

Ivermectin (0.50%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.02.2024
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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 Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

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)**

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Propan-2-ol	67-63-0 200-661-7 603-117-00-0	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	>= 70 - < 90
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	2386-87-0 219-207-4	Skin Sens. 1; H317 Muta. 2; H341 STOT RE 2; H373 (nasal cavity) Aquatic Chronic 3;	>= 1 - < 2,5

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Ivermectin	70288-86-7 274-536-0	H412 Acute Tox. 2; H300 Acute Tox. 3; H311 STOT SE 1; H370 (Central nervous system) STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000	>= 0,25 - < 1
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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.
 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.

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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.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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.
Evacuate area.

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

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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.

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 assessment 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 in a cool, well-ventilated place. Store in accordance with the
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particular national regulations.

Advice on common storage : Do not store with the following product types:
 Strong oxidizing agents
 Gases

7.3 Specific end use(s)

Specific use(s) : No data available

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	OEL-RL	400 ppm	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			
		OEL- RL STEL/C	800 ppm	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			
Ivermectin	70288-86-7	TWA	30 µg/m ³ (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	300 µg/100 cm ²	Internal

Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
Propan-2-ol	67-63-0	Acetone: 40 mg/l (Urine)	End of shift at end of workweek	ZA BEI

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

Substance name	End Use	Exposure routes	Potential health effects	Value
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	Workers	Inhalation	Long-term systemic effects	0,18 mg/m ³
	Workers	Inhalation	Long-term local effects	0,18 mg/m ³
	Workers	Skin contact	Long-term systemic effects	0,05 mg/kg bw/day
Cetyl octanoate	Workers	Inhalation	Long-term systemic effects	6,01 mg/m ³
	Workers	Inhalation	Acute systemic effects	18,029 mg/m ³
	Workers	Skin contact	Long-term systemic effects	17,043 mg/kg bw/day

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	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 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

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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	:	Organic vapour type (A)

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Appearance	:	liquid
Colour	:	clear Straw-coloured
Odour	:	characteristic
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
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable

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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	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
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)	:	No data available
Molecular weight	:	No data available
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	:	Can react with strong oxidizing agents.
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10.4 Conditions to avoid

Conditions to avoid	:	None known.
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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:**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:

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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:**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
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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
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

Suspected of causing genetic defects.

Components:**Propan-2-ol:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES)
	Result: negative
Genotoxicity in vivo	: Test Type: In vitro mammalian cell gene mutation test
	Result: negative
	: 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

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	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
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
	Test Type: Transgenic rodent somatic cell gene mutation assay Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 488 Result: positive
Germ cell mutagenicity- Assessment	: Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

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

Carcinogenicity

Not classified based on available information.

Components:**Propan-2-ol:**

Species : Rat

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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

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

Effects on fertility	: Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 0,6 mg/kg body weight
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	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

STOT - single exposure

May cause drowsiness or dizziness.

Components:**Propan-2-ol:**

Assessment	: May cause drowsiness or dizziness.
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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.

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Repeated dose toxicity**Components:****Propan-2-ol:**

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.

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:

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 (Raphidocelis subcapitata (freshwater green alga)): > 110 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Raphidocelis subcapitata (freshwater green alga)): 30 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC10 (activated sludge): 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

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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-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
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

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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 Other adverse effects**Product:**

Endocrine disrupting potential : 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 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**

ADN	: UN 3082
ADR	: UN 3082
RID	: UN 3082
IMDG	: UN 3082
IATA	: UN 3082

14.2 UN proper shipping name

ADN	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

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(Ivermectin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Ivermectin)

IATA : Environmentally hazardous substance, liquid, n.o.s.
(Ivermectin)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN

Packing group : III

Classification Code : M6

Hazard Identification Number : 90

Labels : 9

ADR

Packing group : III

Classification Code : M6

Hazard Identification Number : 90

Labels : 9

Tunnel restriction code : (-)

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

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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 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:**

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.

H317 : May cause an allergic skin reaction.

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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
ZA BEI	: South Africa. The Regulations for Hazardous Chemical Agents, Biological Exposure Indices
ZA OEL	: South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL	: Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)
ZA OEL / OEL- RL STEL/C	: Occupational Exposure Limit Restricted limit - Short term occupational exposure limits / ceiling limits

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 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

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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 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
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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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.

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