

SAFETY DATA SHEETS

This SDS packet was issued with item:

078345066

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078345074 078345082 078345090 078345108 078408411 078408478 078704949 078704956 078912270

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Eprinex®, liquid (finished product)

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	11.04.2017	000000049068	Date of first issue: 11.04.2017

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

1.1 Product identifier

Trade name : Eprinex®, liquid (finished product)

Synonyms : with API: Eprinomectin
EPRINEX Pour-On for Cattle, Eprinex Pour-On vet. for Cattle

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)

The product is not subject to classification (medicinal product)

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

The product does not need to be labelled (medicinal product).

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).

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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)
Eprinomectin	133305-88-1	Acute Tox. 3; H301 Acute Tox. 3; H311 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	0,5

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 : 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

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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
Nitrogen oxides (NO_x)
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.

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.

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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

- | | | |
|--------------------------|---|---|
| Advice on common storage | : | Keep away from food, drink and animal feedingstuffs.
Advice on Segregation |
| Storage class (TRGS 510) | : | 12, Non Combustible Liquids |

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.

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	: colourless, 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	: 220 °C
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: 0,91 - 0,92
Bulk density	: Not applicable
Solubility(ies)	
Water solubility	: of low solubility
Partition coefficient: n-octanol/water	: No data available

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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 : not auto-flammable

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

Components:

Eprinomectin:

Acute oral toxicity : LD50 (Mouse): 70 mg/kg

LD50 (Rat): 55 mg/kg

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

Acute dermal toxicity : LD50 (Rat): > 660 mg/kg
LD50 (Rabbit): 406 mg/kg

Skin corrosion/irritation

Components:

Eprinomectin:

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Components:

Eprinomectin:

Species: Rabbit
Result: Irritating to eyes.

Respiratory or skin sensitisation

Components:

Eprinomectin:

Species: Guinea pig
Result: Does not cause skin sensitisation.

Germ cell mutagenicity

Components:

Eprinomectin:

Genotoxicity in vitro : Remarks: In vitro tests did not show mutagenic effects
Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Components:

Eprinomectin:

Remarks: No data available

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Reproductive toxicity

Components:

Eprinomectin:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure

Components:

Eprinomectin:

Remarks: No data available

STOT - repeated exposure

Components:

Eprinomectin:

Remarks: No data available

Further information

Components:

Eprinomectin:

Remarks: No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

Eprinomectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,0012 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 0,00045 mg/l
Exposure time: 48 h

Toxicity to algae : Remarks: No data available

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) : Remarks: No data available

12.2 Persistence and degradability

Components:

Eprinomectin:

Biodegradability : Remarks: No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

Components:

Eprinomectin:

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Product:

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

12.6 Other adverse effects

Components:

Eprinomectin:

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.

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SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

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 : Eprinomectin

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water contaminating class (Germany) : WGK 2 significantly water endangering
Classification according to AwSV, Annex 1 (5.2)

TA Luft List (Germany) : Total dust:
Not applicable
Inorganic substances in powdered form:
Not applicable

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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

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. Eprinomectin
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

H301	: Toxic if swallowed.
H311	: Toxic in contact with skin.
H319	: Causes serious eye irritation.
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

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Aquatic Chronic : Chronic aquatic toxicity
Eye Irrit. : Eye irritation

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; 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.

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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