according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 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 : Frontline Combo®, liquid (finished product)

Synonyms : Frontline Combo Spot-On Solution for Dogs and Cats: Front-

line Combo® Spot-On Solution for Dogs and Puppies: FRONTLINE COMBO, FRONTLINE COMBO DOGS,

FRONTLINE COMBO PARA PERROS, FRONTLINE COMBO SPOT ON CHIEN, FRONTLINE COMBO SPOT ON CHIEN S

- M - L - XL, FRONTLINE COMBO SPOT ON DOGS, FRONTLINE COMBO SPOT ON DOGS S - M - L - XL, FRONTLINE COMBO SPOT ON DOGS SOL. AD US. VET., FRONTLINE COMBO SPOT ON KUTYA A.U.V., FRONTLINE

COMP, FRONTLINE PLUS, FRONTLINE PLUS DOG, RONTLINE PLUS KOPEK, FRONTLINE PLUS PARA

**PERROS** 

with API: Fipronil, S-Methoprene

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

Use of the Sub- : Pharmaceutical

stance/Mixture

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

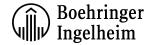
### Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 3 H226: Flammable liquid and vapour.

Acute toxicity, Category 4 H302: Harmful if swallowed.

Specific target organ toxicity - repeated H372: Causes damage to organs through pro-

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

exposure, Category 1 longed or repeated exposure.

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)

Hazard pictograms









Signal word : Danger

Hazard statements : H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H372 Causes damage to organs through prolonged or re-

peated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P210 Keep away from heat, hot surfaces, sparks, open

flames and other ignition sources. No smoking.

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

P264 Wash skin thoroughly after handling.P273 Avoid release to the environment.

Response:

P370 + P378 In case of fire: Use dry sand, dry chemical or

alcohol-resistant foam to extinguish.

P391 Collect spillage.

Hazardous components which must be listed on the label:

**Fipronil** 

#### 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**

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Fipronil	120068-37-3 424-610-5 608-055-00-8	Acute Tox. 3; H301 Acute Tox. 3; H331 Acute Tox. 3; H311 STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	10
(2E,4E,7S)-11-methoxy-3,7,11- trimethyl-2,4-dodecadienoic acid 1-methylethyl ester	65733-16-6 613-834-0	Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 9 - <= 12
ethanol	64-17-5 200-578-6 603-002-00-5 01-2119457610-43- XXXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319	8

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 : No information available.

Harmful if swallowed.

Causes damage to organs through prolonged or repeated

exposure.

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

### 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)

### 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 (NOx) Sulphur oxides

Hydrogen chloride gas

### 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.

Suppress vapours with waterspray.

#### 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.

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

Version Revision Date: Date of last issue: 15.02.2018 SDS Number: 4.0 23.04.2018 000000049050 Date of first issue: 11.04.2017

#### 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.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Breathing must be protected when large quantities are de-

canted without local exhaust ventilation. Keep container closed when not in use.

Advice on protection against :

fire and explosion

No special protective measures against fire required. The

product is not flammable.

General industrial hygiene practice. Wash hands and face Hygiene measures

before breaks and immediately after handling the product.

Keep working clothes separately.

## 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep tightly closed in a dry and cool place. Keep in a wellventilated place. Protect from heat and direct sunlight. Joint-

less smooth floor

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

Advice on Segregation

Storage class (TRGS 510) 3, Flammable Liquids

7.3 Specific end use(s)

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

stance/mixture.

### **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

## **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
2-(2-	111-90-0	AGW (Vapour	6 ppm	DE TRGS
ethoxyeth-		and aerosols)	35 mg/m3	900
oxy)ethanol				
Peak-limit: excur-	2;(I)			
sion factor (catego-				
ry)				
Further information	Commission for dangerous substances, Sum of vapor and aerosols., When			
	there is compliance with the OEL and biological tolerance values, there is no			
	risk of harming the unborn child			

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

ethanol	64-17-5	AGW	500 ppm 960 mg/m3	DE TRGS 900
Peak-limit: excursion factor (category)	2;(II)			
Further information	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Ethanol	Workers	Inhalation	Acute local effects	= 1900 mg/m3
	Workers	Skin contact	Long-term systemic effects	= 343 mg/kg
	Workers	Inhalation	Long-term systemic effects	= 950 mg/m3
	Consumers	Inhalation	Acute local effects	= 950 mg/m3
	Consumers	Skin contact	Long-term systemic effects	= 206 mg/kg
	Consumers	Inhalation	Long-term systemic effects	= 114 mg/m3
	Consumers	Ingestion	Long-term systemic effects	= 87 mg/kg

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

	. , ,	•
Substance name	Environmental Compartment	Value
Ethanol	Fresh water	= 0,96 mg/l
	Fresh water sediment	= 3,6 mg/kg
	Marine water	= 0.79  mg/l
	Soil	= 0.36  mg/kg
	Intermittent use/release	= 2,75 mg/l
	Sewage Treatment Systems	= 580 mg/l
	Oral	= 720 mg/kg

### 8.2 Exposure controls

## **Engineering measures**

Local exhaust

Emergency sprinkling nozzle

Use only appropriately classified electrical equipment and powered industrial trucks.

