

SAFETY DATA SHEET

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



.IVOMEK PO, TOEXL/20L 1/5MG/ML AU IVOMEK Pour On (Aus) 20 L X 1 AUS-335373

Version	Revision Date:	SDS Number:	Date of last issue: 15.12.2022
3.1	02.01.2024	000000049546	Date of first issue: 28.10.2019

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

1.1 Product identifier

Trade name	:	.IVOMEK PO, TOEXL/20L 1/5MG/ML AU IVOMEK Pour On (Aus) 20 L X 1 AUS-335373
Synonyms	:	Ivomec® Pour-On, Ivomec® Pour-On for cattle, Ivomec® Pour-On Lösung zum Auftragen auf die Haut für Tiere, Ivomec® Pour-On 5 MG/ML VET. LIUOS, Ivomec® Pour-On bovin, solution cutanée pour depot, Ivomec® Pour-On cattle, Ivomec® Pour-On for cattle, Ivomec® Pour-On for cattle and deer, Ivomec® Pour-On sol. ad us. Vet, Ivomec® Pour-On voor rundvee, molemec pour-on solution, Molemec Pour on with API: Ivermectin
Product code	:	000000000000130344 000000000000130344

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	:	Safety Data Sheet only for the professional user., For veterinary use only, Refer to the product insert for complete instructions on usage

1.3 Details of the supplier of the safety data sheet

Company	:	Boehringer Ing. Pharma GmbH & Co.KG Binger Straße 173 55216 Ingelheim Germany
Telephone	:	+498007790900
E-mail address of person responsible for the SDS	:	EHS-Services@Boehringer-Ingelheim.com

1.4 Emergency telephone number

Int. Emergency Telephone number: +1 703-527-3887
German Emergency Telephone number: +49800 1817059

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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Flammable liquids, Category 2	H225: Highly flammable liquid and vapour.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Effects on or via lactation	H362: May cause harm to breast-fed children.
Specific target organ toxicity - single exposure, Category 3, Central nervous system	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)

Hazard pictograms :



Signal word : Danger

Hazard statements :

- H225 Highly flammable liquid and vapour.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness.
- H362 May cause harm to breast-fed children.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P263 Avoid contact during pregnancy and while nursing.
- P273 Avoid release to the environment.

Response:

- P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.
- P391 Collect spillage.

Hazardous components which must be listed on the label:

propan-2-ol
Ivermectin

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Additional Labelling

EUH208 Contains Ivermectin. May produce an allergic reaction.

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.

This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)

The pharmacological effect of the medicament has to be considered (see package leaflet).

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Mixture

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 01-2119457558-25-XXXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 (Central nervous system)	>= 50 - < 70
Ivermectin	70288-86-7 274-536-0	Acute Tox. 2; H300 Acute Tox. 3; H311 Skin Sens. 1; H317 Repr. 2; H361 Lact.H362 STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity):	>= 0,3 - < 1

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		10.000 M-Factor (Chronic aquatic toxicity): 100	
		Acute toxicity esti- mate	
		Acute oral toxicity: 42,8 mg/kg Acute dermal toxicity: 406 mg/kg	

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.
(show the package insert where possible).
First Aid responders should pay attention to self-protection
and use the recommended protective clothing
Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
- If inhaled : Move to fresh air.
- In case of skin contact : Wash off immediately with plenty of water.
- In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.
- If swallowed : Rinse mouth.
Drink plenty of water.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Causes serious eye irritation.
May cause drowsiness or dizziness.
May cause harm to breast-fed children.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Observe the summary of product characteristics of proprietary medicinal products
Treat symptomatically.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water mist
Dry chemical
Foam
Carbon dioxide (CO₂)

Unsuitable extinguishing media : Water spray jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.

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.
Complete suit protecting against chemicals

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Wear personal protective equipment.
Ensure adequate ventilation.
High risk of slipping due to leakage/spillage of product.

6.2 Environmental precautions

Environmental precautions : Do not flush into surface water or sanitary sewer system.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and transfer to properly labelled containers.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).

