SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Ivermectin (with Isopropyl Alcohol) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
20 Spartan Road
1619 Spartan, South Africa
Telephone: +27119239300
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Flammable liquids, Category 3
Eye irritation, Category 2
Skin sensitisation, Category 1
Specific target organ toxicity - single exposure, Category 3
Short-term (acute) aquatic hazard, Category 1
Long-term (chronic) aquatic hazard, Category 1

Hazard statements:
H226: Flammable liquid and vapour.
H319: Causes serious eye irritation.
H317: May cause an allergic skin reaction.
H336: May cause drowsiness or dizziness.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Signal word: Warning
Hazard statements: H226 Flammable liquid and vapour.
H317  May cause an allergic skin reaction.
H319  Causes serious eye irritation.
H336  May cause drowsiness or dizziness.
H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P210  Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P273  Avoid release to the environment.
P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P304 + P340 + P312  IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P333 + P313  If skin irritation or rash occurs: Get medical advice/ attention.
P391  Collect spillage.

Hazardous components which must be listed on the label:
Propan-2-ol
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate

2.3 Other hazards
Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>112-34-5</td>
<td>203-961-6</td>
<td>603-096-00-8</td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>603-117-00-0</td>
<td></td>
<td>Flam. Liq. 2; H225</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3; H336</td>
<td></td>
</tr>
<tr>
<td>7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate</td>
<td>2386-87-0</td>
<td>219-207-4</td>
<td></td>
<td></td>
<td>Skin Sens. 1; H317</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>274-536-0</td>
<td></td>
<td></td>
<td>Acute Tox. 2; H300</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3; H311</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT SE 1; H370 (Central nervous system)</td>
<td></td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of first aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled: If inhaled, remove to fresh air. Get medical attention if symptoms occur.

In case of skin contact: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks:
- May cause an allergic skin reaction.
- Causes serious eye irritation.
- May cause drowsiness or dizziness.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment:
- Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:
- Do not use a solid water stream as it may scatter and spread fire.
- Flash back possible over considerable distance.
- Vapours may form explosive mixtures with air.
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Remove all sources of ignition.
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal pro
tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- For large spills, provide dyeing or other appropriate containment to keep material from spreading. If dyed material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling:
- Do not get on skin or clothing.
- Avoid breathing mist or vapours.
- Do not swallow.
- Do not get in eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
- Non-sparking tools should be used.
- Keep container tightly closed.
- Keep away from heat, hot surfaces, sparks, open flames and
other ignition sources. No smoking.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.

Advice on common storage:
Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Flammable solids
- Pyrophoric liquids
- Pyrophoric solids
- Self-heating substances and mixtures
- Substances and mixtures, which in contact with water, emit flammable gases
- Explosives
- Gases

7.3 Specific end use(s):
Specific use(s):
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>112-34-5</td>
<td>TWA</td>
<td>10 ppm 67,5 mg/m3</td>
<td>2006/15/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>15 ppm 101,2 mg/m3</td>
<td>2006/15/EC</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>STEL OEL-RL</td>
<td>500 ppm 1.225 mg/m3</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>

Further information: Absorption through the skin, Recommended Limit
## Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-(2,6-Di-tert-butyl-phenyl)oxy-4-methyl-7-(2-oxabicyclo[4.1.0]hept-3-enyl)carboxylic acid</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>0.18 mg/m³</td>
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<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>0.05 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Propan-2-ol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>888 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>89 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>319 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>26 mg/kg bw/day</td>
</tr>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>67.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>83 mg/kg bw/day</td>
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<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>101.2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>40.5 mg/m³</td>
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<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>50 mg/kg bw/day</td>
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<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>5 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>2,6-Di-tert-butyl-phenylmethanol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
</tr>
</tbody>
</table>
## Workers

