

**Eprinex®, Eprinex® Multi, Ivomec Eprinex®  
(Finished product)**

Version	Revision Date:	SDS Number:	Date of last issue: 28.10.2019
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**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

**1.1 Product identifier**

Trade name : Eprinex®, Eprinex® Multi, Ivomec Eprinex® (Finished product)

Synonyms : Pour-On for: for Beef and Dairy Cattle, sheep and goats  
With API: Eprinomectin 5 mg/ml

**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**

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**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**

**Classification (REGULATION (EC) No 1272/2008)**

Effects on or via lactation : H362: May cause harm to breast-fed children.

Short-term (acute) aquatic hazard , Category 1 : H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard , Category 1 : H410: Very toxic to aquatic life with long lasting effects.

**2.2 Label elements**

**Labelling (REGULATION (EC) No 1272/2008)**

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Hazard pictograms

:



Signal word

: Warning

Hazard statements

: H362 May cause harm to breast-fed children.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P263 Avoid contact during pregnancy and while nursing.  
P273 Avoid release to the environment.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/attention.  
P391 Collect spillage.

**Hazardous components which must be listed on the label:**

Eprinomectin

**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).  
The pharmacological effect of the medicament has to be considered (see package leaflet).  
This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)

**SECTION 3: Composition/information on ingredients**

**3.2 Mixtures**

Chemical nature            : organic

**Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Eprinomectin	123997-26-2	Acute Tox. 3; H301 Repr. 2; H361 Lact.H362 STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1;	>= 0,3 - < 1

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		H410	
		M-Factor (Acute aquatic toxicity): 1.000	
		M-Factor (Chronic aquatic toxicity): 1.000	

For explanation of abbreviations see section 16.

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**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 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).

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**SECTION 5: Firefighting measures**

**5.1 Extinguishing media**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Water  
Dry chemical  
Foam  
Carbon dioxide (CO<sub>2</sub>)

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**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<sub>x</sub>)  
Product itself is non-combustible; fire extinguishing method of surrounding areas must be considered.

**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.

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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.

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**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
Eprinomectin 123997-26-2	BIEL	3A	10 µg/m <sup>3</sup>	
	BIPC	1b		
<p><b>Abbreviations:</b>                      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.</p>				

**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  
 Glove thickness : 0,43 mm  
 Directive : Protective gloves against chemicals and micro-organisms  
 Protective index : Class 6

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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
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.

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**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

Appearance	: liquid
Colour	: colourless, yellow
Odour	: No data available
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	: Not applicable
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	: Not applicable

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Relative vapour density	:	Not applicable
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
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	Not applicable
Explosive properties	:	Not tested
Oxidizing properties	:	No data available

**9.2 Other information**

Self-ignition	:	Not auto-flammable
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**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.
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**10.4 Conditions to avoid**

Conditions to avoid	:	No data available
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**10.5 Incompatible materials**

Materials to avoid	:	No data available
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**10.6 Hazardous decomposition products**

No data available





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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Eprinomectin:**

Genotoxicity in vitro : Test Type: Ames test  
Test system: S. typhimurium and E. coli  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Test system: V79 cells (Chinese hamster)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Test system: Chinese hamster ovary cells  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:**

**Eprinomectin:**

Remarks : The chemical structure does not suggest such an effect.

**Reproductive toxicity**

May cause harm to breast-fed children.

**Components:**

**Eprinomectin:**

Effects on fertility : Remarks: No data available

Effects on foetal development : Test Type: Two-generation study  
Species: Rat  
Application Route: Ingestion  
Dose: 0, 1, 2,5-3, 6 mg/kg /day  
General Toxicity Maternal: NOEL: 1 mg/kg body weight  
Developmental Toxicity: NOEL: 1 mg/kg body weight  
Remarks: Did not show teratogenic effects in animal experiments

Test Type: Embryo-foetal development  
Species: Rabbit

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Application Route: Oral  
Dose: 0,5 to 8 mg/kg/day  
General Toxicity Maternal: NOEL: 0,5 mg/kg body weight  
Embryo-foetal toxicity: NOAEL: 0,5 mg/kg body weight  
Remarks: Did not show teratogenic effects in animal experiments

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments., Effects on or via lactation

**STOT - single exposure**

Not classified based on available information.

