

# SAFETY DATA SHEET

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



## Ivermectin (with Propylene Glycol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	4710823-00017	Date of first issue: 30.07.2019

### 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

Recommended restrictions on use : Not applicable

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

Company : MSD  
Kilsheelan  
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)

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Hazard pictograms



Signal word

: Danger

Hazard statements

: H225 Highly flammable liquid and vapour.  
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

Chemical name	CAS-No. EC-No.	Classification	Concentration (% w/w)
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	Index-No. Registration number		
1,3-Dioxan-5-ol	4740-78-7 225-248-9	Eye Irrit. 2; H319	>= 30 - < 50
Butanone	78-93-3 201-159-0 606-002-00-3	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 EUH066	>= 10 - < 20
Ivermectin	70288-86-7 274-536-0	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 <hr/> M-Factor (Acute aquatic toxicity): 10,000 M-Factor (Chronic aquatic toxicity): 10,000	>= 1 - < 2.5

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 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

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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.

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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 : High volume water jet

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

Specific hazards during fire-fighting : 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.

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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.  
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

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- ventilation.  
Use explosion-proof electrical, ventilating and lighting equip-  
ment.
- 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 contami-  
nated 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  
Self-reactive substances and mixtures  
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  
Very acutely toxic substances and mixtures

### 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
Propylene glycol	57-55-6	OELV - 8 hrs (TWA) (particles)	10 mg/m <sup>3</sup>	IE OEL
		OELV - 8 hrs (TWA) (total (vapour and particles))	150 ppm 470 mg/m <sup>3</sup>	IE OEL
Butanone	78-93-3	STEL	300 ppm 900 mg/m <sup>3</sup>	2000/39/EC
	Further information: Indicative			
		TWA	200 ppm 600 mg/m <sup>3</sup>	2000/39/EC
	Further information: Indicative			
		OELV - 15 min (STEL)	300 ppm 900 mg/m <sup>3</sup>	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 - 8 hrs (TWA)	200 ppm 600 mg/m <sup>3</sup>	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
Butanone	Workers	Inhalation	Long-term systemic effects	600 mg/m <sup>3</sup>
		Skin contact	Long-term systemic effects	1161 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	106 mg/m <sup>3</sup>
		Skin contact	Long-term systemic effects	412 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	31 mg/kg bw/day
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term systemic	168 mg/m <sup>3</sup>

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			effects	
	Consumers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>

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

Substance name	Environmental Compartment	Value
Butanone	Fresh water	55.8 mg/l
	Freshwater - intermittent	55.8 mg/l
	Marine water	55.8 mg/l
	Sewage treatment plant	709 mg/l
	Fresh water sediment	284.74 mg/kg dry weight (d.w.)
	Marine sediment	284.7 mg/kg dry weight (d.w.)
Propylene glycol	Soil	22.5 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	1000 mg/kg food
	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)

## 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/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



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Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

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### 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
Melting point/freezing point	:	< -66 °C
Initial boiling point and boiling range	:	81.5 °C
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	:	16 °C
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available

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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

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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 : 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

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### 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:**

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

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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:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

##### **Butanone:**

Assessment : Repeated exposure may cause skin dryness or cracking.

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

##### **Ivermectin:**

Species : Rabbit  
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

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### 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  
Species : Humans  
Result : Does not cause skin sensitisation.

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 1,3-Dioxan-5-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)

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Species: Mouse  
Result: negative  
Remarks: Based on data from similar materials

### Butanone:

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

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

Test Type: Chromosome aberration test in vitro  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-  
thesis in mammalian cells (in vitro)  
Result: negative

Test Type: Saccharomyces cerevisiae, gene mutation assay  
(in vitro)  
Result: negative

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

### Ivermectin:

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

Test Type: DNA damage and repair, unscheduled DNA syn-  
thesis 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:

#### Ivermectin:

Species : Rat  
Application Route : Oral  
NOAEL : 1.5 mg/kg body weight  
Result : negative

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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 develop-  
ment : 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 develop-  
ment : 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

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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  
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



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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:

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

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

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

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l

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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  
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

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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

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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

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## 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.  
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.

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## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN : UN 1193  
ADR : UN 1193

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**RID** : UN 1193  
**IMDG** : UN 1193  
**IATA** : UN 1193

### 14.2 UN proper shipping name

**ADN** : ETHYL METHYL KETONE, SOLUTION  
**ADR** : ETHYL METHYL KETONE, SOLUTION  
**RID** : ETHYL METHYL KETONE, SOLUTION  
**IMDG** : ETHYL METHYL KETONE, SOLUTION  
(Ivermectin)  
**IATA** : Ethyl methyl ketone, solution

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	: 3	
<b>ADR</b>	: 3	
<b>RID</b>	: 3	
<b>IMDG</b>	: 3	
<b>IATA</b>	: 3	

### 14.4 Packing group

**ADN**  
Packing group : II  
Classification Code : F1  
Hazard Identification Number : 33  
Labels : 3

**ADR**  
Packing group : II  
Classification Code : F1  
Hazard Identification Number : 33  
Labels : 3  
Tunnel restriction code : (D/E)

**RID**  
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)**  
Packing instruction (cargo) : 364

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aircraft)  
Packing instruction (LQ) : Y341  
Packing group : II  
Labels : Flammable Liquids

### IATA (Passenger)

Packing instruction (passen- : 353  
ger aircraft)  
Packing instruction (LQ) : Y341  
Packing group : II  
Labels : Flammable Liquids

### 14.5 Environmental hazards

#### ADN

Environmentally hazardous : yes

#### ADR

Environmentally hazardous : yes

#### RID

Environmentally hazardous : yes

#### IMDG

Marine pollutant : yes

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 14.7 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, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 75, 3

If you intend to use this product as tattoo ink, please contact your vendor.

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

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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 (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

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	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t
P5c	FLAMMABLE LIQUIDS	5,000 t	50,000 t

### 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

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.

H336 : May cause drowsiness or dizziness.

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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.

### 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  
2000/39/EC : Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values  
IE OEL : List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2  
2000/39/EC / TWA : Limit Value - eight hours  
2000/39/EC / STEL : Short term exposure limit  
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 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 Re-



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striction 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; TECl - 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:

Flam. Liq. 2	H225
Eye Irrit. 2	H319
STOT SE 2	H371
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Based on product data or assessment
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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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