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

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.

### **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Appearance : liquid, viscous

Colour : amber

Odour : odourless

Odour Threshold : No data available

pH : 5,2

Melting point/range : Not applicable

Boiling point/boiling range : 78 °C

Flash point : 40 °C(1.013 hPa)

Method: ISO 3679

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper : No data available

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

Version Revision Date: Date of last issue: 15.02.2018 SDS Number: 4.0 23.04.2018 000000049050 Date of first issue: 11.04.2017

flammability limit

Lower explosion limit / Lower : No data available

flammability limit

No data available Vapour pressure

Relative vapour density No data available

Relative density 1,02

Bulk density Not applicable

Solubility(ies)

No data available Water solubility

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

No data available Viscosity, kinematic

Not tested Explosive properties

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

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

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**

Harmful if swallowed.

**Product:** 

Acute oral toxicity : LD50 (Rat): 750 mg/kg

Method: OECD Test Guideline 401

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:

Fipronil:

Acute oral toxicity : LD50 (Rat): 97 mg/kg

Assessment: The component/mixture is toxic after single in-

gestion.

Acute inhalation toxicity : LC50 (Rabbit): 0,68 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The component/mixture is toxic after short term

inhalation.

Acute dermal toxicity : LD50 (Rat): 354 mg/kg

Assessment: The component/mixture is toxic after single con-

tact with skin.

(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Acute oral toxicity : LD50 (Rat, male and female): > 5.050 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC0 (Rat): > 2,38 mg/l

Exposure time: 4 h
Test atmosphere: vapour

Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rabbit): > 5.050 mg/kg

Method: OECD Test Guideline 402

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

ethanol:

Acute oral toxicity : LD50 (Rat): = 10.470 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): = 124,7 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Acute dermal toxicity : Remarks: No data available

#### Skin corrosion/irritation

Not classified based on available information.

**Product:** 

Species: Rabbit

Method: OECD Test Guideline 404

### **Components:**

### Fipronil:

Species: Rabbit Exposure time: 4 h

Method: OECD Test Guideline 404

Result: No skin irritation

## (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Species: Rabbit Exposure time: 4 h

Method: OECD Test Guideline 404

Result: No skin irritation

### ethanol:

Species: Rabbit

Method: OECD Test Guideline 404

Result: No skin irritation

## Serious eye damage/eye irritation

Not classified based on available information.

**Product:** 

Species: Rabbit

Method: OECD Test Guideline 405

Result: No eye irritation

### **Components:**

### Fipronil:

Species: Rabbit

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

Method: OECD Test Guideline 405

Result: No eye irritation Remarks: No data available

### (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Species: Rabbit Exposure time: 72 h

Method: OECD Test Guideline 405

Result: No eye irritation

### ethanol:

Species: Rabbit

Method: OECD Test Guideline 405

Result: Irritating to eyes.

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

Not classified based on available information.

### **Product:**

Test Type: Buehler Test Species: Guinea pig

Method: OECD Test Guideline 406 Result: Does not cause skin sensitisation.

### Components:

### Fipronil:

Test Type: Maximisation Test

Species: Guinea pig

Method: OECD Test Guideline 406 Result: Does not cause skin sensitisation.

## (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Test Type: Buehler Test Species: Guinea pig

Method: OECD Test Guideline 406 Result: Does not cause skin sensitisation.

#### ethanol:

Species: Guinea pig

Method: OECD Test Guideline 406

Result: Did not cause sensitisation on laboratory animals.

### Germ cell mutagenicity

Not classified based on available information.

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

**Components:** 

Fipronil:

Genotoxicity in vitro : Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative

Test system: Escherichia coli

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative

Test Type: Cytogenetic assay Test system: Human lymphocytes

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 473

Result: negative

Test Type: Chromosomal aberration test Test system: V79 cells (Chinese hamster)

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 473

Result: negative

Test Type: Mammalian cell gene mutation assay

Test system: V79 cells (Chinese hamster)

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse (male and female)

Application Route: Oral

Result: negative

Test Type: Unscheduled DNA synthesis

Species: Rat (male) Application Route: Oral

Result: negative

(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Genotoxicity in vitro : Test Type: Ames test

Test system: S. typhimurium and E. coli Method: OECD Test Guideline 471

Result: negative

Test Type: Chromosomal aberration test Test system: Chinese hamster ovary cells Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Remarks: No data available

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

ethanol:

Genotoxicity in vitro : Test Type: Ames-test

Test system: Salmonella typhimurium Method: OECD Test Guideline 471

Result: negative

Test Type: Mouse lymphoma assay Test system: mouse lymphoma cells Method: OECD Test Guideline 476

Result: negative

Genotoxicity in vivo : Remarks: No data available

### Carcinogenicity

Not classified based on available information.

