

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ivermectin (0.50%) Liquid Formulation

Version  
6.0

Revision Date:  
14.04.2025

SDS Number:  
10875049-00011

Date of last issue: 04.02.2025  
Date of first issue: 20.10.2022

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

### 1.1 Product identifier

Trade name : Ivermectin (0.50%) Liquid Formulation  
Other means of identification : COOPERS PARAMAX POUR-ON FOR BEEF AND DAIRY CATTLE (50558)

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product  
Recommended restrictions on use : Not applicable

### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland  
Telephone : +1-908-740-4000  
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

+1-908-423-6000

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## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

|  |   |
|--|---|
| Eye irritation, Category 2                                   | H319: Causes serious eye irritation.                        |
| Skin sensitisation, Category 1                               | H317: May cause an allergic skin reaction.                  |
| Germ cell mutagenicity, Category 2                           | H341: Suspected of causing genetic defects.                 |
| Specific target organ toxicity - single exposure, Category 3 | H336: May cause drowsiness or dizziness.                    |
| 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)

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Hazard pictograms



Signal word

: Warning

Hazard statements

: H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H336 May cause drowsiness or dizziness.  
H341 Suspected of causing genetic defects.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**

P201 Obtain special instructions before use.  
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.  
P308 + P313 IF exposed or concerned: 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

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.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name | CAS-No.<br>EC-No.<br>Index-No. | Classification | Concentration<br>(% w/w) |
|---------------|--------------------------------|----------------|--------------------------|
|               |                                |                |                          |

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|   | Registration number                    |  |               |
|---|--|--|---------------|
| Propan-2-ol   | 67-63-0<br>200-661-7<br>603-117-00-0   | Flam. Liq. 2; H225<br>Eye Irrit. 2; H319<br>STOT SE 3; H336  | >= 70 - < 90  |
| 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate | 2386-87-0<br>219-207-4<br>607-773-00-9 | Skin Sens. 1; H317<br>Muta. 2; H341<br>STOT RE 2; H373 (nasal cavity)<br>Aquatic Chronic 3; H412   | >= 1 - < 2.5  |
| Ivermectin  | 70288-86-7<br>274-536-0                | Acute Tox. 2; H300<br>Acute Tox. 3; H311<br>STOT SE 1; H370 (Central nervous system)<br>STOT RE 1; H372 (Central nervous system)<br>Aquatic Acute 1; H400<br>Aquatic Chronic 1; H410<br><br>M-Factor (Acute aquatic toxicity): 10,000<br>M-Factor (Chronic aquatic toxicity): 10,000 | >= 0.25 - < 1 |

For explanation of abbreviations see section 16.

## 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.

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

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|----------------|------------------------------|-------------------------------|---|

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.  
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.  
Suspected of causing genetic defects.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : 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.

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Evacuate area.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : 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 : Soak up with inert absorbent material.  
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.

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## 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.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe 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 as-

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|                  |   |
|------------------|---|
| Hygiene measures | <p>essment<br/>Take care to prevent spills, waste and minimize release to the environment.</p> <p>: 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.</p> <p>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.</p> |
|------------------|---|

### 7.2 Conditions for safe storage, including any incompatibilities

|   |   |
|---|---|
| Requirements for storage areas and containers | : Keep in properly labelled containers. Store locked up. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. |
| Advice on common storage                      | : Do not store with the following product types:<br>Strong oxidizing agents<br>Gases  |

### 7.3 Specific end use(s)

|                 |                     |
|-----------------|---------------------|
| Specific use(s) | : No data available |
|-----------------|---------------------|

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

| Components  | CAS-No.   | Value type (Form of exposure) | Control parameters           | Basis    |
|-------------|---|-------------------------------|------------------------------|----------|
| Propan-2-ol | 67-63-0   | OELV - 8 hrs (TWA)            | 200 ppm                      | IE OEL   |
|             | Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body |                               |                              |          |
|             |   | OELV - 15 min (STEL)          | 400 ppm                      | IE OEL   |
|             | Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body |                               |                              |          |
| Ivermectin  | 70288-86-7  | TWA                           | 30 µg/m <sup>3</sup> (OEB 3) | Internal |
|             | Further information: Skin   |                               |                              |          |
|             |   | Wipe limit                    | 300 µg/100 cm <sup>2</sup>   | Internal |

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name | End Use | Exposure routes | Potential health effects   | Value                  |
|----------------|---------|-----------------|----------------------------|------------------------|
| 7-Oxabicy-     | Workers | Inhalation      | Long-term systemic effects | 0.18 mg/m <sup>3</sup> |

