to organs (blood, bone marrow, lymphatic system, spleen) through prolonged or repeated exposure.

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.

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 instructions 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code None known.

Waste from residues / unused products 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

TDG
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

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

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

Country(s) or region	Inventory name	On inventory (yes/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	15-February-2022
Version No.	04
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.