### Inhalation

Long-term systemic effects: 0.5 mg/kg bw/day

### Dermal

Long-term systemic effects: 0.86 mg/m3

### Ingestion

Long-term systemic effects: 0.25 mg/kg bw/day

## Consumers

### Inhalation

Long-term systemic effects: 0.5 mg/kg bw/day

### Dermal

Long-term systemic effects: 0.25 mg/kg bw/day

### Ingestion

Long-term systemic effects: 0.25 mg/kg bw/day

## Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate</td>
<td>Fresh water</td>
<td>0.024 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0024 mg/l</td>
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<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.24 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>19.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.211 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.0211 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.0282 mg/kg</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>Fresh water</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2251 mg/l</td>
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<tr>
<td></td>
<td>Fresh water sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>28 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Oral (Secondary Poisoning)</td>
<td></td>
<td>160 mg/kg food</td>
</tr>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>Fresh water</td>
<td>1.1 mg/l</td>
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<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>11 mg/l</td>
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<td></td>
<td>Marine water</td>
<td>0.11 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>200 mg/l</td>
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<tr>
<td></td>
<td>Fresh water sediment</td>
<td>4.4 mg/kg dry weight (d.w.)</td>
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<td></td>
<td>Marine sediment</td>
<td>0.44 mg/kg dry weight (d.w.)</td>
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<tr>
<td></td>
<td>Soil</td>
<td>0.32 mg/kg dry weight (d.w.)</td>
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<tr>
<td>Secondary Poisoning</td>
<td></td>
<td>56 mg/kg food</td>
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<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Fresh water</td>
<td>0.199 µg/l</td>
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<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.02 µg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.02 µg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>0.17 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.0996 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.00996 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.04769 mg/kg</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

Engineering measures
Use explosion-proof electrical, ventilating and lighting equipment.
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

Eye protection:
Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material: Chemical-resistant gloves
Remarks: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

Skin and body protection:
Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection:
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Organic vapour type (A)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: liquid
Colour: yellow
Odour: solvent-like
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

Version 3.4  Revision Date: 10.10.2020  SDS Number: 1496904-00009  Date of last issue: 23.03.2020

Flash point : 28 °C
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : 0.855 - 0.905 g/cm³
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids) : Not applicable
Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:
2-(2-Butoxyethoxy)ethanol:
Acute oral toxicity: LD50 (Mouse): 2.410 mg/kg

Acute dermal toxicity: LD50 (Rabbit): 2.764 mg/kg

Propan-2-ol:
Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 25 mg/l
Exposure time: 6 h
Test atmosphere: vapour

Acute dermal toxicity: LD50 (Rabbit): > 5.000 mg/kg

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Acute oral toxicity: LD50 (Rat, male): 2.959 - 5.000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity: LC50 (Rat): >= 5.19 mg/l
Exposure time: 4 h
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

Test atmosphere: dust/mist
Method: OECD Test Guideline 436
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Ivermectin:
Acute oral toxicity: LD50 (Rat): 50 mg/kg
LD50 (Mouse): 25 mg/kg
LD50 (Monkey): > 24 mg/kg
Target Organs: Central nervous system
Symptoms: Vomiting, Dilatation of the pupil
Remarks: No mortality observed at this dose.

Acute inhalation toxicity: LC50 (Rat): 5,11 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): 406 mg/kg
LD50 (Rat): > 660 mg/kg

2,6-Di-tert-butyl-p-cresol:
Acute oral toxicity: LD50 (Rat): > 6,000 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:

2-(2-Butoxyethoxy)ethanol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Mild skin irritation

Propan-2-ol:
Species: Rabbit
Result: No skin irritation
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Ivermectin:
Species : Rabbit
Result : No skin irritation

2,6-Di-tert-butyl-p-cresol:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:
2-(2-Butoxyethoxy)ethanol:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

Propan-2-ol:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation

Ivermectin:
Species : Rabbit
Result : Mild eye irritation

2,6-Di-tert-butyl-p-cresol:
Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation
Remarks : Based on data from similar materials

Respiratory or skin sensitisation
Skin sensitisation
May cause an allergic skin reaction.
Respiratory sensitisation
Not classified based on available information.

Components:

2-(2-Butoxyethoxy)ethanol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Propan-2-ol:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: positive
Assessment: Probability or evidence of skin sensitisation in humans

Ivermectin:
Exposure routes: Dermal
Species: Humans
Result: Does not cause skin sensitisation.

2,6-Di-tert-butyl-p-cresol:
Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: Skin contact
Species: Humans
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

2-(2-Butoxyethoxy)ethanol:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Genotoxicity in vivo:
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative

Propan-2-ol:
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative

- Genotoxicity in vivo:
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    - Species: Mouse
    - Application Route: Intraperitoneal injection
    - Result: negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
- Genotoxicity in vitro:
  - Test Type: In vitro mammalian cell gene mutation test
    - Result: positive

- Genotoxicity in vivo:
  - Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
    - Species: Rat
    - Application Route: Ingestion
    - Method: OECD Test Guideline 486
    - Result: negative

  - Test Type: Micronucleus test
    - Species: Mouse
    - Application Route: Intraperitoneal injection
    - Result: negative

Germ cell mutagenicity assessment:
- Weight of evidence does not support classification as a germ cell mutagen.

