

SAFETY DATA SHEET



1. Identification

Product identifier	APOQUEL Chewable Tablets (3.6 mg, 5.4 mg and 16 mg)
Other means of identification	
Synonyms	Apoquel 3.6 mg Chewable Tablets for Dogs * Apoquel 5.4 mg Chewable Tablets for Dogs * Apoquel 16 mg Chewable Tablets for Dogs
Recommended use	Veterinary product used as Antipruritic
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 & Drug Safety	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
	Hazardous to the aquatic environment, long-term 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 with long lasting effects.

Precautionary statement

Prevention	Do not breathe dust. 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. Get medical advice/attention if you feel unwell.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental information None.

Other hazards None known.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Oclacitinib Maleate		*	< 5
Glycerol		56-81-5	10-15

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments *Designates that a specific chemical identity and/or percentage of composition 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. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. 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 unconscious person.
Most important symptoms/effects, acute and delayed	Causes serious eye damage. 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.
General information	IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Water spray. Alcohol resistant foam. Dry 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	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not get in eyes, on skin, or on clothing. Ensure adequate ventilation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained.
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Methods and materials for containment and cleaning up

Wear appropriate protective equipment and clothing during clean-up. Avoid the generation of dusts during clean-up. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. 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.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not get this material in contact with eyes. Do not taste or swallow. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Keep tightly closed in a dry, cool and well-ventilated place. Store below 25°C. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS).

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

Components	Type	Value
Oclacitinib Maleate	TWA	15 µg/m ³

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

Components	Type	Value	Form
Glycerol (CAS 56-81-5)	TWA	10 mg/m ³	Mist.
Silica colloidal, Ph. Eur. (CAS 112945-52-5)	TWA	3 mg/m ³	Respirable particles.
		10 mg/m ³	Total particulate.

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

Components	Type	Value	Form
Glycerol (CAS 56-81-5)	TWA	3 mg/m ³	Respirable mist.
		10 mg/m ³	Mist.
Silica colloidal, Ph. Eur. (CAS 112945-52-5)	TWA	3 mg/m ³	Respirable fraction.
		10 mg/m ³	Total dust.

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

Components	Type	Value	Form
Glycerol (CAS 56-81-5)	TWA	10 mg/m ³	Mist.
Silica colloidal, Ph. Eur. (CAS 112945-52-5)	TWA	10 mg/m ³	Total dust.

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

Components	Type	Value	Form
Glycerol (CAS 56-81-5)	15 minute	20 mg/m ³	Mist.
	8 hour	10 mg/m ³	Mist.
Silica colloidal, Ph. Eur. (CAS 112945-52-5)	15 minute	6 mg/m ³	Respirable fraction.
		20 mg/m ³	Inhalable fraction.
	8 hour	3 mg/m ³	Respirable fraction.
		10 mg/m ³	Inhalable fraction.

Biological limit values	No biological exposure limits noted for the ingredient(s).
Control banding approach	Not available.
Appropriate engineering controls	General ventilation normally adequate. Provide eyewash station.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
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.
Thermal hazards	Not applicable.
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	Tablet.
Physical state	Solid.
Form	Solid.
Colour	Not available.
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 available.
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.
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. Sunlight. High temperatures. Keep away from heat, sparks and open flame.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation No adverse effects due to inhalation are expected.

Skin contact Prolonged skin contact may cause temporary irritation.

Glycerol Species: Rabbit
Severity: Mild

Oclacitinib Maleate Species: Rabbit
Severity: Minimal

Eye contact Causes serious eye damage.

Glycerol Species: Rabbit
Severity: Mild

Oclacitinib Maleate Species: Rabbit
Severity: Severe

Ingestion May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Causes serious eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Prolonged exposure may cause chronic effects.

Information on toxicological effects

Acute toxicity Not acutely toxic

Components	Species	Test Results
Glycerol (CAS 56-81-5)		
<u>Acute</u>		
Oral		
LD50	Rat	12600 mg/kg
<u>Chronic</u>		
Oral		
LOAEL	Rat	16800 mg/kg, 28 days Endocrine system
Oclacitinib Maleate		
<u>Acute</u>		
Dermal		
LD50	Rat	> 2000 mg/kg
Oral		
LD50	Rat	310 mg/kg
<u>Subacute</u>		
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)

Components	Species	Test Results
<u>Subchronic</u>		
Oral		
LOAEL	Dog	0.5 mg/kg/day, 90 days (Target organ(s): Blood, Bone Marrow, Spleen, Lymphoid tissue)
Silica colloidal, Ph. Eur. (CAS 112945-52-5)		
<u>Acute</u>		
Oral		
LD50	Rat	> 22500 mg/kg
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		
Glycerol		Species: Rabbit Severity: Mild
Oclacitinib Maleate		Species: Rabbit Severity: Severe
Respiratory or skin sensitisation		
Canada - Alberta OELs: Irritant		
Glycerol (CAS 56-81-5)		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.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Silica colloidal, Ph. Eur. (CAS 112945-52-5)		3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Based on available data, the classification criteria are not met. This product is not expected to cause reproductive or developmental effects.

Reproductivity

Glycerol

100 mg/kg Reproductive & Fertility-Males, Fertility
Result: LOEL
Species: Rat
Organ: Oral

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.

Further information Caution - Pharmaceutical agent. Compound, not fully tested, additional hazards may exist.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects. Avoid release to the environment.

Components	Species	Test Results
Glycerol (CAS 56-81-5)		
Aquatic		
<i>Acute</i>		
Fish	LC50 Rainbow trout,donaldson trout (Oncorhynchus mykiss)	>= 51000 - <= 57000 mg/l, 96 hours
Oclacitinib Maleate		
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 The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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
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

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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.