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|  |           |              |                            |                     |
|--|-----------|--------------|----------------------------|---------------------|
| clo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate |           |              |                            |                     |
|  | Workers   | Inhalation   | Long-term local effects    | 0.18 mg/m3          |
|  | Workers   | Skin contact | Long-term systemic effects | 0.05 mg/kg bw/day   |
| Cetyl octanoate  | Workers   | Inhalation   | Long-term systemic effects | 6.01 mg/m3          |
|  | Workers   | Inhalation   | Acute systemic effects     | 18.029 mg/m3        |
|  | Workers   | Skin contact | Long-term systemic effects | 17.043 mg/kg bw/day |
|  | Workers   | Skin contact | Acute systemic effects     | 51.128 mg/kg bw/day |
|  | Consumers | Inhalation   | Long-term systemic effects | 1.483 mg/m3         |
|  | Consumers | Inhalation   | Acute systemic effects     | 4.448 mg/m3         |
|  | Consumers | Skin contact | Long-term systemic effects | 8.52 mg/kg bw/day   |
|  | Consumers | Skin contact | Acute systemic effects     | 25.56 mg/kg bw/day  |
|  | Consumers | Ingestion    | Long-term systemic effects | 0.851 mg/kg bw/day  |
|  | Consumers | Ingestion    | Acute systemic effects     | 2.554 mg/kg bw/day  |
| Propan-2-ol  | Workers   | Inhalation   | Long-term systemic effects | 500 mg/m3           |
|  | Workers   | Skin contact | Long-term systemic effects | 888 mg/kg bw/day    |
|  | Consumers | Inhalation   | Long-term systemic effects | 89 mg/m3            |
|  | Consumers | Skin contact | Long-term systemic effects | 319 mg/kg bw/day    |
|  | Consumers | Ingestion    | Long-term systemic effects | 26 mg/kg bw/day     |

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

| Substance name  | Environmental Compartment | Value                         |
|---|---------------------------|-------------------------------|
| 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate | Fresh water               | 0.024 mg/l                    |
|   | Freshwater - intermittent | 0.24 mg/l                     |
|   | Marine water              | 0.0024 mg/l                   |
|   | Sewage treatment plant    | 19.5 mg/l                     |
|   | Fresh water sediment      | 0.211 mg/kg dry weight (d.w.) |
|   | Marine sediment           | 0.0211 mg/kg dry              |

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|             |                            | weight (d.w.)                  |
|-------------|----------------------------|--------------------------------|
|             | Soil                       | 0.0282 mg/kg dry weight (d.w.) |
| Propan-2-ol | Fresh water                | 140.9 mg/l                     |
|             | Marine water               | 140.9 mg/l                     |
|             | Intermittent use/release   | 140.9 mg/l                     |
|             | Sewage treatment plant     | 2251 mg/l                      |
|             | Fresh water sediment       | 552 mg/kg dry weight (d.w.)    |
|             | Marine sediment            | 552 mg/kg dry weight (d.w.)    |
|             | Soil                       | 28 mg/kg dry weight (d.w.)     |
|             | Oral (Secondary Poisoning) | 160 mg/kg food                 |
| Ivermectin  | Fresh water                | 0.000004 mg/l                  |
|             | Marine water               | 0.000004 mg/l                  |

## 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.

### Personal protective equipment

Eye/face 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.

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 : Filter should conform to I.S. EN 14387

Filter type : Organic vapour type (A)

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : clear

Odour : Straw-coloured

Odour : characteristic

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

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 : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

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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

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## 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 : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## 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:

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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:

#### **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  
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

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### Skin corrosion/irritation

|| Not classified based on available information.

### Components:

#### 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

### Serious eye damage/eye irritation

|| Causes serious eye irritation.

### Components:

#### 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

### Respiratory or skin sensitisation

#### Skin sensitisation

|| May cause an allergic skin reaction.

#### Respiratory sensitisation

|| Not classified based on available information.

### Components:

#### Propan-2-ol:

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig

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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.

### Germ cell mutagenicity

II Suspected of causing genetic defects.

### Components:

#### Propan-2-ol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Test Type: In vitro mammalian cell gene mutation test  
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: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: positive  
Test Type: In vitro mammalian cell gene mutation test  
Result: positive  
Test Type: In vitro sister chromatid exchange assay in mammalian cells  
Result: positive  
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: positive

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|                                    |   |
|------------------------------------|---|
| Genotoxicity in vivo               | : Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 486<br>Result: negative |
|                                    | Test Type: Micronucleus test<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative  |
|                                    | Test Type: Transgenic rodent somatic cell gene mutation assay<br>Species: Mouse<br>Application Route: Ingestion<br>Method: OECD Test Guideline 488<br>Result: positive                      |
| Germ cell mutagenicity- Assessment | : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.  |
| <b>Ivermectin:</b>                 |   |
| Genotoxicity in vitro              | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative  |
|                                    | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Test system: human diploid fibroblasts<br>Result: negative                                     |
|                                    | Test Type: Mouse Lymphoma<br>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                |

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

|                   |                |
|-------------------|----------------|
| Species           | : Mouse        |
| Application Route | : Skin contact |
| Exposure time     | : 29 Months    |
| Result            | : negative     |

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### 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:

#### Propan-2-ol:

|                               |   |   |
|-------------------------------|---|---|
| Effects on fertility          | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 414<br>Result: negative |
|-------------------------------|---|---|

### Ivermectin:

|                               |   |  |
|-------------------------------|---|--|
| Effects on fertility          | : | Test Type: Fertility<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 0.6 mg/kg body weight<br>Result: Animal testing did not show any effects on fertility.  |
| Effects on foetal development | : | Test Type: Development<br>Species: Mouse<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 0.2 mg/kg body weight<br>Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally |

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|----------------|------------------------------|-------------------------------|---|

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 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:

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

Exposure routes : Ingestion

Target Organs : nasal cavity

Assessment : Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

##### **Ivermectin:**

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

##### **Propan-2-ol:**

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Species : Rat  
NOAEL : 12.5 mg/l  
Application Route : inhalation (vapour)  
Exposure time : 104 Weeks

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

Species : Rat  
NOAEL : 5 mg/kg  
LOAEL : 50 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Method : OECD Test Guideline 408

### 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.

## 11.2 Information on other hazards

### Endocrine disrupting properties

|| Not classified based on available information.