**Components:**

**Eprinomectin:**

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

**STOT - repeated exposure**

Not classified based on available information.

**Components:**

**Eprinomectin:**

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:**

**Eprinomectin:**

Species : Rabbit  
NOEL : 1,5 mg/kg  
Application Route : Oral  
Exposure time : 28-day  
Dose : 1,5 - 25 mg/kg/day

Species : Rat  
NOEL : 5 mg/kg  
Application Route : Oral  
Dose : 1 - 30 mg/kg/day

Species : Rat  
NOEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 28-day  
Dose : 0,5 - 60 mg/kg/day

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**Aspiration toxicity**

Not classified based on available information.

**Components:**

**Eprinomectin:**

No data available

**Further information**

**Components:**

**Eprinomectin:**

Remarks : Neurotoxic effect.

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**SECTION 12: Ecological information**

**12.1 Toxicity**

**Components:**

**Eprinomectin:**

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,37 mg/l Method: OECD Test Guideline 203
		LC50 (Oncorhynchus mykiss (rainbow trout)): 1,2 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0,00045 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 The value is given in analogy to the following substances: Avermectin A1a, 4''-(acetylamino)-5-O-demethyl-4''-deoxy-, (4''R)-
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (algae)): 3,4 mg/l Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1.000
Toxicity to microorganisms	:	Remarks: No data available
Toxicity to fish (Chronic toxicity)	:	Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0,000028 mg/l End point: reproduction rate Species: Daphnia magna (Water flea)

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Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1.000

Toxicity to soil dwelling organisms : NOEC: 19 mg/kg  
Species: Eisenia fetida (earthworms)  
Method: OECD Test Guideline 222

Sediment toxicity : NOEC: 0,00034 mg/l  
Species: Chironomus riparius (Midge larvae)  
Method: OECD Test Guideline 218

**12.2 Persistence and degradability**

**Product:**

Biodegradability : Result: No data available

**Components:**

**Eprinomectin:**

Biodegradability : Inoculum: Soil  
Result: Persistent substance with a half life of more than 60 days.  
Method: OECD Test Guideline 307

Inoculum: Sediment  
Result: Persistent substance with a half life of more than 60 days.  
Method: OECD Test Guideline 308

**12.3 Bioaccumulative potential**

**Product:**

Bioaccumulation : Remarks: No data available

**Components:**

**Eprinomectin:**

Bioaccumulation : Remarks: An appreciable bioaccumulation potential is to be expected ( $\log P(o/w) > 3$ ).

Species: Fish  
Method: OECD Test Guideline 305  
Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : Pow: 5,4

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**12.4 Mobility in soil**

**Product:**

Distribution among environmental compartments : Remarks: No data available

**Components:**

**Eprinomectin:**

Distribution among environmental compartments : Medium: Soil  
Koc: 1000  
Kd: 15,7  
Method: Adsorption/Desorption

Medium: Soil  
Koc: 9208  
Kd: 133,5  
Method: Adsorption/Desorption

**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:**

**Eprinomectin:**

Assessment : Persistent and Toxic.  
: PBT substance.

**12.6 Other adverse effects**

**Components:**

**Eprinomectin:**

Additional ecological information : 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.



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according to Regulation (EC) No. 1907/2006



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### 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

Remarks : ADR/RID: Special provision 601  
ADR/RID: Special provision 375  
IATA: Special provision A197  
IMDG-Code: Chapter 2.10.2.7

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

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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 : 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.

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:  
portion Class 1: 0,01 %  
  
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).

### The components of this product are reported in the following inventories:

TCSI : Not in compliance with the inventory



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TSCA	:	Substance(s) not listed on TSCA inventory
AICS	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.  Eprinomectin Decanoic acid, mixed diesters with octanoic acid and propylene glycol
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory

### 15.2 Chemical safety assessment

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

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### SECTION 16: Other information

#### Full text of H-Statements

H301	:	Toxic if swallowed.
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
Lact.	:	Effects on or via lactation
Repr.	:	Reproductive toxicity
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



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DE / EN