Ivermectin:
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative

  - Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
    - Test system: human diploid fibroblasts
    - Result: negative

  - Test Type: Mouse Lymphoma
    - Result: negative
2,6-Di-tert-buty1-p-cresol:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
Test Type: In vitro mammalian cell gene mutation test  
Result: negative
Test Type: Chromosome aberration test in vitro  
Result: negative
Genotoxicity in vivo:
Test Type: Mutagenicity (in vivo mammalian bone-marrow cyto genetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Propan-2-ol:
Species: Rat  
Application Route: Inhalation (vapour)  
Exposure time: 104 weeks  
Method: OECD Test Guideline 451  
Result: negative

Ivermectin:
Species: Rat  
Application Route: Oral  
NOAEL: 1,5 mg/kg body weight  
Result: negative  
Remarks: Based on data from similar materials
Species: Mouse  
Application Route: Oral  
NOAEL: 2,0 mg/kg body weight  
Result: negative  
Remarks: Based on data from similar materials

2,6-Di-tert-buty1-p-cresol:
Species: Rat  
Application Route: Ingestion  
Exposure time: 22 Months  
Result: negative

Reproductive toxicity
Not classified based on available information.
Components:

2-(2-Butoxyethoxy)ethanol:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 415
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Propan-2-ol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

Ivermectin:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 0.6 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal development: Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 0.2 mg/kg body weight
Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0.4 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected.
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Development
Species: Rabbit
Application Route: Oral
Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

2,6-Di-tert-butyl-p-cresol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure
May cause drowsiness or dizziness.

Components:

Propan-2-ol:
Assessment: May cause drowsiness or dizziness.

Ivermectin:
Target Organs: Central nervous system
Assessment: Causes damage to organs.

STOT - repeated exposure
Not classified based on available information.

Components:

Ivermectin:
Target Organs: Central nervous system
Assessment: Causes damage to organs through prolonged or repeated exposure.

2,6-Di-tert-butyl-p-cresol:
Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.
Repeated dose toxicity

Components:

2-(2-Butoxyethoxy)ethanol:
Species: Rat
NOAEL: 250 mg/kg
LOAEL: 1,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Method: OECD Test Guideline 408

Species: Rat
NOAEL: >= 0,094 mg/l
Application Route: inhalation (vapour)
Exposure time: 90 Days
Method: OECD Test Guideline 413

Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 90 Days

Propan-2-ol:
Species: Rat
NOAEL: 12,5 mg/l
Application Route: inhalation (vapour)
Exposure time: 104 Weeks

Ivermectin:
Species: Dog
NOAEL: 0,5 mg/kg
LOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 14 Weeks
Target Organs: Central nervous system
Symptoms: Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species: Monkey
NOAEL: 1,2 mg/kg
Application Route: Oral
Exposure time: 2 Weeks
Remarks: No significant adverse effects were reported

Species: Rat
NOAEL: 0,4 mg/kg
LOAEL: 0,8 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: spleen, Bone marrow, Kidney

2,6-Di-tert-butyl-p-cresol:
**SAFETY DATA SHEET**

**Ivermectin (with Isopropyl Alcohol) Formula-**

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<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<tr>
<td>3.4</td>
<td>10.10.2020</td>
<td>1496904-00009</td>
<td>23.03.2020</td>
<td>29.03.2017</td>
</tr>
</tbody>
</table>

**Species:** Rat  
**NOAEL:** 25 mg/kg  
**Application Route:** Ingestion  
**Exposure time:** 22 Months

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Ivermectin:**
- **Skin contact:** Remarks: Can be absorbed through skin.  
- **Eye contact:** Remarks: May irritate eyes.  
- **Ingestion:** Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vomiting, anorexia, Lack of coordination

**SECTION 12: Ecological information**

**12.1 Toxicity**

**Components:**

**2-(2-Butoxyethoxy)ethanol:**
- **Toxicity to fish:** LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.300 mg/l  
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 100 mg/l  
  Exposure time: 48 h  
  Method: OECD Test Guideline 202
- **Toxicity to algae/aquatic plants:** ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l  
  Exposure time: 96 h  
  Method: OECD Test Guideline 201
  NOEC (Desmodesmus subspicatus (green algae)): >= 100 mg/l  
  Exposure time: 96 h  
  Method: OECD Test Guideline 201

**Toxicity to microorganisms:** EC10: > 1.995 mg/l  
  Exposure time: 30 min

**Propan-2-ol:**
- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): 9.640 mg/l  
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 10.000 mg/l  
  Exposure time: 24 h
- **Toxicity to microorganisms:** EC50 (Pseudomonas putida): > 1.050 mg/l  
  Exposure time: 16 h
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 24 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 40 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: ErC50 (Selenastrum capricornutum (green algae)): > 110 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 30 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms: EC10 (Natural microorganism): 409 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Ivermectin:

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 0,003 mg/l
Exposure time: 96 h
LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0048 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0,000025 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 9,1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9,1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 10.000