### 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.

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## 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 |

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## SECTION 12: Ecological information

## 12.1 Toxicity

## Components:

| <b>Propan-2-ol:</b>                                 |  |
|---|--|
| Toxicity to fish                                    | : LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l<br>Exposure time: 24 h        |
| Toxicity to microorganisms                          | : EC50 (Pseudomonas putida): > 1,050 mg/l<br>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<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203                  |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 40 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                           |
| Toxicity to algae/aquatic plants                    | : | ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 110 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
|   |   | NOEC (Raphidocelis subcapitata (freshwater green alga)): 30 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201     |
| Toxicity to microorganisms                          | : | EC10 (activated sludge): 409 mg/l<br>Exposure time: 3 h<br>Method: OECD Test Guideline 209                                     |

## Ivermectin:

Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): 0.003 mg/l

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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:

##### **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 : Result: Not readily biodegradable.  
Biodegradation: 71 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

##### **Ivermectin:**

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

### 12.3 Bioaccumulative potential

#### Components:

##### **Propan-2-ol:**

Partition coefficient: n- : log Pow: 0.05

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octanol/water

### 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  
Method: OECD Test Guideline 107

#### 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.  
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 14: Transport information

### 14.1 UN number or ID number

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|----------------|------------------------------|-------------------------------|---|

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|             |   |         |
|-------------|---|---------|
| <b>ADN</b>  | : | UN 3082 |
| <b>ADR</b>  | : | UN 3082 |
| <b>RID</b>  | : | UN 3082 |
| <b>IMDG</b> | : | UN 3082 |
| <b>IATA</b> | : | UN 3082 |

### 14.2 UN proper shipping name

|             |   |  |
|-------------|---|--|
| <b>ADN</b>  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(Ivermectin) |
| <b>ADR</b>  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(Ivermectin) |
| <b>RID</b>  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(Ivermectin) |
| <b>IMDG</b> | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(Ivermectin) |
| <b>IATA</b> | : | Environmentally hazardous substance, liquid, n.o.s.<br>(Ivermectin)    |

### 14.3 Transport hazard class(es)

|             | Class | Subsidiary risks |
|-------------|-------|------------------|
| <b>ADN</b>  | :     | 9                |
| <b>ADR</b>  | :     | 9                |
| <b>RID</b>  | :     | 9                |
| <b>IMDG</b> | :     | 9                |
| <b>IATA</b> | :     | 9                |

### 14.4 Packing group

|                              |   |     |
|------------------------------|---|-----|
| <b>ADN</b>                   |   |     |
| Packing group                | : | III |
| Classification Code          | : | M6  |
| Hazard Identification Number | : | 90  |
| Labels                       | : | 9   |
| <b>ADR</b>                   |   |     |
| Packing group                | : | III |
| Classification Code          | : | M6  |
| Hazard Identification Number | : | 90  |
| Labels                       | : | 9   |
| Tunnel restriction code      | : | (-) |

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|----------------|------------------------------|-------------------------------|---|

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### RID

Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

### IMDG

Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

### IATA (Cargo)

Packing instruction (cargo aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : 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.

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### 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, mixtures and articles (Annex XVII)

: Conditions of restriction for the following entries should be considered:  
Number on list 3

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

: Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer

: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)

: Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

: Not applicable

REACH - List of substances subject to authorisation (Annex XIV)

: Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Quantity 1  
100 t

Quantity 2  
200 t

E1  
ENVIRONMENTAL  
HAZARDS

#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

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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.  
H317 : May cause an allergic skin reaction.  
H319 : Causes serious eye irritation.  
H336 : May cause drowsiness or dizziness.  
H341 : Suspected of causing genetic defects.  
H370 : Causes damage to organs if swallowed.  
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.  
H373 : May cause damage to organs through prolonged or repeated exposure.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.  
H412 : Harmful 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  
Muta. : Germ cell mutagenicity  
Skin Sens. : Skin sensitisation  
STOT RE : Specific target organ toxicity - repeated exposure  
STOT SE : Specific target organ toxicity - single exposure  
IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2  
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)  
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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

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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 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; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

|                   |      |
|-------------------|------|
| Eye Irrit. 2      | H319 |
| Skin Sens. 1      | H317 |
| Muta. 2           | H341 |
| STOT SE 3         | H336 |
| Aquatic Acute 1   | H400 |
| Aquatic Chronic 1 | H410 |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |

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

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

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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.

IE / EN