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6.4 Reference to other sections

For personal protection see section 8., For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
- Advice on protection against fire and explosion : Keep away from heat and sources of ignition.
- Hygiene measures : General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Protect from heat and direct sunlight. Refer to the product insert for instructions on storage.
- Advice on common storage : Keep away from food, drink and animal feedingstuffs. Observe joint storage prohibition.
- Storage class (TRGS 510) : 3

7.3 Specific end use(s)

- Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.

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	AGW	200 ppm 500 mg/m ³	DE TRGS 900
Peak-limit: excursion factor (category): 2;(II)				
Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child				

Components	Basis	Category	Values	Remarks
Ivermectin 70288-86-7	BIEL	3A	10 µg/m ³	
	BIPC	3		

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Abbreviations:

BIEL = Boehringer Ingelheim Exposure Limit (internal value)

BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)

BIPC = Boehringer Ingelheim Pregnancy Category

BIPC 3: There is evidence in animals and/or humans or the mechanism of actions indicates that the compound has the potential to cause harm to the unborn. Harm to the unborn can occur even if exposure does not exceed the BIEL value.

Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
propan-2-ol	67-63-0	Acetone: 25 mg/l (Blood)	Immediately after exposure or after working hours	TRGS 903
		Acetone: 25 mg/l (Urine)	Immediately after exposure or after working hours	TRGS 903

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

Substance name	End Use	Exposure routes	Potential health effects	Value
propan-2-ol	Workers	Skin contact	Long-term systemic effects	888 mg/kg
	Workers	Inhalation	Long-term systemic effects	500 mg/m3
	Workers	Inhalation	Systemic effects	500 mg/kg
	Workers	Dermal	Systemic effects	888 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Ivomec® Pour-On, Ivomec® Pour-On for cattle, Ivomec® Pour-On Lösung zum Auftragen auf die Haut für Tiere, Ivomec® Pour-On 5 MG/ML VET. LIUOS, Ivomec® Pour-On bovin, solution cutanée pour depot, Ivomec® Pour-On cattle, Ivomec® Pour-On for cattle, Ivomec® Pour-On for cattle and deer, Ivomec® Pour-On sol. ad us. Vet, Ivomec® Pour-On voor rundvee, molemec pour-on solution, Molemec Pour on	Water	< 0,000057 mg/l
	Sediment	< 0,000012 mg/kg
	Soil	0,03 mg/kg

8.2 Exposure controls

Engineering measures

Local exhaust

Emergency sprinkling nozzle

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Personal protective equipment

Eye/face protection	: Tightly fitting safety goggles Face-shield (Not necessary when using full face mask)
Hand protection	
Material	: Nitrile rubber
Glove thickness	: 0,43 mm
Protective index	: Class 6
Remarks	: The break through time depends amongst other things on the material, the thickness and the type of glove and therefore has to be measured for each case.
Skin and body protection	: Laboratory: laboratory coat; Factory: disposable Overall. Wear as appropriate: Complete suit protecting against chemicals
Respiratory protection	: Breathing apparatus needed only when aerosol or mist is formed. Half protecting mask with filter: ABEK-P2-filter
Protective measures	: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: liquid
Colour	: blue
Odour	: alcohol-like
Odour Threshold	: No data available
Melting point/range	: No data available
Boiling point/boiling range	: 82 °C

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(related to the solvent(s))

Flammability : Not applicable

Upper explosion limit / Upper flammability limit : 12 %(V)
(related to the solvent(s))

Lower explosion limit / Lower flammability limit : 2 %(V)
(related to the solvent(s))

Flash point : 14 °C

Auto-ignition temperature : No data available

Decomposition temperature : No decomposition if used as directed.

pH : No data available

Viscosity
Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : 43 hPa (20 °C)

Relative density : No data available

Density : No data available

Bulk density : Not applicable

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Relative vapour density : No data available

Particle characteristics
Particle size : Not applicable

9.2 Other information

Explosives : Not tested

Oxidizing properties : No data available

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

No decomposition if stored and applied as directed.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No data available

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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): 5.840 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 10000 ppm
Exposure time: 6 h
Test atmosphere: vapour
Method: OECD Test Guideline 403

