according to Regulation (EC) No. 1907/2006



# Ivomec® F, Injectable solution (finished product)

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

1.1 Product identifier

Trade name : Ivomec® F, Injectable solution (finished product)

Synonyms : with API: Ivermectin, Clorsulon

Ivomec® Plus, Ivomec® Super, Ivomec® C, Ivomec® D

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

Use of the Sub- : Pharmaceutical

stance/Mixture

Recommended restrictions

Safety Data Sheet only for the professional user.

on use

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)

Eye irritation , Category 2 H319: Causes serious eye irritation.

Acute aquatic toxicity, Category 1 H400: Very toxic to aquatic life.

Chronic aquatic toxicity, 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 : H319 Causes serious eye irritation.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling.P273 Avoid release to the environment.P280 Wear eye protection/ face protection.

Response:

P337 + P313 If eye irritation persists: Get medical advice/

attention.

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.	Classification	Concentration (% w/w)
	Index-No.		
	Registration number		
Ivermectin	70288-86-7	Acute Tox. 2; H300	>= 1 - < 2,5
	274-536-0	Acute Tox. 4; H332	
		Acute Tox. 3; H311	
		Aquatic Acute 1; H400	
		Aquatic Chronic 1;	
		H410	
Clorsulon	60200-06-8	Eye Irrit. 2; H319	>= 10 - < 20
	262-100-2		

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Glycerol Formal	5464-28-8 226-758-4	Eye Irrit. 2; H319	>= 30 - < 50

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical 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.

Drink plenty of water.

## 4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes serious eye irritation.

### 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

Dry chemical

Foam

Carbon dioxide (CO2)

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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

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.

### **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.

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Advice on common storage : Keep away from food, drink and animal feedingstuffs.

Advice on Segregation

Storage class (TRGS 510) : 12, Non-comb.Liq.,cant be assig.to any of the above stor.

class.

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

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 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.

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## **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

Odour Threshold : No data available

pH : No data available

Melting point/range : Not applicable

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Bulk density : Not applicable

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Explosive properties : Not tested

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Oxidizing properties : No data available

9.2 Other information

Self-ignition : No data available

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

#### 10.2 Chemical stability

No decomposition if stored and applied as directed.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : Extremes of temperature and direct sunlight.

10.5 Incompatible materials

Materials to avoid : No data available

## 10.6 Hazardous decomposition products

No data available

## **SECTION 11: Toxicological information**

### 11.1 Information on toxicological effects

#### Acute toxicity

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg

Method: Calculation method

**Components:** 

Ivermectin:

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

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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

Clorsulon:

Acute oral toxicity : LD50 (Rat): > 10.000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Assessment: Toxic effects cannot be excluded

**Glycerol Formal:** 

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

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Assessment: Toxic effects cannot be excluded

Skin corrosion/irritation

**Components:** 

Ivermectin:

Species: Rabbit

Result: No skin irritation

Clorsulon:

Remarks: No data available

**Glycerol Formal:** 

Remarks: No data available

Serious eye damage/eye irritation

**Components:** 

Ivermectin:

Species: Rabbit

Result: Mild eye irritation

Clorsulon:

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Result: Eye irritation

**Glycerol Formal:** Result: Eye irritation

Respiratory or skin sensitisation

**Components:** 

Ivermectin:

Remarks: No data available

Clorsulon:

Remarks: No data available

**Glycerol Formal:** 

Remarks: No data available

Germ cell mutagenicity

**Components:** 

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

Clorsulon:

Genotoxicity in vitro : Test Type: Ames test

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Dose: 2000 Result: positive

Test Type: Chromosome aberration test in vitro

Species: Mouse Dose: 500 Result: positive

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**Glycerol Formal:** 

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Components:

Ivermectin:

Remarks: No data available

Clorsulon:

Remarks: No data available

**Glycerol Formal:** 

Remarks: No data available

Reproductive toxicity

Components:

Ivermectin:

Effects on fertility : Remarks: No data available

Effects on foetal develop-

ment

Remarks: No data available

Reproductive toxicity - As-

sessment

No toxicity to reproduction

Animal testing did not show any effects on foetal develop-

ment.

Clorsulon:

Effects on fertility : Test Type: reproductive and developmental toxicity study

Species: Rat

Application Route: Ingestion

Dose: 2,20,100 milligram per kilogram

Result: No effects on fertility and early embryonic develop-

ment were detected.

