

Ivomec® F, Injectable solution (finished product)

Version	Revision Date:	SDS Number:	Date of last issue: 28.10.2019
2.0	10.06.2020	000000049426	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 : Ivomec® F, Injectable solution (finished product)

Synonyms : with API: Ivermectin, Clorsulon
Ivomec® Plus, Ivomec® Super, Ivomec® C, Ivomec® D

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Safety Data Sheet only for the professional user.

1.3 Details of the supplier of the safety data sheet

Company : Boehringer Ingelheim Vetmedica
800 5th St NW
50501 Fort Dodge
USA

Telephone : +15159554661

E-mail address of person responsible for the SDS : EHS-Services@Boehringer-Ingelheim.com

1.4 Emergency telephone number

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation , Category 2	H319: Causes serious eye irritation.
Skin sensitisation , Category 1	H317: May cause an allergic skin reaction.
Effects on or via lactation	H362: May cause harm to breast-fed children.
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 ,	H410: Very toxic to aquatic life with long lasting


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Category 1 effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H362 May cause harm to breast-fed children.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P263 Avoid contact during pregnancy and while nursing.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.

Response:
P391 Collect spillage.

Hazardous components which must be listed on the label:

Ivermectin

2.3 Other hazards

This substance/mixture contains components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).

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)

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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 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 1 - < 2,5
Clorsulon	60200-06-8 262-100-2		>= 10 - < 20
1,3-Dioxolane-4-methanol	5464-28-8 226-758-4	Eye Irrit. 2; H319	>= 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 (show the label 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 : May cause an allergic skin reaction.
Causes serious eye irritation.
May cause harm to breast-fed children.
May cause damage to organs through prolonged or repeated exposure.

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4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Observe the summary of product characteristics of proprietary medicinal products
Symptomatic treatment (decontamination, vital functions).

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
Dry chemical
Foam
Carbon dioxide (CO₂)

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.
Can be released in case of fire:
Carbon oxides
Product itself is non-combustible; fire extinguishing method of surrounding areas must be considered.
Hydrogen chloride gas

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.

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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 : No special protective measures against fire required. The product is not flammable.
- 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 : No special storage conditions required.
- Advice on common storage : Keep away from food, drink and animal feedingstuffs. Observe joint storage prohibition.
- Storage class (TRGS 510) : 10, Combustible liquids not in Storage Class 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

Contains no substances with occupational exposure limit values.

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

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.

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Components	Basis	Category	Values	Remark
Clorsulon 60200-06-8	BIEL	2	200 µg/m ³	
	BIPC	1b		
Abbreviations: BIEL = Boehringer Ingelheim Exposure Limit (internal value) BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit) BIPC = Boehringer Ingelheim Pregnancy Category BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.				

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

Substance name	Environmental Compartment	Value
Ivermectin	Sediment	< 0,000012 mg/kg
	surface water	< 0,000057 mg/l
	Soil	0,03 mg/kg

8.2 Exposure controls

Engineering measures

Local exhaust
Emergency sprinkling nozzle

Personal protective equipment

Eye protection : Tightly fitting safety goggles (splash goggles) (EN 166)

Hand protection

Material : Nitrile rubber
 Glove thickness : 0,43 mm
 Directive : Protective gloves against chemicals and micro-organisms
 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.

Respiratory protection : No personal respiratory protective equipment normally required.
 Breathing apparatus needed only when aerosol or mist is formed.
 Respiratory protection
 ABEK2

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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

Appearance	: liquid
Colour	: slightly yellow
Odour	: odourless
Odour Threshold	: No data available
pH	: No data available
Melting point/range	: Not applicable
Boiling point/boiling range	: No data available
Flash point	: 81 °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	: No data available
Bulk density	: Not applicable
Solubility(ies) Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available

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Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : No data available

Explosive properties : Not tested

Oxidizing properties : No data available

9.2 Other information

Self-ignition : 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 : Extremes of temperature and direct sunlight.

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

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Components:

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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 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

Clorsulon:

Acute oral toxicity : LD50 (Rat, male and female): > 10.000 mg/kg
LD50 (Mouse, male and female): > 20.000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

1,3-Dioxolane-4-methanol:

Acute oral toxicity : LD50 (Rat): 10.200 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Not classified based on available information.

Components:

Ivermectin:

Species : Rabbit
Result : No skin irritation

Clorsulon:

Species : Rabbit
Result : No skin irritation

1,3-Dioxolane-4-methanol:

Remarks : No data available

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Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Ivermectin:

Species : Rabbit
Result : Slightly irritating.

Clorsulon:

Species : Rabbit
Remarks : Based on available data, the classification criteria are not met.
Contact with eyes may cause irritation.

1,3-Dioxolane-4-methanol:

Result : Eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

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.

Clorsulon:

Remarks : No data available

1,3-Dioxolane-4-methanol:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Ivermectin:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium

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

Clorsulon:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 2 - 2500 µg/plate
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: Unscheduled DNA synthesis
Test system: human diploid fibroblasts
Concentration: 0,3 - 3 mM
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: comet assay
Test system: human diploid fibroblasts
Concentration: 0,3 - 3 mM
Metabolic activation: with and without metabolic activation
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Dose: 2000 mg/kg bw
Result: positive
Remarks: In vivo tests showed mutagenic effects

Test Type: Chromosome aberration test in vitro
Species: Mouse
Dose: 2000 mg/kg bw
Result: positive
Remarks: In vivo tests showed mutagenic effects

1,3-Dioxolane-4-methanol:

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Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Not classified based on available information.

Components:

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.

Clorsulon:

Species : Rat
Exposure time : 126 weeks
Dose : 3,8; 12,6; 48,8 mg/kg/day
Remarks : Did not show carcinogenic effects in animal experiments.