LC50 (Rat): 72,6 mg/l
Exposure time: 4 h
Test atmosphere: vapour

LC50 (Rat, male and female): 37,5 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rat): 13.900 mg/kg
LD50 (Rabbit): 12.800 mg/kg

Ivermectin:

Acute oral toxicity : LD50 (Rat, male): 42,8 mg/kg
LD50 (Rat, female): 44,3 mg/kg
LD50 (Mouse, male): 11,6 mg/kg
Acute toxicity estimate: 42,8 mg/kg
Method: Calculation method

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Acute inhalation toxicity : LC50 (Rat): 5,11 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit, male and female): = 406 mg/kg

Acute toxicity estimate: 406 mg/kg
Method: Calculation method

Skin corrosion/irritation

Not classified based on available information.

Components:

propan-2-ol:

Species : Rabbit
Result : Mildly irritating.

Ivermectin:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

propan-2-ol:

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

Ivermectin:

Species : Rabbit
Result : Slightly irritating.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

propan-2-ol:

Test Type : Buehler Test
Species : Guinea pig
Method : OECD Test Guideline 406

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Result : Non-sensitizing.

Ivermectin:

Test Type	: Buehler test
Species	: Guinea pig
Result	: May cause sensitisation by skin contact.
Test Type	: Mouse Local Lymph Node Assay (LLNA)
Species	: Mouse
Result	: Does not cause skin sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Components:

propan-2-ol:

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 476 Result: negative Test Type: Ames test Test system: Salmonella typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Method: OECD Test Guideline 474 Result: negative

Ivermectin:

Genotoxicity in vitro	: Test Type: Ames test Test system: Salmonella typhimurium Concentration: 2000 µg/plate Result: negative Test Type: Mouse lymphoma assay Concentration: 1000 µg/ml Result: negative Test Type: Unscheduled DNA synthesis Test system: fibroblast cell line Concentration: 1000 µg/ml Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test

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Species: Rat
Application Route: Oral
Dose: 20 mg/kg/day
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

propan-2-ol:

Remarks : Not classified due to data which are conclusive although insufficient for classification.

Ivermectin:

Species : Mouse
Exposure time : 2 Years
Dose : 10 mg/kg/day
Remarks : Did not show carcinogenic effects in animal experiments.

Species : Rat, male
Application Route : Oral
Exposure time : 2 Years
Dose : 9 mg/kg/day
Remarks : Not classified due to data which are conclusive although insufficient for classification.

Species : Rat, female
Application Route : Oral
Exposure time : 2 Years
Dose : 9 mg/kg/day
Remarks : Did not show carcinogenic effects in animal experiments.

Reproductive toxicity

May cause harm to breast-fed children.

Components:

propan-2-ol:

Effects on fertility : Remarks: Not classified due to data which are conclusive although insufficient for classification.

Effects on foetal development : Remarks: Not classified due to data which are conclusive although insufficient for classification.

Ivermectin:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Dose: 0.1, 1, 9 mg/kg/day

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Effects on foetal development	: General Toxicity - Parent: NOEL: 1 mg/kg body weight Fertility: NOEL: 1 mg/kg body weight
	: Test Type: Embryo-foetal development Species: Mouse Application Route: Oral Dose: 0.1; 0.2; 0.4; 0.8 mg/kg/day General Toxicity Maternal: NOEL: 0,1 mg/kg body weight Embryo-foetal toxicity: NOEL: 0,2 mg/kg body weight Result: Teratogenic effects
	: Test Type: Embryo-foetal development Species: Rat Application Route: Oral Dose: 1.5; 4; 12 mg/kg/day General Toxicity Maternal: NOAEL: 4 mg/kg body weight Embryo-foetal toxicity: NOAEL: 4 mg/kg body weight Result: Teratogenic effects
	: Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Dose: 1.5; 3; 6 mg/kg/day General Toxicity Maternal: NOEL: 3 mg/kg body weight Embryo-foetal toxicity: NOEL: 1,5 mg/kg body weight Result: Teratogenic effects
Reproductive toxicity - Assessment	: Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments. Effects on or via lactation

STOT - single exposure

May cause drowsiness or dizziness.

