

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Ivomec® Liquid 0.08% (finished product)

Version	Revision Date:	SDS Number:	Date of last issue: 19.06.2018
2.1	19.06.2018	000000050412	Date of first issue: 29.09.2017

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

1.1 Product identifier

Trade name : Ivomec® Liquid 0.08% (finished product)

Synonyms : Ivomec® Drench, Ivomec® Drench for Sheep, Ivomec® liquid, Ivomec® liquid for Sheep and Goats, Ivomec® liquid Sheep, Ivomec® liquide, Ivomec® oral 0.08%, Ivomec® Sheep oral, Oramec®, Oramec® Drench, Oramec® Liquid, molemec® Drench for Sheep
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 Ing. Pharma GmbH & Co.KG
Binger Str. 173
55216 Ingelheim am Rhein

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 Chemtrec 24-hours

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Chronic aquatic toxicity , Category 2 H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Hazard statements : H411 Toxic to aquatic life with long lasting effects.

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Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
Response:
P391 Collect spillage.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

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.

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : organic

Hazardous components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
benzyl alcohol	100-51-6 202-859-9 603-057-00-5 01-2119492630-38-XXXX	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319	>= 1 - < 10
Ivermectin	70288-86-7 274-536-0	Acute Tox. 2; H300 Acute Tox. 4; H332 Acute Tox. 3; H311 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 0,025 - < 0,1

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 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.

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- 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 : No information available.

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.

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.

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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.

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.
Advice on Segregation

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.

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

Substance name	End Use	Exposure routes	Potential health effects	Value
benzyl alcohol	Workers	Inhalation	Acute systemic effects	450 mg/m ³
	Workers	Dermal	Acute systemic effects	47 mg/m ³
	Workers	Inhalation	Long-term systemic effects	90 mg/m ³
	Workers	Dermal	Long-term systemic effects	9,5 mg/m ³
	Consumers	Oral	Acute systemic effects	25 mg/m ³
	Consumers	Inhalation	Acute systemic effects	96,5 mg/m ³
	Consumers	Dermal	Acute systemic effects	28,5 mg/m ³
	Consumers	Oral	Long-term systemic effects	5 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	19,1 mg/m ³
	Consumers	Dermal	Long-term systemic effects	5,7 mg/m ³

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

Substance name	Environmental Compartment	Value
benzyl alcohol	Fresh water	1 mg/l
	Fresh water sediment	5,27 mg/l
	Marine sediment	0,527 mg/l
	Soil	0,456 mg/l
	Intermittent use/release	2,3 mg/l

8.2 Exposure controls

Engineering measures

Local exhaust
Emergency sprinkling nozzle

Personal protective equipment

Eye protection : Safety glasses with side-shields

Hand protection

Material : Nitrile rubber
Break through time : 480 min
Glove thickness : 0,43 mm
Directive : Protective gloves against chemicals and micro-organisms
Protective index : Class 6

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.

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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 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	: No data available
Odour	: No data available
pH	: No data available
	: No data available
	: No data available
Flash point	: 101 °C
Evaporation rate	: No data available
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
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

9.2 Other information

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

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 inhalation toxicity : Acute toxicity estimate: > 20 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Components:

benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.620 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 8,8 mg/l
Exposure time: 4 h
Test atmosphere: vapour

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Acute dermal toxicity : LD50 (Rabbit): 2.000 mg/kg

Ivermectin:

Acute oral toxicity : LD50 (Mouse): = 25 mg/kg

LD50 (Rat): = 50 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,11 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist
Assessment: The component/mixture is moderately toxic after short term inhalation.

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

Skin corrosion/irritation

Not classified based on available information.

Components:

benzyl alcohol:

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

Ivermectin:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

benzyl alcohol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Eye irritation

Ivermectin:

Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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Components:

benzyl alcohol:

Remarks : No data available

Ivermectin:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

benzyl alcohol:

Genotoxicity in vitro : Test Type: Ames-test
Result: negative

Genotoxicity in vivo : Remarks: No data available

Ivermectin:

Genotoxicity in vitro : Test Type: Ames-test
Test system: Salmonella typhimurium
Result: negative

Test Type: Mouse lymphoma assay
Result: negative

Test Type: Unscheduled DNA synthesis
Test system: fibroblast cell line
Result: negative

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Not classified based on available information.

