

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	
Manufacturer	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

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

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/vapors/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 center/doctor.
Storage	Store away from incompatible materials.

Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	May cause slight skin irritation.

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	*

Composition comments *Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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 center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. 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 (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 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	No unusual fire or explosion hazards noted.

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. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained.
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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. Following product recovery, flush area with water.

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

Environmental precautions**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. Minimize 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/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value****Form**

Microcrystalline cellulose (CAS 9004-34-6)

PEL

5 mg/m³

Respirable fraction.

15 mg/m³

Total dust.

US. ACGIH Threshold Limit Values**Components****Type****Value**

Magnesium stearate (CAS 557-04-0)

TWA

10 mg/m³

Microcrystalline cellulose (CAS 9004-34-6)

TWA

10 mg/m³

US. NIOSH: Pocket Guide to Chemical Hazards**Components****Type****Value****Form**

Microcrystalline cellulose (CAS 9004-34-6)

TWA

5 mg/m³

Respirable.

10 mg/m³

Total

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 vapor 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.
Color	White
Odor	Not available.
Odor 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 available.
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.
Vapor pressure	Not available.
Vapor 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
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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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 oxidizing agents. Fluorine.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

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 Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Magnesium stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2000 mg/m ³
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)

Components	Species	Test Results
NOAEL	Rat	1 mg/kg/day, 28 days (Target organ(s): Bone Marrow) 100 mg/kg/day, 7 days (Target organ(s): Blood, Spleen, Lymphoid tissue, Heart, Bone marrow, Thymus)
<u>Subchronic</u>		
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 sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Skin sensitization		
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.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not available.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

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)	EC50	Daphnia magna (Water Flea) 18 mg/L, 48 Hours
		Pseudokirchneriella subcapitata (Green Alga) 6.1 mg/L, 72 Hours
	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

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. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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 (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

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

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Microcrystalline cellulose (CAS 9004-34-6)

US. New Jersey Worker and Community Right-to-Know Act

Microcrystalline cellulose (CAS 9004-34-6)

US. Pennsylvania Worker and Community Right-to-Know Law

Microcrystalline cellulose (CAS 9004-34-6)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	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

Country(s) or region	Inventory name	On inventory (yes/no)*
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	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, including date of preparation or last revision

Issue date 11-03-2016

Version # 01

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Revision information This document has undergone significant changes and should be reviewed in its entirety.