

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ivermectin (with Propylene Glycol) Formulation

Version 5.1 Revision Date: 30.09.2023 SDS Number: 9374187-00012 Date of last issue: 04.04.2023
Date of first issue: 27.08.2021

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
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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.

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

- 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.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
1,3-Dioxan-5-ol	4740-78-7	Eye Irrit. 2; H319	>= 30 - < 50

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	225-248-9		
Butanone	78-93-3 201-159-0 606-002-00-3	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	$\geq 10 - < 20$
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	$\geq 1 - < 2.5$
Substances with a workplace exposure limit :			
Propylene glycol	57-55-6 200-338-0		$\geq 30 - < 50$

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 for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

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If swallowed : If swallowed, DO NOT induce vomiting.
If vomiting occurs have person lean forward.
Call a physician or poison control centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during 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.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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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.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

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- 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 assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.
- Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
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	TWA (Total vapour and particles)	150 ppm 474 mg/m ³	GB EH40
		TWA (particles)	10 mg/m ³	GB EH40
Butanone	78-93-3	TWA	200 ppm 600 mg/m ³	GB EH40
	Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		STEL	300 ppm 899 mg/m ³	GB EH40
	Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		STEL	300 ppm 900 mg/m ³	2000/39/EC
	Further information: Indicative			
		TWA	200 ppm 600 mg/m ³	2000/39/EC
	Further information: Indicative			
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
Butanone	78-93-3	butan-2-one: 70 micromol per litre (Urine)	After shift	GB EH40 BAT

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Butanone	Workers	Inhalation	Long-term systemic effects	600 mg/m ³
	Workers	Skin contact	Long-term systemic effects	1161 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	106 mg/m ³
	Workers	Skin contact	Long-term systemic effects	412 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic	31 mg/kg

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			effects	bw/day
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m ³
	Workers	Inhalation	Long-term systemic effects	168 mg/m ³
	Consumers	Inhalation	Long-term local effects	10 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	50 mg/m ³

Predicted No Effect Concentration (PNEC):

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.)
	Soil	22.5 mg/kg dry weight (d.w.)
Propylene glycol	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

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Hand protection	:	potential for direct contact to the face with dusts, mists, or aerosols.
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 BS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	liquid
Colour	:	Colorless to pale yellow
Odour	:	characteristic
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	< -66 °C
Initial boiling point and boiling range	:	81.5 °C
Flash point	:	16 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	1.04 - 1.08

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Density : No data available

Solubility(ies)
Water solubility : slightly soluble
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 : Highly flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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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:

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
Symptoms: Vomiting, Dilatation of the pupil
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 5.11 mg/l

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Exposure time: 1 h
Test atmosphere: dust/mist

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

LD50 (Rat): > 660 mg/kg

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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

Propylene glycol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

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Components:

1,3-Dioxan-5-ol:

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

Butanone:

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

Ivermectin:

Species	:	Rabbit
Result	:	Mild eye irritation

Propylene glycol:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	No 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

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

Propylene glycol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

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)
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

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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

Propylene glycol:

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

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

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

Carcinogenicity

Not classified based on available information.

Components:

Ivermectin:

Species : Rat
Application Route : Oral
NOAEL : 1.5 mg/kg body weight
Result : negative
Remarks : Based on data from similar materials

Species : Mouse
Application Route : Oral
NOAEL : 2.0 mg/kg body weight
Result : negative
Remarks : Based on data from similar materials

Propylene glycol:

Species : Rat
Application Route : Ingestion

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Exposure time : 2 Years
Result : negative

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

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Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal develop- : Test Type: Embryo-foetal development
ment Species: Mouse
Application Route: Ingestion
Result: negative

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

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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

Propylene glycol:

Species : Rat, male
NOAEL : $\geq 1,700$ mg/kg
Application Route : Ingestion
Exposure time : 2 yr

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.

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:

1,3-Dioxan-5-ol:

- Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials
- NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials
- Toxicity to microorganisms : EC10 : > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Butanone:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 2,993 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 308 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 2,029 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 1,240 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

Ivermectin:

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Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l Exposure time: 96 h
		LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0.000025 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	10,000
M-Factor (Chronic aquatic toxicity)	:	10,000
Propylene glycol:		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 13,020 mg/l Exposure time: 7 d Species: Ceriodaphnia dubia (water flea)

12.2 Persistence and degradability

Components:

1,3-Dioxan-5-ol:

Biodegradability	:	Result: Inherently biodegradable. Remarks: Based on data from similar materials
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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

Propylene glycol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

12.3 Bioaccumulative potential

Components:

1,3-Dioxan-5-ol:

Partition coefficient: n-
octanol/water : log Pow: -0.65

Butanone:

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

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-
octanol/water : log Pow: 3.22

Propylene glycol:

Partition coefficient: n-
octanol/water : log Pow: -1.07
Method: Regulation (EC) No. 440/2008, Annex, A.8

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.

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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. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN : UN 1193
ADR : UN 1193
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)

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IATA : Ethyl methyl ketone, solution

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 3	
ADR	: 3	
RID	: 3	
IMDG	: 3	
IATA	: 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 aircraft) : 364
Packing instruction (LQ) : Y341
Packing group : II
Labels : Flammable Liquids

IATA (Passenger)

Packing instruction (passenger aircraft) : 353
Packing instruction (LQ) : Y341
Packing group : II
Labels : Flammable Liquids

14.5 Environmental hazards

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ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

14.6 Special precautions for user

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

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	: Conditions of restriction for the following entries should be considered: Number on list 3
	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.
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	: Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	: Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	: Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	: Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	: Not applicable
Control of Major Accident Hazards Regulations 2015 (COMAH)	

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P5c	FLAMMABLE LIQUIDS	Quantity 1 5,000 t	Quantity 2 50,000 t
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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.
H370 : Causes damage to organs if swallowed.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
STOT RE : Specific target organ toxicity - repeated exposure

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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
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
GB EH40 BAT : UK. Biological monitoring guidance values
2000/39/EC / TWA : Limit Value - eight hours
2000/39/EC / STEL : Short term exposure limit
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (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; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No 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; 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:

Flam. Liq. 2 H225

Classification procedure:

Based on product data or assessment

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Eye Irrit. 2	H319	Calculation method
STOT SE 2	H371	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	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.

GB / EN