SAFETY DATA SHEET

1. Identification

Product identifier: Micotil 300

Other means of identification

Item Code: AH0230

Synonyms: Tylosin, 4A-O-de(2,6-dideoxy-3-C-methyl-a-L-ribo-hexopyranosyl)-20-deoxo-20-[(3R,5S)-3,5-dimethyl-1-piperidinyl]-p-hosphate (1:1) (salt) * Tilmicosin Formulation * Tilmicosin Phosphate Formulation

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: Elanco Product Technical Support / Human or Animal Exposure Reporting:

Numbers: 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: Sensitization, respiratory Category 1
Sensitization, skin Category 1
Specific target organ toxicity, repeated exposure Category 2

OSHA defined hazards: Not classified.

Label elements

Signal word: Danger

Hazard statement:

H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H373 May cause damage to organs (Heart) through prolonged or repeated exposure.

Precautionary statement

Prevention:
P261 Avoid breathing mist or vapor.
P284 In case of inadequate ventilation wear respiratory protection.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.
Get medical advice/attention if you feel unwell.

Not available.

Dispose of contents/container in accordance with local/regional/national/international regulations.

Injection of Micotil 300 in humans has been associated with fatalities.

None.

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>Tilmicosin Phosphate</td>
<td></td>
<td>137330-13-3</td>
<td>30</td>
</tr>
</tbody>
</table>

Composition comments

Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation
Move to fresh air. Oxygen or artificial respiration if needed. Call a physician or poison control center immediately.

Skin contact
Wash off immediately with soap and plenty of water. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash before reuse.

Eye contact
Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Call a physician or poison control center immediately.

Ingestion
Call a physician or poison control center immediately. Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed

Human Warnings: Not for human use. Injection of Micotil 300 in humans has been associated with fatalities. Keep out of the reach of children. Do not use in automatically powered syringes. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a physician immediately. Emergency medical telephone numbers are 1-800-722-0987 (Rocky Mountain Poison Control Center) or 1-800-428-4441 (Elanco). Avoid contact with eyes.

(Micotil 300) No allergic reactions in a manufacturing setting have been reported. Compounds of similar structure have been reported to cause transient alterations in heart rate. Clinical signs from accidental human injection include off taste in the mouth, nausea, headache, dizziness, rapid heart rate, chest pain, anxiety or lightheadedness. Local reactions such as injection site pain, bleeding, swelling or inflammation have been reported. Injection of this drug in humans has been associated with fatalities.

(Tilmicosin Phosphate) Allergic reactions in a manufacturing setting have been reported. Allergy symptoms may include skin rash, watery eyes, shortness of breath, nasal congestion, coughing, and wheezing.

Indication of immediate medical attention and special treatment needed

In case of human injection, consult a physician immediately and apply ice or cold pack to the injection site while avoiding direct contact with the skin.

The cardiovascular system is the target of toxicity and should be monitored closely. Cardiovascular toxicity may be due to calcium channel blockade. In dogs, administration of intravenous calcium offset Micotil-induced tachycardia and negative inotropy (decreased contractility). Dobutamine partially offset the negative inotropic effects induced by Micotil in dogs. Beta-adrenergic antagonists, such as propranolol, exacerbated the negative inotropy of Micotil in dogs. Epinephrine potentiated lethality of Micotil in pigs. This antibiotic persists in tissues for several days.

5. Fire-fighting measures

Suitable extinguishing media
Alcohol resistant foam. Dry chemical. 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
Fire or excessive heat may produce hazardous decomposition products.

Special protective equipment and precautions for firefighters
Wear self-contained breathing apparatus and protective clothing.

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

Do not breathe mist or vapor. 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. See Section 8 of the SDS for Personal Protective Equipment. Avoid contact with skin, eyes and clothing.

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. Absorb in vermiculite, dry sand or earth and place into containers. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Environmental precautions

Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

7. Handling and storage

Precautions for safe handling

Human Warnings: Not for human use. Injection of Micotil 300 in humans has been associated with fatalities. Keep out of the reach of children. Do not use in automatically powered syringes. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a physician immediately and apply ice or cold pack to the injection site while avoiding direct contact with the skin. Emergency medical telephone numbers are 1-800-722-0987 (Rocky Mountain Poison Control Center) or 1-800-428-4441 (Elanco). Avoid contact with eyes.

Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep at temperature not exceeding 30°C / 86°F. Avoid moisture. Protect against direct sunlight. Avoid contact with oxidizing agents.

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

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

Exposure guidelines

Lilly Exposure Guideline (LEG): 12 hour TWA <100 ug/m3 (Tilmicosin)

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.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear chemical goggles. Use face shield in case of splash risk.

Skin protection

Hand protection

Wear appropriate chemical resistant gloves.

Other

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection

Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor.

Thermal hazards

Not available.