Components:

propan-2-ol:

Target Organs	: Central nervous system
Assessment	: The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with narcotic effects.

Ivermectin:

Remarks	: Not classified due to data which are conclusive although insufficient for classification.
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STOT - repeated exposure

Not classified based on available information.

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Components:

Ivermectin:

Exposure routes	: Ingestion
Target Organs	: Central nervous system
Assessment	: The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 1.

Repeated dose toxicity

Components:

propan-2-ol:

Remarks	: Not classified due to data which are conclusive although insufficient for classification.
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Ivermectin:

Species	: Mouse
NOAEL	: 10 mg/kg
Application Route	: Dermal
Exposure time	: 13 weeks
Dose	: 1, 3, 10 mg/kg/day
Remarks	: No significant adverse effects were reported

Species	: Rat
NOAEL	: 3 mg/kg
Application Route	: Oral
Exposure time	: 13 weeks
Dose	: 0.1, 0.3, 1.0, 3.0 mg/kg/day

Species	: Dog
NOAEL	: 0,5 mg/kg
Application Route	: Oral
Exposure time	: 13 weeks
Dose	: 0.1, 0.25, 0.5, 1.5 mg/kg/day

Aspiration toxicity

Not classified based on available information.

Components:

Ivermectin:

No data available

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment	: The substance/mixture does not contain components consid-
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ered 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.

Further information

Components:

Ivermectin:

Remarks : No data available

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
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 10.000 mg/l
aquatic invertebrates Exposure time: 24 h
Method: OECD Test Guideline 202

EC50 (Daphnia magna (Water flea)): 9.714 mg/l
Exposure time: 24 h

EC50 (Daphnia magna (Water flea)): 13.299 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic : NOEC (algae): 1.000 mg/l
plants Exposure time: 8 d

IC50 (Desmodesmus subspicatus (green algae)): > 1.000 mg/l
Exposure time: 72 h

Toxicity to microorganisms : (Pseudomonas putida): 1.050 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,003 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0053 mg/l
Exposure time: 96 h

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Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0,000013 mg/l End point: Immobilization Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 4 mg/l End point: Growth rate Exposure time: 72 h Method: OECD Test Guideline 201 Lowest Observed Effect Concentration (Pseudokirchneriella subcapitata (green algae)): 1,25 mg/l End point: Growth rate Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0,391 mg/l End point: Growth rate Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	:	10.000
Toxicity to microorganisms	:	Remarks: No data available
Toxicity to fish (Chronic toxicity)	:	Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	Remarks: No data available
M-Factor (Chronic aquatic toxicity)	:	100
Toxicity to soil dwelling organisms	:	Test Type: artificial soil EC50: 5,3 mg/kg Exposure time: 56 d Species: Eisenia fetida (earthworms) Method: OECD Test Guideline 222 Test Type: artificial soil NOEC: 2,5 mg/kg Exposure time: 56 d Species: Eisenia fetida (earthworms) Method: OECD Test Guideline 222
Sediment toxicity	:	NOEC: 0,024 mg/kg Test Type: static test

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Exposure duration: 10 d
Species: Chironomus sp. (midge)

EC50: 0,12 mg/kg
Test Type: static test
Exposure duration: 10 d
Species: Chironomus sp. (midge)

NOEC: 0,066 mg/kg
Test Type: static test
Exposure duration: 10 d
Species: Hexagenia limbata (Mayfly)

EC50: 0,79 mg/kg
Test Type: static test
Exposure duration: 10 d
Species: Hexagenia limbata (Mayfly)

NOEC: 0,21 mg/kg
Test Type: static test
Exposure duration: 10 d
Species: Hyalella azteca (Amphipod)

EC50: 1,7 mg/kg
Test Type: static test
Exposure duration: 10 d
Species: Hyalella azteca (Amphipod)

12.2 Persistence and degradability

Components:

propan-2-ol:

Biodegradability : Remarks: No data available

Ivermectin:

Biodegradability : Result: Persistent substance with a half life of more than 60 days.

