according to Regulation (EC) No. 1907/2006



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

1.1 Product identifier

Trade name : Ivomec® Pour On

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

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

Use of the Sub-

stance/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)

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 ex-

posure , Category 3 , Central nervous

system

H336: May cause drowsiness or dizziness.

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Short-term (acute) aquatic hazard, Cate-

gory 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.

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 lvermectin

Additional Labelling

EUH208 Contains Ivermectin. May produce an allergic reaction.

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).

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No.	Classification	Concentration (% w/w)
	Index-No. Registration number		
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	>= 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 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 100	>= 0,3 - < 1

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 ad-

vice 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.

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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

Symptomatic treatment (decontamination, vital functions).

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Water mist
Dry chemical

Foam

Carbon dioxide (CO2)

Unsuitable extinguishing

media

High volume water 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.

Can be released in case of fire:

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.

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6.3 Methods and material for containment and cleaning up

: Pick up and transfer to properly labelled containers. Methods for cleaning up

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

: Provide sufficient air exchange and/or exhaust in work rooms. Advice on safe handling

fire and explosion

Advice on protection against : Keep away from heat and sources of ignition.

General industrial hygiene practice. Wash hands and face Hygiene measures

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.

Advice on common storage

: Keep away from food, drink and animal feedingstuffs.

Observe joint storage prohibition.

Storage class (TRGS 510) : 3, Flammable Liquids

7.3 Specific end use(s)

Specific use(s) : Consult the technical guidelines for the use of this sub-

stance/mixture.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form	Control parameters	Basis
		of exposure)		
propan-2-ol	67-63-0	AGW	200 ppm	DE TRGS
			500 mg/m3	900
	Peak-limit: excursion factor (category): 2;(II)			
	Further information: Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			

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Components	Basis	Category	Values	Remark
Ivermectin 70288-86-7	BIEL	3A	10 μg/m3	
	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.

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	Dermal	Long-term systemic effects	888 mg/kg
	Workers	Inhalation	Long-term systemic effects	500 mg/m3
	Consumers	Inhalation	Long-term systemic effects	89 mg/m3
	Consumers	Dermal	Long-term systemic effects	319 mg/kg
	Consumers	Ingestion	Long-term systemic effects	26 mg/kg

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

Substance name	Environmental Compartment Value		
propan-2-ol	Fresh water	140,9 mg/l	
	Marine water	140,9 mg/l	
	Sewage treatment plant	2251 mg/l	
	Fresh water sediment	552 mg/l	
	Marine sediment	552 mg/l	
	Water	160 mg/l	
	Soil	28 mg/l	
	Water	140,9 mg/l	
Ivermectin	Sediment	< 0,000012	

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	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 : Always wear eye protection when the potential for inadvertent

eye contact with the product cannot be excluded.

Safety glasses with side-shields

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 : Protective work clothing

Respiratory protection : No personal respiratory protective equipment normally re-

quired.

Breathing apparatus needed only when aerosol or mist is

formed.

Respiratory protection

ABEK2

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 warran-

ty 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 : blue

Odour : alcohol-like

Odour Threshold : No data available

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pH : No data available

Melting point/range : No data available

Boiling point/boiling range : 82 °C(related to the solvent(s))

Flash point : 14 °C

Evaporation rate : No data available

Flammability (solid, gas) : 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))

Vapour pressure : 43 hPa (20 °C)

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

Auto-ignition temperature : No data available

Decomposition temperature : No decomposition if used as directed.

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.

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10.3 Possibility of hazardous reactions

Hazardous reactions : No data available

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

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

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): > 10.000 mg/l

Exposure time: 6 h
Test atmosphere: vapour

Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rabbit): > 2.000 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 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

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Skin corrosion/irritation

Components:

propan-2-ol:

Result : No skin irritation

Ivermectin:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

propan-2-ol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : irritating

Ivermectin:

Species : Rabbit

Result : Slightly irritating.