#### Components:

### Fipronil:

Application Route: Oral 0,06 mg/kg bw/day

### (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Species: Rat

Application Route: Oral Exposure time: 104 weeks

Result: negative

Remarks: Did not show carcinogenic effects in animal experiments.

Species: Mouse Application Route: Oral Exposure time: 72-78 weeks

Result: negative

Remarks: Did not show carcinogenic effects in animal experiments.

### ethanol:

Remarks: No data available

#### Reproductive toxicity

Not classified based on available information.

### **Components:**

Fipronil:

Effects on fertility : Remarks: No data available

Effects on foetal develop-

ment

Species: Rat

General Toxicity Maternal: NOAEL: 4 mg/kg body weight Developmental Toxicity: NOAEL: 20 mg/kg body weight

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Effects on fertility : Remarks: The results of animal studies gave no indication of a

fertility impairing effect.

Effects on foetal develop-

ment

Species: Rabbit

Application Route: Oral

General Toxicity Maternal: NOAEL: 100 mg/kg body weight

Teratogenicity: NOAEL: 100 mg/kg body weight

Developmental Toxicity: NOAEL: 100 mg/kg body weight

Method: OECD Test Guideline 414

Species: Rat

Application Route: Oral

General Toxicity Maternal: NOAEL: 250 mg/kg body weight

Teratogenicity: NOAEL: 250 mg/kg body weight

Developmental Toxicity: NOAEL: 250 mg/kg body weight

Method: OECD Test Guideline 414

ethanol:

Effects on fertility : Remarks: No data available

Effects on foetal develop-

ment

Remarks: No data available

### STOT - single exposure

Not classified based on available information.

## **Components:**

Fipronil:

Remarks: No data available

#### (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Remarks: No data available

ethanol:

Remarks: No data available

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

### **Components:**

### Fipronil:

Assessment: The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 1.

#### (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Remarks: No data available

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

ethanol:

Remarks: No data available

### Repeated dose toxicity

### **Components:**

### Fipronil:

Species: Rat

Application Route: Oral Exposure time: 13 weeks Dose: 1,5,30,300 ppm

### (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Species: Rat

NOAEL: < 200 mg/kg LOAEL: 200 mg/kg Application Route: Oral Exposure time: 90-day

Species: dog NOAEL: 100 mg/kg LOAEL: 300 mg/kg Application Route: Oral Exposure time: 90-day

### **Aspiration toxicity**

Not classified based on available information.

### **Components:**

#### Fipronil:

No data available

### (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

No data available

#### ethanol:

No data available

## **Further information**

### **Components:**

#### Fipronil:

Remarks: No data available

### (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Remarks: No data available

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

ethanol:

Remarks: Evaporation of solvents may cause irritation to eyes and mucous membranes.

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

### 12.1 Toxicity

#### Components:

Fipronil:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,248 mg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0852 mg/l

Exposure time: 96 h

NOEC (Lepomis macrochirus (Bluegill sunfish)): 0,0432 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0,190 mg/l

Exposure time: 48 h

Toxicity to algae : EC50 (Desmodesmus subspicatus (green algae)): 0,068 mg/l

End point: Growth rate Exposure time: 96 h

Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 0,04 mg/l

End point: Growth rate Exposure time: 96 h

Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): > 0,17 mg/l

End point: Growth rate Exposure time: 120 h

NOEC (Anabaena flos-aquae (cyanobacterium)): 0,17 mg/l

End point: Growth rate Exposure time: 120 h

EC50 (Selenastrum capricornutum (green algae)): > 0,14 mg/l

End point: Growth rate Exposure time: 120 h

NOEC (Selenastrum capricornutum (green algae)): 0,14 mg/l

End point: Growth rate Exposure time: 120 h

M-Factor (Acute aquatic tox-

icity)

10

Toxicity to microorganisms : EC50 (activated sludge): > 1.000 mg/l

Exposure time: 3 h

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 0,015 mg/l Exposure time: 90 d

Species: Oncorhynchus mykiss (rainbow trout)

Method: OECD Test Guideline 210

Lowest observed effect concentration: 0,026 mg/l

Exposure time: 90 d

Species: Oncorhynchus mykiss (rainbow trout)

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 5 - 20 µg/l End point: Immobilization Exposure time: 21 d

Species: Daphnia (water flea) Test Type: flow-through test

Method: Daphnia sp., Reproduction Test.