Test Type: reproductive and developmental toxicity study

Species: Rat

Application Route: Ingestion

Dose: 3,30,100 milligram per kilogram

Result: No effects on fertility and early embryonic develop-

ment were detected.

Effects on foetal develop: : Test Type: Fertility/early embryonic development

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ment Species: Mouse

Application Route: Ingestion

Dose: 2,10,50 milligram per kilogram

Remarks: Showed no teratogenic and / or embryotoxic effects

in animal experiments.

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Dose: 2,10,50 milligram per kilogram

Remarks: Showed no teratogenic and / or embryotoxic effects

in animal experiments.

**Glycerol Formal:** 

Effects on fertility : Remarks: No data available

Effects on foetal develop-

ment

Remarks: No data available

STOT - single exposure

**Components:** 

Ivermectin:

Remarks: No data available

Clorsulon:

Remarks: No data available

**Glycerol Formal:** 

Remarks: No data available

STOT - repeated exposure

**Components:** 

Ivermectin:

Remarks: No data available

Clorsulon:

Remarks: No data available

**Glycerol Formal:** 

Remarks: No data available

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#### **Aspiration toxicity**

### **Components:**

Ivermectin:

No data available

Clorsulon:

No data available

**Glycerol Formal:** 

No data available

**Further information** 

Components:

Ivermectin:

Remarks: No data available

### **SECTION 12: Ecological information**

### 12.1 Toxicity

### **Components:**

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,003 mg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0053 mg/l

Exposure time: 96 h

Toxicity to algae : Remarks: No data available

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: Hyallela azteca (Amphipod)

NOEC: 0,00021 mg/l Exposure time: 10 d

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Species: Hyallela azteca (Amphipod)

M-Factor (Chronic aquatic

toxicity)

100

Clorsulon:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other :

aquatic invertebrates

Remarks: No data available

Toxicity to algae : Remarks: No data available

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)

Remarks: No data available

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

**Glycerol Formal:** 

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other :

aquatic invertebrates

Remarks: No data available

Toxicity to algae : Remarks: No data available

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)

Remarks: No data available

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

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#### 12.2 Persistence and degradability

**Components:** 

Ivermectin:

Biodegradability : Remarks: No data available

Clorsulon:

Biodegradability : Result: No data available

**Glycerol Formal:** 

Biodegradability : Result: No data available

12.3 Bioaccumulative potential

**Components:** 

Ivermectin:

Bioaccumulation : Remarks: No data available

Clorsulon:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-

octanol/water

Remarks: No data available

**Glycerol Formal:** 

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

**Components:** 

Ivermectin:

Distribution among environ-

mental compartments

: Remarks: No data available

Clorsulon:

Distribution among environ-

mental compartments

Remarks: No data available

**Glycerol Formal:** 

Distribution among environ-

mental 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 infor-

mation

: No data available

Clorsulon:

Additional ecological infor-

mation

No data available

**Glycerol Formal:** 

Additional ecological infor-

mation

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)

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RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Ivermectin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Ivermectin)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(Ivermectin)

14.3 Transport hazard class(es)

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

14.4 Packing group

**ADR** 

Packing group : III
Classification Code : M6
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 : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous Dangerous Goods

IATA (Passenger)

Packing instruction (passen- : 964

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

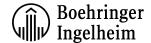
Labels : Miscellaneous Dangerous Goods

14.5 Environmental hazards

ADR

Environmentally hazardous : yes

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RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

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

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

of dangerous chemicals

Ivermectin

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Not applicable

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

plete the ozone layer

: Not applicable

Regulation (EC) No 850/2004 on persistent organic pol:

lutants

: 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.

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

**HAZARDS** 

Water contaminating class

(Germany)

: WGK 3 highly 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

Carcinogenic substances:

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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.

Glycerol Formal Clorsulon

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Not On TSCA Inventory

#### 15.2 Chemical safety assessment

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

### **SECTION 16: Other information**

### **Full text of H-Statements**

H300 : Fatal if swallowed.

H311 : Toxic in contact with skin. 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

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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 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.

#### Classification of the mixture: Classification procedure:

Eye Irrit. 2 H319 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 guid-

according to Regulation (EC) No. 1907/2006



# Ivomec® F, Injectable solution (finished product)

Version Revision Date: SDS Number: Date of last issue: -

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