General hygiene considerations

In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Under normal use and handling conditions, wear goggles to protect eyes and wear impermeable gloves and protective equipment to avoid direct contact with skin. Wash thoroughly with soap and water after handling.

9. Physical and chemical properties

Appearance

Solution.

Physical state

Liquid.

Form

Liquid.

Color

Yellow to Amber.

Odor

Faint sweet odor.

Odor threshold

No data available.

pH

5.5 - 6.5 (aqueous 50/50)

Melting point/freezing point

No data available.
Initial boiling point and boiling range
No data available.
Flash point
No data available.
Evaporation rate
No data available.
Flammability (solid, gas)
Not applicable.
Upper/lower flammability or explosive limits
| Flammability limit - lower (%) | No data available. |
| Flammability limit - upper (%) | No data available. |
| Explosive limit - lower (%) | 20 % |
| Explosive limit - lower temperature | 212 °F (100 °C) |
| Explosive limit - upper (%) | No data available. |
Vapor pressure
No data available.
Vapor density
No data available.
Relative density
No data available.
Solubility(ies)
Solubility (water) Soluble.
Partition coefficient (n-octanol/water)
No data available.
Auto-ignition temperature
784.4 °F (418 °C)
Decomposition temperature
No data available.
Viscosity
No data available.
Other information
Density
No data available.
Explosive properties
No data available.
Oxidizing properties
No data available.
Percent volatile
No data available.
VOC
No data 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 Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information
Information on toxicological effects
Acute toxicity Harmful if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micotil 300</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>LD</td>
<td>Rabbit</td>
<td>0.5 ml/kg No mortality. No toxicity.</td>
</tr>
<tr>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC</td>
<td>Rat</td>
<td>2750 mg/m3, 4 hr No mortality.</td>
</tr>
<tr>
<td>Product</td>
<td>Species</td>
<td>Test Results</td>
</tr>
<tr>
<td>---------------</td>
<td>---------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Other</td>
<td>Monkey</td>
<td>Intramuscular: a single dose of 10 mg/kg caused no signs of toxicity. A single dose of 20 mg/kg caused vomiting, and 30 mg/kg caused the death of the only monkey tested.</td>
</tr>
<tr>
<td></td>
<td>Swine</td>
<td>Intramuscular: 10 mg/kg caused increased respiration, emesis, and a convulsion; 20 mg/kg resulted in mortality in 3 of 4 pigs, and 30 mg/kg caused the death of all 4 pigs tested.</td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>318 mg/kg Subcutaneous: reduced activity, leg weakness, hunched posture.</td>
</tr>
</tbody>
</table>

### Test Results

#### Components

**Tilmicosin Phosphate (CAS 137330-13-3)**

**Acute**

**Dermal**
- **LD** Rabbit: > 5000 mg/kg

**Inhalation**
- **LC50** Rat: 3800 mg/m3, 4 h

**Oral**
- **LD50** Rat: 855 mg/kg (fasted)

**Other**
- **LD50** Rat: > 185 mg/kg Subcutaneous: coma, lethargy, incoordination, reduced activity.

**Skin corrosion/irritation**
Rabbit: Slight irritation. Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation**
Rabbit: Slightly irritating to the eyes of rabbits. Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization**
- **Respiratory sensitization**: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Allergic reactions in a manufacturing setting have been reported. (Tilmicosin Phosphate)
- **Skin sensitization**: May cause an allergic skin reaction. Did not cause sensitization on laboratory animals. Allergic reactions in a manufacturing setting have been reported. (Tilmicosin Phosphate)

**Germ cell mutagenicity**
In vitro and in vivo tests did not show mutagenic effects. (Tilmicosin)
Based on available data, the classification criteria are not met.

**Carcinogenicity**
No carcinogenicity data available for this product. Not listed by IARC, NTP, ACGIH or OSHA. Due to lack of data the classification is not possible.

**IARC Monographs. Overall Evaluation of Carcinogenicity**
Not listed.

Not regulated.

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

**Reproductive toxicity**
Slight increase in offspring mortality at maternally toxic doses. (Tilmicosin Phosphate)
Based on available data, the classification criteria are not met.

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

**Specific target organ toxicity - repeated exposure**
May cause damage to organs through prolonged or repeated exposure. The heart is the target of toxicity in laboratory and domestic animals given Micotil®300 by oral or parenteral routes. The primary cardiac effects are increased heart rate (tachycardia) and decreased contractility (negative inotropy). Cardiovascular toxicity may be due to calcium channel blockade.