Components:

benzyl alcohol:

Remarks : No data available

Ivermectin:

Remarks : No data available

Reproductive toxicity

Not classified based on available information.

Components:

benzyl alcohol:

Effects on fertility : Remarks: No data available

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Effects on foetal development : Remarks: No data available

Ivermectin:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Reproductive toxicity - Assessment : No toxicity to reproduction
Animal testing did not show any effects on foetal development.

STOT - single exposure

Not classified based on available information.

Components:

benzyl alcohol:

Remarks : No data available

Ivermectin:

Remarks : No data available

STOT - repeated exposure

Not classified based on available information.

Components:

benzyl alcohol:

Remarks : No data available

Ivermectin:

Remarks : No data available

Aspiration toxicity

Not classified based on available information.

Components:

benzyl alcohol:

No data available

Ivermectin:

No data available

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Further information

Components:

Ivermectin:

Remarks : No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

benzyl alcohol:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): 400 mg/l
Exposure time: 24 h

Toxicity to algae : (Scenedesmus quadricauda (Green algae)): 640 mg/l
Exposure time: 96 h

Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): = 71,4 mg/l
Exposure time: 0,5 h

EC50 (protozoa): = 854 mg/l
Exposure time: 48 h

Toxicity to fish (Chronic toxicity) : Remarks: No data available

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

M-Factor (Acute aquatic toxicity) : 100

Toxicity to microorganisms : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other : EC50: 0,0017 mg/l

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aquatic invertebrates (Chronic toxicity) : Exposure time: 10 d
Species: Hyallela azteca (Amphipod)

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

M-Factor (Chronic aquatic toxicity) : 100

12.2 Persistence and degradability

Components:

benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Biochemical Oxygen Demand (BOD) : 1.550 mg/g
Incubation time: 5 d

Ivermectin:

Biodegradability : Remarks: No data available

12.3 Bioaccumulative potential

Components:

benzyl alcohol:

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

Partition coefficient: n-octanol/water : log Pow: 1,05 (20 °C)

Ivermectin:

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Components:

benzyl alcohol:

Distribution among environmental compartments : Remarks: No data available

Ivermectin:

Distribution among environmental compartments : Remarks: No data available

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12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..

12.6 Other adverse effects

Components:

Ivermectin:

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)

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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
Hazard Identification Number	: 90
Labels	: 9
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 Dangerous Goods

IATA (Passenger)

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

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	: Single or inner packaging less than 5 L (liquid) or 5 Kg net
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(solids) excepted from Dangerous Goods regulations - see IATA Special Provision A197.
Single or inner packaging less than 5 L (liquid) or 5 Kg net (solids) excepted from Dangerous Goods regulations - see IMDG-Code 2.10.2.7.
Single or inner packaging less than 5 L (liquid) or 5 Kg net (solids) excepted from Dangerous Goods regulations - see 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 - 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 (EC) No 850/2004 on persistent organic pollutants : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : benzyl alcohol
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.

		Quantity 1	Quantity 2
E2	ENVIRONMENTAL HAZARDS	200 t	500 t

H2

Water contaminating class (Germany) : WGK 2 water endangering

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

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Carcinogenic substances:
Not applicable
Mutagenic:
Not applicable
Toxic to reproduction:
Not 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.
Sorbitan monooleate, ethoxylated

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 : Not On TSCA Inventory

15.2 Chemical safety assessment

SECTION 16: Other information

Full text of H-Statements

H300 : Fatal if swallowed.
H302 : Harmful if swallowed.
H311 : Toxic in contact with skin.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
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 : Acute aquatic toxicity
Aquatic Chronic : Chronic aquatic toxicity
Eye Irrit. : Eye irritation

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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.
- 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:

Aquatic Chronic 2 H411

Classification procedure:

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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DE / EN