SAFETY DATA SHEET

1. Identification

Product identifier Osurnia

Other means of identification

Item Code CA4710

Recommended use Veterinary Pharmaceutical

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company Name Elanco Animal Health

2500 Innovation Way

Greenfield, IN 46140

US

Phone: 1-877-Elanco1 (1-877-352-6261)

Email: lilly_msds@lilly.com

Emergency Telephone Numbers:

Elanco Product Technical Support / Human or Animal Exposure Reporting:

1-888-545-5973

Transportation Emergency Telephone:

CHEMTREC: 1-800-424-9300

(Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Serious eye damage/eye irritation Category 2

Reproductive toxicity (fertility) Category 2

OSHA defined hazards Not classified.

Label elements

Signal word Warning

Hazard statement

H319 Causes serious eye irritation.

H361 Suspected of damaging fertility or the unborn child.

Precautionary statement

Prevention

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P264 Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response

P305 + P351 + IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P338

P308 + P313 IF exposed or concerned: Get medical advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/attention.

Storage

P405 Store locked up.

Disposal
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>Propylene Carbonate</td>
<td></td>
<td>108-32-7</td>
<td>50 - 75</td>
</tr>
<tr>
<td>Glycerol Formal</td>
<td></td>
<td>5464-28-8</td>
<td>25 - 50</td>
</tr>
<tr>
<td>Florfenicol</td>
<td>2,2-dichloro-N-[(1R,2S)-3-fluoro-1-hydroxy-1-(4-flonylphenyl)propan-2-yl]acetamide</td>
<td>73231-34-2</td>
<td>0.834</td>
</tr>
<tr>
<td>Terbinafine</td>
<td></td>
<td>91161-71-6</td>
<td>0.834</td>
</tr>
<tr>
<td>Betamethasone Acetate</td>
<td></td>
<td>987-24-6</td>
<td>0.083</td>
</tr>
<tr>
<td>BHT</td>
<td></td>
<td>128-37-0</td>
<td>&lt;= 0.1</td>
</tr>
</tbody>
</table>

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 eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

**Ingestion**
Causes serious eye irritation. Suspected of damaging fertility or the unborn child.

**Most important symptoms/effects, acute and delayed**
Treat symptomatically.

**Indication of immediate medical attention and special treatment needed**
IF exposed or concerned: Get medical advice/attention. 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 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**
Move containers from fire area if you can do so without risk.

**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. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up**
Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. 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.

**Environmental precautions**
Never return spills to original containers for re-use.

Avoid discharge into drains, water courses or onto the ground.
7. Handling and storage

Precautions for safe handling
Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Provide adequate ventilation. Avoid contact with eyes. Avoid prolonged exposure. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities
Store locked up. Store in original tightly closed container. Store at: 2 - 8 C.

8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>US. ACGIH Threshold Limit Values</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BHT (CAS 128-37-0)</td>
<td>TWA</td>
<td>2 mg/m3</td>
<td>Inhalable fraction and vapor.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>US. NIOSH: Pocket Guide to Chemical Hazards</th>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BHT (CAS 128-37-0)</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td></td>
</tr>
</tbody>
</table>

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

Exposure guidelines
Novartis Internal Exposure Limit (NPIEL):
0.1 mg/m3 8 hour TWA (Florfenicol)
2 mg/m3 8 hour TWA (Terbinafine base)

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. 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 appropriate chemical resistant clothing.

Respiratory protection
In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards
Not available.

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. Observe any medical surveillance requirements.

9. Physical and chemical properties

Appearance

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Form</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid</td>
<td>Gel.</td>
<td>White to yellow.</td>
</tr>
</tbody>
</table>

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
> 194.0 °F (> 90.0 °C)

Evaporation rate
Not available.

Flammability (solid, gas)
Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)
Not available.
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
Hazardous polymerization does not occur.

Conditions to avoid
Contact with incompatible materials.

Incompatible materials
Strong oxidizing agents.

Hazardous decomposition products
No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osurnia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 2020 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Components</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BHT (CAS 128-37-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td>&gt; 6000 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Florfenicol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(CAS 73231-34-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
</tbody>
</table>
Components | Species | Test Results
--- | --- | ---
**Chronic**
**Oral**
NOEL | Dog | 1 mg/kg
Rat | 1 mg/kg Adverse effects on the male reproductive system.

**Skin corrosion/irritation**
Rabbit: No irritation
Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation**
Rabbit: Moderate eye irritation.

**Respiratory or skin sensitization**
**Respiratory sensitization**
Due to partial or complete lack of data the classification is not possible.

**Skin sensitization**
Local Lymph Node Assay (LLNA) Negative.
Based on available data, the classification criteria are not met.

**Germ cell mutagenicity**
Due to partial or complete lack of data the classification is not possible.

**Carcinogenicity**
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Not classifiable as to carcinogenicity to humans.
Due to partial or complete lack of data the classification is not possible.

