1. Identification

Product identifier APOQUEL

Other means of identification

Synonyms Oclacinib 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

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oclacitinib Maleate</td>
<td></td>
<td>1208319-27-0</td>
<td>5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td></td>
<td>557-04-0</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td></td>
<td>9004-34-6</td>
<td></td>
</tr>
</tbody>
</table>

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.
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.

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.

Methods and materials for containment and cleaning up

Environmental precautions

8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>Zoetis Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oclacitinib Maleate (CAS 1208319-27-0)</td>
<td>TWA</td>
<td>15 µg/m³</td>
</tr>
</tbody>
</table>

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>PEL</td>
<td>5 mg/m³</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>TWA</td>
<td>15 mg/m³</td>
<td>Total dust.</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate (CAS 557-04-0)</td>
<td>TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>TWA</td>
<td>5 mg/m³</td>
<td>Respirable.</td>
</tr>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>Total</td>
</tr>
</tbody>
</table>

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

Control banding approach: 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.

Exposure guidelines: OEL Additional Information: Severe Eye Irritant

Biological limit values

Appropriate engineering controls

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.

Material name: APOQUEL

559    Version #: 01    Issue date: 11-03-2016
Material is stable under normal conditions.

No dangerous reaction known under conditions of normal use.

Contact with incompatible materials. Keep away from heat, spark, open flames and other sources of ignition.

Strong oxidizing agents. Fluorine.

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.

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**

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate (CAS 557-04-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td>LC50</td>
<td>Rat</td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>Rat</td>
</tr>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>Rat</td>
</tr>
<tr>
<td>Oclacitinib Maleate (CAS 1208319-27-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
<td>Rat</td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>Rat</td>
</tr>
<tr>
<td><strong>Subacute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LOAEL</td>
<td>Dog</td>
</tr>
<tr>
<td>Components</td>
<td>Species</td>
<td>Test Results</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>NOAEL</td>
<td>Rat</td>
<td>1 mg/kg/day, 28 days (Target organ(s): Bone Marrow)</td>
</tr>
<tr>
<td>LOAEL</td>
<td>Dog</td>
<td>100 mg/kg/day, 7 days (Target organ(s): Blood, Spleen, Lymphoid tissue, Heart, Bone marrow, Thymus)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Subchronic</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td>0.5 mg/kg/day, 90 days (Target organ(s): Blood, Bone Marrow, Spleen, Lymphoid tissue)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin corrosion/irritation</td>
</tr>
<tr>
<td>Prolonged skin contact may cause temporary irritation.</td>
<td></td>
<td>Oclacitinib Maleate Result: Minimal Species: Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Serious eye damage/eye irritation</td>
</tr>
<tr>
<td>Causes serious eye damage.</td>
<td></td>
<td>Microcrystalline cellulose Species: Rabbit Severity: Non-irritating</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oclacitinib Maleate Species: Rabbit Severity: Severe</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Respiratory or skin sensitization</td>
</tr>
<tr>
<td>Not a respiratory sensitizer.</td>
<td></td>
<td>Oclacitinib Maleate LLNA Species: Mouse Severity: Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Germ cell mutagenicity</td>
</tr>
<tr>
<td>No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.</td>
<td></td>
<td>Oclacitinib Maleate Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella, E. coli</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mutagenicity</td>
</tr>
<tr>
<td>Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella, E. coli</td>
<td></td>
<td>In Vitro Chromosome Aberration Result: Negative with activation, without activation Species: Human Lymphocytes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In Vitro Micronucleus Result: Positive with activation, without activation Species: Chinese Hamster Ovary (CHO) cells</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oclacitinib Maleate In Vivo Micronucleus Result: Negative Species: Rat Bone Marrow</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td></td>
<td>This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.</td>
</tr>
<tr>
<td>IARC Monographs. Overall Evaluation of Carcinogenicity</td>
<td></td>
<td>Not available.</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oclacitinib Maleate (CAS 1208319-27-0)</td>
<td>Daphnia magna (Water Flea)</td>
<td>EC50 18 mg/L, 48 Hours</td>
</tr>
<tr>
<td></td>
<td>Pseudokirchneriella subcapitata (Green Alga)</td>
<td>LC50 6.1 mg/L, 72 Hours</td>
</tr>
<tr>
<td></td>
<td>Oncorhynchus mykiss (Rainbow Trout)</td>
<td>LC50 38 mg/L, 96 Hours</td>
</tr>
</tbody>
</table>

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential

<table>
<thead>
<tr>
<th>Partition coefficient n-octanol / water (log Kow)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oclacitinib Maleate</td>
</tr>
</tbody>
</table>

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
<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
</tbody>
</table>

Material name: APOQUEL
Version #: 01  Issue date: 11-03-2016
<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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

**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.

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