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

1.1 Product identifier
   Trade name : Ivermectin (with Propylene Glycol) 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
             : Kilsheolan
             : Clonmel Tipperary, IE
   Telephone : 353-51-601000
   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 2 : H225: Highly flammable liquid and vapour.
   Eye irritation, Category 2    : H319: Causes serious eye irritation.
   Specific target organ toxicity - single exposure, Category 2 : H371: May cause damage to organs.
   Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.
   Short-term (acute) aquatic hazard, Category 1   : H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1  : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : 
   Signal word : Danger
   Hazard statements : H225 Highly flammable liquid and vapour.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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H319  Causes serious eye irritation.
H371  May cause damage to organs.
H373  May cause damage to organs through prolonged or repeated exposure.
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.
P233  Keep container tightly closed.
P273  Avoid release to the environment.
P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P311  IF exposed or concerned: Call a POISON CENTER/ doctor.
P391  Collect spillage.

Hazardous components which must be listed on the label:
Ivermectin

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Registration number</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1,3-Dioxan-5-ol</td>
<td>4740-78-7</td>
<td>225-248-9</td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Butanone</td>
<td>78-93-3</td>
<td>201-159-0</td>
<td>Flam. Liq. 2; H225 Eye Irrit. 2; H319</td>
<td>&gt;= 10 - &lt; 20</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: Remove contaminated clothing and shoes.

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. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes serious eye irritation. May cause damage to organs. May cause damage to organs through prolonged or repeated exposure.

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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Ventilate the area.
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective 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 dyking or other appropriate containment to keep material from spreading. If dyked 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 breathe mist or vapours.
- Do not swallow.
- Do not get in eyes.
- Avoid prolonged or repeated contact with skin.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-
sessment
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.
Do not eat, drink or smoke when using this product.
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. 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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>25 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>79 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Butanone</td>
<td>78-93-3</td>
<td>TWA</td>
<td>75 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
</tbody>
</table>
## Ivermectin (with Propylene Glycol) Formulation

<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>Butanone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>600 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1161 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>106 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>412 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>31 mg/kg bw/day</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
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</tbody>
</table>

### Derived No Effect Level (DNEL) 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>Butanone</td>
<td>Fresh water</td>
<td>55.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>55.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>55.8 mg/l</td>
</tr>
<tr>
<td>Sewage treatment plant</td>
<td></td>
<td>709 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>284.7 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Marine sediment</td>
<td></td>
<td>284.7 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Soil</td>
<td></td>
<td>22.5 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Oral (Secondary Poisoning)</td>
<td></td>
<td>1000 mg/kg food</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td>Sewage treatment plant</td>
<td></td>
<td>20000 mg/l</td>
</tr>
</tbody>
</table>
Ivermectin (with Propylene Glycol) Formulation

8.2 Exposure controls

Engineering measures
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.
Use explosion-proof electrical, ventilating and lighting equipment.

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
Material : Work uniform or laboratory coat.
Remarks : 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
Material : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to NS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid
Colour : Colorless to pale yellow
Odour : characteristic
Odour Threshold : No data available
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Melting point/freezing point: < -66 °C
Initial boiling point and boiling range: 81,5 °C
Flammability (solid, gas): Not applicable
Flammability (liquids): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: 16 °C
Auto-ignition temperature: No data available
Decomposition temperature: No data available
pH: No data available
Viscosity
   Viscosity, kinematic: No data available
Solubility(ies)
   Water solubility: slightly soluble
Partition coefficient: n-octanol/water: Not applicable
Vapour pressure: No data available
Relative density: 1,04 - 1,08
Density: No data available
Relative vapour density: No data available
Particle characteristics
   Particle size: Not applicable

9.2 Other information
Explosives: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: No data available
Molecular weight: No data available
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: Highly 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 hazard classes as defined in Regulation (EC) No 1272/2008
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:
1,3-Dioxan-5-ol:
Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
Remarks: Based on data from similar materials

Butanone:
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4</td>
<td>27.08.2021</td>
<td>4710828-00006</td>
<td>09.04.2021</td>
<td>30.07.2019</td>
</tr>
</tbody>
</table>

**Acute oral toxicity**  
LD50 (Rat): > 2,000 - 5,000 mg/kg  
**Remarks:** Based on data from similar materials

**Acute inhalation toxicity**  
LC50 (Rat): > 25,5 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Method: OECD Test Guideline 436  
**Remarks:** Based on data from similar materials

**Acute dermal toxicity**  
LD50 (Rabbit): > 5,000 mg/kg

**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

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

1,3-Dioxan-5-ol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Butanone:

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeated exposure may cause skin dryness or cracking.</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Ivermectin:

<table>
<thead>
<tr>
<th>Species</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td></td>
</tr>
</tbody>
</table>
Ivermectin (with Propylene Glycol) Formula-
tion

Result : No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

1,3-Dioxan-5-ol:
Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days
Remarks : Based on data from similar materials

Butanone:
Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

Ivermectin:
Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

1,3-Dioxan-5-ol:
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Butanone:
Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Ivermectin:
Exposure routes : Dermal
### Germ cell mutagenicity

Not classified based on available information.