**Aspiration hazard**
No aspiration toxicity classification

**Further information**
Increased adrenal and kidney weights, increased cell size in adrenal cortex, mucosal edema of the gallbladder, and subretinal fluid accumulation. Decreased food consumption and body weight gains, slightly decreased urine pH, occult blood in urine, increased serum alanine transaminase. (Tilmicosin Phosphate)
12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilmicosin (CAS 108050-54-0)</td>
<td><strong>Acute</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50</td>
<td>&gt; 918 mg/kg, 28 day (Earthworm (Eisenia fetida))</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>&gt; 250 mg/l Soil bacteria (Comamonas acidovaorans)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 5 mg/l N-fixing bacteria (Azotobacter chroococcum)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 4710 ppm, 5 day Anas platyrhynchos (Mallard), Dietary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 4820 ppm, 5 day Colinus virginianus (Bobwhite), Dietary</td>
</tr>
<tr>
<td></td>
<td>MIC</td>
<td>&gt; 1000 mg/l Mold (Aspergillus flavus)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 mg/l Fungus (Chaetomium globosum)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>250 mg/l Soil bacteria (Comamonas acidovaorans)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 mg/l N-fixing bacteria (Azotobacter chroococcum)</td>
</tr>
</tbody>
</table>

**Aquatic**

<table>
<thead>
<tr>
<th>Acute</th>
<th>Ec50</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae</td>
<td>0.354 mg/l (Selenastrum capricornutum, average specific growth rate)</td>
<td></td>
</tr>
<tr>
<td>MIC</td>
<td>0.5 mg/l (Blue-green algae)</td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>57.3 mg/l, 48 hours</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>716 mg/l, 96 hr</td>
</tr>
<tr>
<td></td>
<td>Oncorhynchus mykiss</td>
<td>851 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

Persistence and degradability

Photolysis half-life (hours): 0.84, 0.82, 0.82 (pH 5, 7, 9)
Photolysis rate constant (1/hours): 0.83, 0.84, 0.84 (pH 5, 7, 9)
Hydrolysis half-life (days): >= 365, >= 365, 156 (pH 5, 7, 9)
Hydrolysis rate constant (1/hours): 0.0001853 (pH 9)
Aerobic biodegradation: none measured after 64 days (sandy loam, loam, clay loam) Anaerobic biodegradation: none measured after 73 days
Decline in loam soil: 45.9% after 52 weeks
Decline in clay loam soil: none after 52 weeks (Tilmicosin)

Bioaccumulative potential

No data available for this product.

Partition coefficient n-octanol / water (log Kow)

| Tilmicosin | < 1 (pH 5) |
|           | < 1 (pH 7) |
|           | 2.6 (pH 9) |

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.

Ecotoxicological Properties

Drinking Water

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilmicosin</td>
<td>280 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
</tbody>
</table>

Chronic Exposure of Aquatic Organisms

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
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</thead>
<tbody>
<tr>
<td>Tilmicosin</td>
<td>54 µg/l, (Lilly Aquatic Exposure Guideline)</td>
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</table>

Acute Exposure of Aquatic Organisms

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilmicosin</td>
<td>354 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
</tbody>
</table>
13. Disposal considerations

Disposal methods/information: 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. (TILMICOSIN PHOSPHATE)</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>Class 9</td>
</tr>
<tr>
<td></td>
<td>Subsidiary risk  -</td>
</tr>
<tr>
<td></td>
<td>Packing group III</td>
</tr>
<tr>
<td></td>
<td>Environmental hazards Yes</td>
</tr>
<tr>
<td>ERG Code</td>
<td>9L</td>
</tr>
<tr>
<td>Special precautions for user</td>
<td>Read safety instructions, SDS and emergency procedures before handling.</td>
</tr>
<tr>
<td>Other information</td>
<td>Allowed with restrictions.</td>
</tr>
<tr>
<td>Passenger and cargo aircraft</td>
<td></td>
</tr>
<tr>
<td>Cargo aircraft only</td>
<td>Allowed with restrictions.</td>
</tr>
</tbody>
</table>

IMDG

<table>
<thead>
<tr>
<th>UN number</th>
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<tr>
<td></td>
<td>Subsidiary risk  -</td>
</tr>
<tr>
<td></td>
<td>Packing group III</td>
</tr>
<tr>
<td>Environmental hazards</td>
<td>Yes</td>
</tr>
<tr>
<td>Marine pollutant</td>
<td>Yes</td>
</tr>
<tr>
<td>EmS</td>
<td>F-A, S-F</td>
</tr>
<tr>
<td>Special precautions for user</td>
<td>Read safety instructions, SDS and emergency procedures before handling.</td>
</tr>
<tr>
<td>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

IATA; IMDG

Material name: Micotil 300

4899 Version #: 10 Revision date: 09-22-2016 Issue date: 08-15-2014 SDS US
15. Regulatory information

US federal regulations
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
One or more components are not listed on TSCA.

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

<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>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>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: 08-15-2014
Revision date: 09-22-2016
Version #: 10

List of abbreviations
LEG: Lilly Exposure Guideline
TWA: Time Weighted Average

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 MERCHANTABILITY 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
Physical & Chemical Properties: Multiple Properties
Toxicological information: Eye contact
GHS: Classification