Respiratory or skin sensitisation

Components:

propan-2-ol:

Assessment : Does not cause skin sensitisation.

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

Components:

propan-2-ol:

Genotoxicity in vitro : Remarks: In vitro tests did not show mutagenic effects

Genotoxicity in vivo : Remarks: No mutagenic effects reported.

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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

Species: Rat

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

Carcinogenicity

Components:

propan-2-ol:

Remarks : Not classified due to data which are conclusive although insuf-

ficient 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 insuf-

ficient 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.

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Components:

propan-2-ol:

Effects on fertility : Remarks: Not classified due to data which are conclusive

although insufficient for classification.

Effects on foetal develop-

ment

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

General Toxicity - Parent: NOEL: 1 mg/kg body weight

Fertility: NOEL: 1 mg/kg body weight

Effects on foetal develop-

ment

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 - As-

sessment

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:

Assessment : The substance or mixture is classified as specific target organ

toxicant, single exposure, category 3 with narcotic effects.

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Ivermectin:

Remarks : Not classified due to data which are conclusive although insuf-

ficient for classification.

STOT - repeated exposure

Components:

propan-2-ol:

Remarks : Not classified due to data which are conclusive although insuf-

ficient for classification.

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:

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

Components:

propan-2-ol:

No data available

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Ivermectin:

No data available

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 :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10.000 mg/l

Exposure time: 24 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

Remarks: Not classified due to data which are conclusive

although insufficient for classification.

Toxicity to microorganisms : (Pseudomonas putida): 1.050 mg/l

Exposure time: 16 h

Toxicity to fish (Chronic tox-

icity)

Remarks: No data available

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

Remarks: No data available

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

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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

mq/

End point: Growth rate Exposure time: 72 h

M-Factor (Acute aquatic tox-

icity)

100

Toxicity to microorganisms

Remarks: No data available

Toxicity to fish (Chronic tox-

icity)

Remarks: No data available

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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 or-

ganisms

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

12.2 Persistence and degradability

Components:

propan-2-ol:

Biodegradability : Result: Readily biodegradable.

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Ivermectin:

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

days.

12.3 Bioaccumulative potential

Components:

propan-2-ol:

Partition coefficient: n-

octanol/water

: log Pow: 0,05 (25 °C)

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)

12.4 Mobility in soil

Components:

Ivermectin:

Distribution among environ-

mental compartments

: log Koc: 3,6 - 4,4

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 infor-

mation

: No data available

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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

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)

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

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

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IMDG

Packing group : II Labels : 3

EmS Code : F-E, S-E

IATA (Cargo)

Packing instruction (cargo : 364

aircraft)

Packing instruction (LQ) : Y341
Packing group : II

Labels : Flammable Liquids

IATA (Passenger)

Packing instruction (passen- : 353

ger aircraft)

Packing instruction (LQ) : Y341
Packing group : II

Labels : Flammable Liquids

14.5 Environmental hazards

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

Remarks : IATA: Special provision A197

IMDG-Code: Chapter 2.10.2.7 ADR/RID: Special provision 375

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.

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

according to Regulation (EC) No. 1907/2006



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REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation Not applicable

(Annex XIV)

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-Not applicable tants (recast)

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

Ivermectin

Not applicable

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.

FLAMMABLE LIQUIDS P5c

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)

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

according to Regulation (EC) No. 1907/2006



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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.

Crodamol CAP

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

H225 : Highly flammable liquid and vapour.

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

according to Regulation (EC) No. 1907/2006



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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 - 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 op-

erators.

Other information : Vertical lines in the left hand margin indicate an amendment

from the previous version.

Sources of key data used to compile the Safety Data

Sheet

The specifications are based on own tests and/or literature

data.

according to Regulation (EC) No. 1907/2006



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Classification of the mixture:		Classification procedure:	
Flam. Liq. 2	H225	Based on product data or assessment	
Eye Irrit. 2	H319	Calculation method	
Lact.	H362	Calculation method	
STOT SE 3	H336	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 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.

DE / EN