M-Factor (Chronic aquatic toxicity): 10.000

2,6-Di-tert-butyl-p-cresol:

Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 0,57 mg/l
Exposure time: 96 h
**Toxicity to daphnia and other aquatic invertebrates**

EC50 (Daphnia magna (Water flea)): 0,48 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0,24 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,24 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

**M-Factor (Acute aquatic toxicity)**

: 1

**Toxicity to microorganisms**

EC50 : > 10.000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

**Toxicity to fish (Chronic toxicity)**

NOEC: 0,053 mg/l  
Exposure time: 30 d  
Species: Oryzias latipes (Japanese medaka)  
Method: OECD Test Guideline 210

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

NOEC: 0,316 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  

**M-Factor (Chronic aquatic toxicity)**

: 1

### 12.2 Persistence and degradability

**Components:**

**2-(2-Butoxyethoxy)ethanol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 85 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

**Propan-2-ol:**

Biodegradability : Result: rapidly degradable

BOD/COD :  
BOD: 1.19 (BOD5)  
COD: 2.23  
BOD/COD: 53 %

**7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:**

Biodegradability : Biodegradation: 71 %
Exposure time: 28 d  
Method: OECD Test Guideline 301B

Stability in water: Degradation half life (DT50): 2 d

Ivermectin:
Biodegradability: Result: Not readily biodegradable.  
Biodegradation: 50 %  
Exposure time: 240 d

2,6-Di-tert-butyl-p-cresol:
Biodegradability: Result: Not readily biodegradable.  
Biodegradation: 4,5 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

12.3 Bioaccumulative potential

Components:

2-(2-Butoxyethoxy)ethanol:
Partition coefficient: n-octanol/water: log Pow: 1

Propan-2-ol:
Partition coefficient: n-octanol/water: log Pow: 0,05

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Partition coefficient: n-octanol/water: log Pow: 1,34

Ivermectin:
Bioaccumulation: Bioconcentration factor (BCF): 74
Partition coefficient: n-octanol/water: log Pow: 3,22

2,6-Di-tert-butyl-p-cresol:
Bioaccumulation: Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): 330 - 1.800
Partition coefficient: n-octanol/water: log Pow: 5,1

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available
SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

<table>
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<tr>
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<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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14.2 UN proper shipping name

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<th>ADR</th>
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<th>IMDG</th>
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14.3 Transport hazard class(es)

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<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
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<tr>
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14.4 Packing group
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### Ivermectin (with Isopropyl Alcohol) Formulation

<table>
<thead>
<tr>
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</tbody>
</table>

### ADN
- **Packing group**: III
- **Classification Code**: F1
- **Hazard Identification Number**: 30
- **Labels**: 3

### ADR
- **Packing group**: III
- **Classification Code**: F1
- **Hazard Identification Number**: 30
- **Labels**: 3
- **Tunnel restriction code**: (D/E)

### RID
- **Packing group**: III
- **Classification Code**: F1
- **Hazard Identification Number**: 30
- **Labels**: 3

### IMDG
- **Packing group**: III
- **Labels**: 3
- **EmS Code**: F-E, S-E

### IATA (Cargo)
- **Packing instruction (cargo aircraft)**: 366
- **Packing instruction (LQ)**: Y344
- **Packing group**: III
- **Labels**: Flammable Liquids

### IATA (Passenger)
- **Packing instruction (passenger aircraft)**: 355
- **Packing instruction (LQ)**: Y344
- **Packing group**: III
- **Labels**: Flammable Liquids

### 14.5 Environmental hazards

| ADN       | Environmentally hazardous: yes |
| ADR       | Environmentally hazardous: yes |
| RID       | Environmentally hazardous: yes |
| IMDG      | Marine pollutant: yes |

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The components of this product are reported in the following inventories:

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<thead>
<tr>
<th>Inventory</th>
<th>Determined</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
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<tr>
<td>DSL</td>
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<tr>
<td>IECSC</td>
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</tbody>
</table>

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H225 : Highly flammable liquid and vapour.
H300 : Fatal if swallowed.
H311 : Toxic in contact with skin.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H336 : May cause drowsiness or dizziness.
H370 : Causes damage to organs if swallowed.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
2006/15/EC : Europe. Indicative occupational exposure limit values
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
2006/15/EC / TWA : Limit Value - eight hours
2006/15/EC / STEL : Short term exposure limit
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substance in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCS1 - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information


Classification of the mixture:

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<th>Property</th>
<th>Value</th>
<th>Code</th>
<th>Classification procedure</th>
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<td>Based on product data or assessment</td>
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<td>Eye Irrit. 2</td>
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for
safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

ZA / EN