**IARC Monographs. Overall Evaluation of Carcinogenicity**
BHT (CAS 128-37-0) 3 Not classifiable as to carcinogenicity to humans.

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**
Not listed.

**Reproductive toxicity**
Suspected of damaging fertility or the unborn child.

**Specific target organ toxicity - single exposure**
Due to partial or complete lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure**
Due to partial or complete lack of data the classification is not possible.

**Aspiration hazard**
Not an aspiration hazard.

**12. Ecological information**

**Ecotoxicity**
Very toxic to aquatic life with long lasting effects.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
</table>
| **BHT (CAS 128-37-0)**
**Aquatic**
**Acute**
Algae | EC50 | Algae | 0.758 mg/l, 96 h
Crustacea | EC50 | Daphnia magna | 0.48 mg/l, 48 h
Fish | LC50 | Fish | 0.199 mg/l, 96 h
**Chronic**
Crustacea | NOEC | Daphnia magna | 0.15 mg/l, 48 h
| **Florfenicol (CAS 73231-34-2)**
**Aquatic**
**Acute**
Algae | EC50 | Algae | 3.83 mg/l, 72 hours OECD Test Guideline 201
NOEC | Algae | 0.32 mg/l, 72 hours OECD Test Guideline 201
Crustacea | EC50 | Daphnia magna | > 495 mg/l, 48 hours OECD Test Guideline 202
NOEC | Daphnia magna | 84.5 mg/l OECD Test Guideline 202
Fish | LC50 | Oncorhynchus mykiss | > 900 mg/l, 96 hours OECD Test Guideline 203

Material name: Osurnia
6350 Version #: 08 Revision date: 08-10-2017 Issue date: 05-11-2016
<table>
<thead>
<tr>
<th>Components Test Results</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terrestrial Acute NOEC</td>
<td>Oncorhynchus mykiss</td>
<td>&gt; 900 mg/l, 96 hours OECD Test Guideline 203</td>
</tr>
<tr>
<td>Terrestrial Other NOEC</td>
<td>Earthworm (Eisenia fetida)</td>
<td>5.6 mg/kg, 56 hours OECD Test Guideline 222</td>
</tr>
<tr>
<td>Terbinafine (CAS 91161-71-6) Other IC50</td>
<td>Activated sludge of a predominantly domestic sewage</td>
<td>&gt; 100 mg/l</td>
</tr>
<tr>
<td>Terbinafine (CAS 91161-71-6) Other NOEC</td>
<td>Pseudokirchnerella subcapitata</td>
<td>0.0005 mg/l</td>
</tr>
<tr>
<td>Aquatic Acute Algae EC50</td>
<td>Algae</td>
<td>0.029 mg/l</td>
</tr>
<tr>
<td>Aquatic Acute Crustacea EC50</td>
<td>Daphnia</td>
<td>0.35 mg/l, 48 hours</td>
</tr>
<tr>
<td>Aquatic Chronic Fish NOEC</td>
<td>Fathead minnow (Pimephales promelas)</td>
<td>0.047 mg/l, 32 days</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>Florfenicol</td>
</tr>
<tr>
<td>Propylene Carbonate</td>
</tr>
</tbody>
</table>

Mobility in soil
No data available.

Other adverse effects
Not available.

13. Disposal considerations

Disposal instructions
Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

General information
Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

DOT
Not regulated as dangerous goods.

IATA

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN3082</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (TERBINAFINE, Florfenicol)</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td></td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
</tr>
<tr>
<td>Subsidiary risk</td>
<td>-</td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Environmental hazards</td>
<td>Yes</td>
</tr>
<tr>
<td>ERG Code</td>
<td>9L</td>
</tr>
<tr>
<td>Special precautions for user</td>
<td>Not available.</td>
</tr>
<tr>
<td>Other information</td>
<td></td>
</tr>
<tr>
<td>Passenger and cargo aircraft</td>
<td>Allowed with restrictions.</td>
</tr>
<tr>
<td>Cargo aircraft only</td>
<td>Allowed with restrictions.</td>
</tr>
</tbody>
</table>

IMDG

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN3082</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TERBINAFINE, Florfenicol)</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td></td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
</tr>
<tr>
<td>Subsidiary risk</td>
<td>-</td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
</tbody>
</table>
Environmental hazards
Marine pollutant: Yes
EmS: F-A, S-F
Special precautions for user: Not available.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
IATA; IMDG

Marine pollutant

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 regulated.

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 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.

International Inventories

Country(s) or region Inventory name On inventory (yes/no)*
Canada Domestic Substances List (DSL) No
<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>05-11-2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>08-10-2017</td>
</tr>
<tr>
<td>Version #</td>
<td>08</td>
</tr>
</tbody>
</table>

Lilly Lab Code

Health: 2  
Fire: 1  
Reactivity: 1  

Disclaimer

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Elanco Animal Health
0011+1-877-352-6261
0011+1-800-428-4441

Revision information

Toxicological Information: Toxicological Property Data  
GHS: Classification