12.3 Bioaccumulative potential

Components:

propan-2-ol:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log P(o/w)<1).

Partition coefficient: n-octanol/water : log Pow: 0,05 (25 °C)

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Ivermectin:

Bioaccumulation : Species: Danio rerio (zebra fish)
Bioconcentration factor (BCF): 63 - 111
Remarks: Bioaccumulation is unlikely.

Partition coefficient: n- : log Pow: 3,22 (20 °C)
octanol/water

12.4 Mobility in soil

Components:

Ivermectin:

Distribution among environ- : log Koc: 3,6 - 4,4
mental compartments

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.

Components:

Ivermectin:

Assessment : Persistent and Toxic

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

Components:

Ivermectin:

Additional ecological infor- : No data available
mation

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14: Transport information

14.1 UN number or ID number

ADR : UN 1993

RID : UN 1993

IMDG : UN 1993

IATA : UN 1993

14.2 UN proper shipping name

ADR : FLAMMABLE LIQUID, N.O.S.
(Isopropanol, Ivermectin)

RID : FLAMMABLE LIQUID, N.O.S.
(Isopropanol, Ivermectin)

IMDG : FLAMMABLE LIQUID, N.O.S.
(Isopropanol, Ivermectin)

IATA : Flammable liquid, n.o.s.
(Isopropanol, Ivermectin)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADR	: 3	
RID	: 3	
IMDG	: 3	
IATA	: 3	

14.4 Packing group

ADR

Packing group : II

Classification Code : F1

Hazard Identification Number : 33

Labels : 3

Tunnel restriction code : (D/E)

RID

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

IMDG

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

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

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

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

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

REACH - 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 : Ivermectin

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. P5c FLAMMABLE LIQUIDS

E1 ENVIRONMENTAL HAZARDS

Water hazard class (Germany) : WGK 3 highly hazardous to water
Classification according to AwSV, Annex 1 (5.2)

TA Luft List (Germany) : 5.2.1: Total dust:
Not applicable
5.2.2: Inorganic substances in powdered form:
Not applicable
5.2.4: Inorganic substances in gaseous form:
Not applicable
5.2.5: Organic Substances:
Class 1: 0,56 % Ivermectin
5.2.7.1.1: Carcinogenic substance:
Not applicable
5.2.7.1.1: Quartz fine dust PM4:
Not applicable
5.2.7.1.1: Formaldehyde:
Not applicable
5.2.7.1.2: Germ cell mutagens:
Not applicable
5.2.7.1.3: Substances toxic to reproduction:
Not applicable
5.2.7.2: Poorly degradable, easily enrichable and highly toxic organic substances:

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Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

Other regulations:

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

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:

TCSI	: Not in compliance with the inventory
TSCA	: Product contains substance(s) not listed on TSCA inventory.
AIIC	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Crodamol CAP
ENCS	: Not in compliance with the inventory
ISHL	: Not in compliance with the inventory
KECI	: Not in compliance with the inventory
PICCS	: Not in compliance with the inventory
IECSC	: Not in compliance with the inventory
NZIoC	: Not in compliance with the inventory
TECI	: Not in compliance with the inventory

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of H-Statements

H225 : Highly flammable liquid and vapour.

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H300	: Fatal if swallowed.
H311	: Toxic in contact with skin.
H317	: May cause an allergic skin reaction.
H319	: Causes serious eye irritation.
H336	: May cause drowsiness or dizziness.
H361	: Suspected of damaging fertility or the unborn child.
H362	: May cause harm to breast-fed children.
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
Lact.	: Effects on or via lactation
Repr.	: Reproductive toxicity
Skin Sens.	: Skin sensitisation
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure
DE TRGS 900	: Germany. TRGS 900 - Occupational exposure limit values.
TRGS 903	: TRGS 903 - Biological limit values
DE TRGS 900 / AGW	: Time Weighted Average

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

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tative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Training advice : Provide adequate information, instruction and training for operators.

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

Classification of the mixture:

Flam. Liq. 2	H225
Eye Irrit. 2	H319
Lact.	H362
STOT SE 3	H336
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

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