1,3-Dioxolane-4-methanol:

Remarks : No data available

Reproductive toxicity

May cause harm to breast-fed children.

Components:

Ivermectin:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Dose: 0.1, 1, 9 mg/kg/day
General Toxicity - Parent: NOEL: 1 mg/kg body weight
Fertility: NOEL: 1 mg/kg body weight

Effects on foetal develop- : Test Type: Embryo-foetal development

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ment	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

Clorsulon:

Effects on fertility : Remarks: No data available

Effects on foetal development	: Test Type: Embryo-foetal development Species: Mouse Application Route: Oral Dose: 2, 10, 50 mg/kg/day General Toxicity Maternal: NOEL: 50 mg/kg body weight Embryo-foetal toxicity: NOEL: 10 mg/kg body weight Remarks: embryotoxic effects Did not show teratogenic effects in animal experiments Test Type: Three-generation study Species: Rat Application Route: Oral Dose: 3, 30, 300 mg/kg/day Symptoms: Reduced body weight Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Dose: 2, 10, 50 mg/kg/day General Toxicity Maternal: NOEL: 2 mg/kg body weight Embryo-foetal toxicity: NOEL: 10 mg/kg body weight Remarks: embryotoxic effects
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Did not show teratogenic effects in animal experiments

1,3-Dioxolane-4-methanol:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure

Not classified based on available information.

Components:

Ivermectin:

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

Clorsulon:

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

1,3-Dioxolane-4-methanol:

Remarks : No data available

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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.

Clorsulon:

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

1,3-Dioxolane-4-methanol:

Remarks : No data available

Repeated dose toxicity

Components:

Ivermectin:

Species : Mouse

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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

Clorsulon:

Species : Dog
NOEL : 2 mg/kg
Application Route : Oral
Exposure time : 14 Weeks
Dose : 2; 8; 32 mg/kg/day

Species : Rat
NOEL : 20 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Dose : 20; 150; 425 mg/kg/day

Species : Rat
NOEL : 3,8 mg/kg
Application Route : Oral
Exposure time : 104 Weeks
Dose : 3,8; 12,6; 48,8 mg/kg/day

Aspiration toxicity

Not classified based on available information.

Components:

Ivermectin:

No data available

Clorsulon:

No data available

1,3-Dioxolane-4-methanol:

No data available

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Further information

Components:

Ivermectin:

Remarks : No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

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
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (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)	:	100
Toxicity to microorganisms	:	Remarks: No data available
Toxicity to fish (Chronic toxicity)	:	Remarks: No data available

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC50: 0,0017 mg/l
Exposure time: 10 d
Species: *Hyalella azteca* (Amphipod)

NOEC: 0,00021 mg/l
Exposure time: 10 d
Species: *Hyalella azteca* (Amphipod)

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

Clorsulon:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : LC50 (*Daphnia magna* (Water flea)): 356 parts per million

Toxicity to algae/aquatic plants : Remarks: No data available

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

Ecotoxicology Assessment

Chronic aquatic toxicity : Toxic effects cannot be excluded

1,3-Dioxolane-4-methanol:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

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Toxicity to algae/aquatic plants : Remarks: No data available

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

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

12.2 Persistence and degradability

Components:

Ivermectin:

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

Clorsulon:

Biodegradability : Result: No data available

1,3-Dioxolane-4-methanol:

Biodegradability : Result: No data available

12.3 Bioaccumulative potential

Components:

Ivermectin:

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

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

Clorsulon:

Bioaccumulation : Remarks: No appreciable bioaccumulation potential is to be expected (log P(o/w) 1-3).

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Partition coefficient: n-octanol/water : log Pow: 1,09

1,3-Dioxolane-4-methanol:

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Components:

Ivermectin:

Distribution among environmental compartments : log Koc: 3,6 - 4,4

Clorsulon:

Distribution among environmental compartments : Remarks: No data available

1,3-Dioxolane-4-methanol:

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB)..

Components:

Ivermectin:

Assessment : PBT substance.

12.6 Other adverse effects

Components:

Ivermectin:

Additional ecological information : No data available

Clorsulon:

Additional ecological information : No data available

1,3-Dioxolane-4-methanol:

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Additional ecological information : No data available

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

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

14.2 UN proper shipping name

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

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

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

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

14.3 Transport hazard class(es)

ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADR
Packing group : III
Classification Code : M6

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Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

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

IMDG

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

IATA (Cargo)

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

IATA (Passenger)

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

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

Not applicable for product as supplied.

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SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations 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

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

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

E1 ENVIRONMENTAL HAZARDS

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

TA Luft List (Germany) : Total dust:
Not applicable
Inorganic substances in powdered form:
Not applicable
Inorganic substances in vapour or gaseous form:
Not applicable
Organic Substances:
Not applicable
Carcinogenic substances:
Not applicable
Mutagenic:
Not applicable
Toxic to reproduction:
Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Volatile organic compounds (VOC) content: 50 %

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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:

REACH	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. 1,3-Dioxolane-4-methanol Clorsulon
AICS	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
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
TCSI	:	Not in compliance with the inventory
TSCA	:	Substance(s) not listed on TSCA 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

H300	:	Fatal if swallowed.
H311	:	Toxic in contact with skin.
H317	:	May cause an allergic skin reaction.
H319	:	Causes serious eye irritation.
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.

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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
Lact. : Effects on or via lactation
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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; 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.

Other information : Vertical lines in the left hand margin indicate an amendment from the previous version.

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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:

Eye Irrit. 2	H319
Skin Sens. 1	H317
Lact.	H362
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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