### Components:

**1,3-Dioxan-5-ol:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Genotoxicity in vitro: In vitro mammalian cell gene mutation test</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Butanone:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Genotoxicity in vitro: In vitro mammalian cell gene mutation test</td>
<td>negative</td>
</tr>
<tr>
<td>Genotoxicity in vitro: Chromosome aberration test in vitro</td>
<td>negative</td>
</tr>
<tr>
<td>Genotoxicity in vitro: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td>negative</td>
</tr>
<tr>
<td>Genotoxicity in vitro: Saccharomyces cerevisiae, gene mutation assay (in vitro)</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Ivermectin:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Genotoxicity in vitro: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td>negative</td>
</tr>
</tbody>
</table>
Test system: human diploid fibroblasts  
Result: negative  

Test Type: Mouse Lymphoma  
Result: negative  

Carcinogenicity  
Not classified based on available information.  

Components:  

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  

Reproductive toxicity  
Not classified based on available information.  

Components:  

Butanone:  
Effects on fertility: Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials  

Effects on foetal development: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Inhalation  
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
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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

STOT - single exposure
May cause damage to organs.
Components:

Butanone:
Assessment: May cause drowsiness or dizziness.

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

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.
Components:

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

Repeated dose toxicity
Components:

Butanone:
Species: Rat
NOAEL: 14,84 mg/l
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according to Regulation (EC) No. 1907/2006

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Application Route: inhalation (vapour)
Exposure time: 90 Days
Method: OECD Test Guideline 413

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

Aspiration toxicity
Not classified based on available information.

Components:

Butanone:
The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

11.2 Information on other hazards
Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure
Components:

Ivermectin:
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tion

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Date of first issue: 30.07.2019

<table>
<thead>
<tr>
<th>Remarks</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>Remarks: Can be absorbed through skin.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Remarks: May irritate eyes.</td>
</tr>
</tbody>
</table>
| Ingestion                                                              | Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vom-
ing, anorexia, Lack of coordination |

SECTION 12: Ecological information

12.1 Toxicity

**Components:**

1,3-Dioxan-5-ol:

Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:

- EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  Exposure time: 72 h
  Remarks: Based on data from similar materials
- NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  Exposure time: 72 h
  Remarks: Based on data from similar materials

Toxicity to microorganisms: EC10 : > 1.000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Butanone:

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 2.993 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 308 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

- ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.029 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 1.240 mg/l
  Exposure time: 96 h
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Method: OECD Test Guideline 201

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

12.2 Persistence and degradability

Components:

1,3-Dioxan-5-ol:
Biodegradability: Result: Inherently biodegradable.
Remarks: Based on data from similar materials

Butanone:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 98 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

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

Components:

1,3-Dioxan-5-ol:
Partition coefficient: n-octanol/water : log Pow: -0.65

Butanone:
Partition coefficient: n-octanol/water : log Pow: 0.3

Ivermectin:
Bioaccumulation : Bioconcentration factor (BCF): 74
Partition coefficient: n-octanol/water : log Pow: 3.22

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product: Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product: Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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 or ID number

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>UN 1193</td>
</tr>
<tr>
<td>ADR</td>
<td>UN 1193</td>
</tr>
<tr>
<td>RID</td>
<td>UN 1193</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 1193</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 1193</td>
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</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
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<tbody>
<tr>
<td>ADN</td>
<td>ETHYL METHYL KETONE, SOLUTION</td>
</tr>
<tr>
<td>ADR</td>
<td>ETHYL METHYL KETONE, SOLUTION</td>
</tr>
<tr>
<td>RID</td>
<td>ETHYL METHYL KETONE, SOLUTION</td>
</tr>
<tr>
<td>IMDG</td>
<td>ETHYL METHYL KETONE, SOLUTION (Ivermectin)</td>
</tr>
<tr>
<td>IATA</td>
<td>Ethyl methyl ketone, solution</td>
</tr>
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</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>Type</th>
<th>Class</th>
</tr>
</thead>
<tbody>
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<td>ADN</td>
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</tr>
<tr>
<td>ADR</td>
<td>3</td>
</tr>
<tr>
<td>RID</td>
<td>3</td>
</tr>
<tr>
<td>IMDG</td>
<td>3</td>
</tr>
<tr>
<td>IATA</td>
<td>3</td>
</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>Type</th>
<th>Packing group</th>
<th>Classification Code</th>
<th>Hazard Identification Number</th>
<th>Labels</th>
<th>Tunnel restriction code</th>
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</thead>
<tbody>
<tr>
<td>ADN</td>
<td>II</td>
<td>F1</td>
<td>33</td>
<td>3</td>
<td>(D/E)</td>
</tr>
<tr>
<td>ADR</td>
<td>II</td>
<td>F1</td>
<td>33</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>
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Packing group: II  Classification Code: F1  Hazard Identification Number: 33  Labels: 3

IMDG
Packing group: II  Labels: 3  EmS Code: F-E, S-D

IATA (Cargo)

IATA (Passenger)

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 Maritime transport in bulk according to IMO instruments
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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered:
Number on list: Not applicable
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REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Quantity 1 Quantity 2
P5c FLAMMABLE LIQUIDS 5.000 t 50.000 t
E1 ENVIRONMENTAL HAZARDS 100 t 200 t

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

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.
H319: Causes serious eye irritation.
H36: 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.
EUH066: Repeated exposure may cause skin dryness or cracking.
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tion

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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
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
list of indicative occupational exposure limit values
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
2000/39/EC / TWA : Limit Value - eight hours
2000/39/EC / STEL : Short term exposure limit
FOR-2011-12-06-1358 / TWA : Long term exposure 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; AIIIC - 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; DSL - 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 Substances 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 Obserable 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; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals 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
Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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## Classification of the mixture:

<table>
<thead>
<tr>
<th>Category</th>
<th>Classification</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flam. Liq. 2</td>
<td>H225</td>
<td>Based on product data or assessment</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT SE 2</td>
<td>H371</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

NO / EN