M-Factor (Chronic aquatic

toxicity)

10

Toxicity to soil dwelling or-

ganisms

Test Type: artificial soil LC50: > 1.000 mg/kg Exposure time: 14 d

Species: 'Eisenia foetida'

Method: Earthworm, Acute Toxicity Test.

Toxicity to terrestrial organ-

isms

LD50: 0,00000417 Exposure time: 48 d

End point: Acute oral toxicity Species: Apis mellifera (bees)

(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): 4,26 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0,22 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae : EC50 (Algae): 2,264 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 (activated sludge): > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

Remarks: No data available

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

Version Revision Date: Date of last issue: 15.02.2018 SDS Number: 4.0 23.04.2018 000000049050 Date of first issue: 11.04.2017

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0,019 mg/l Exposure time: 21 d

Species: Daphnia (water flea) Method: OECD Test Guideline 211

ethanol:

Toxicity to fish LC50 (golden orfe): = 8.140 mg/l

Exposure time: 48 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): = 9.268 - 14.221 mg/l

Exposure time: 48 h

EC5 (Scenedesmus quadricauda (Green algae)): = 5.000 mg/l Toxicity to algae

Exposure time: 7 d

EC5 (Pseudomonas putida): = 6.500 mg/l Toxicity to microorganisms

Exposure time: 16 h

Toxicity to fish (Chronic tox-

icity)

Remarks: No data available

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

Remarks: No data available

### 12.2 Persistence and degradability

### **Components:**

Fipronil:

Biodegradability Result: not rapidly degradable

> Biodegradation: 47 % Exposure time: 28 d

Method: OECD Test Guideline 301B

(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Biodegradability Result: Not readily biodegradable.

Method: OECD Test Guideline 301D

Biodegradation: 85,8 % Exposure time: 28 d

Method: MITI Test (II), inherent.

ethanol:

Biodegradability Result: Readily biodegradable.

Biodegradation: 94 %

Method: OECD Test Guideline 301E

Biochemical Oxygen De-

mand (BOD)

930 - 1.670 mg/g Incubation time: 5 d

18 / 25

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

Version Revision Date: SDS Number: Date of last issue: 15.02.2018 4.0 23.04.2018 000000049050 Date of first issue: 11.04.2017

Chemical Oxygen Demand

(COD)

1,99 mg/g

**ThOD** 2.100 mg/g

### 12.3 Bioaccumulative potential

**Components:** 

Fipronil:

Bioaccumulation : Exposure time: 14 d

Bioconcentration factor (BCF): 321

Remarks: No bioaccumulation is to be expected (log Pow <=

4).

Partition coefficient: n-

octanol/water

log Pow: 3,5 - 4,0 (20 °C)

(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Bioaccumulation Bioconcentration factor (BCF): 516

Method: calculated

Partition coefficient: n-

octanol/water

log Pow: 6,34

Method: calculated

ethanol:

Bioaccumulation Remarks: No bioaccumulation is to be expected (log

P(o/w) < 1).

Partition coefficient: n-

octanol/water

log Pow: -0,32

12.4 Mobility in soil

**Components:** 

Fipronil:

Distribution among environ-

mental compartments

Remarks: No data available

(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Distribution among environ-

mental compartments

: Remarks: No data available

ethanol:

Distribution among environ-

mental compartments

: Remarks: No data available

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

### 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:** 

Fipronil:

Additional ecological infor-

mation

: No data available

(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-methylethyl ester:

Additional ecological infor-

mation

: No data available

ethanol:

Adsorbed organic bound

halogens (AOX)

Remarks: No data available

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 1170
RID : UN 1170
IMDG : UN 1170
IATA : UN 1170

14.2 UN proper shipping name

ADR : ETHYL ALCOHOL SOLUTION

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

RID : ETHYL ALCOHOL SOLUTION IMDG : ETHYL ALCOHOL SOLUTION

IATA : Ethyl alcohol solution

14.3 Transport hazard class(es)

 ADR
 : 3

 RID
 : 3

 IMDG
 : 3

 IATA
 : 3

14.4 Packing group

**ADR** 

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3
Tunnel restriction code : (D/E)

RID

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

**IMDG** 

Packing group : III Labels : 3

EmS Code : F-E, S-D

IATA (Cargo)

Packing instruction (cargo : 366

aircraft)

Packing instruction (LQ) : Y344
Packing group : III

Labels : Flammable Liquids

IATA (Passenger)

Packing instruction (passen: 355

ger aircraft)

Packing instruction (LQ) : Y344
Packing group : III

Labels : Flammable Liquids

14.5 Environmental hazards

**ADR** 

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

### 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

REACH - List of substances subject to authorisation

(Annex XIV)

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

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

of dangerous chemicals

Fipronil

(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic acid 1-

methylethyl ester

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances,

preparations and articles (Annex XVII)

See Annex XVII to Regulation (EC) no 1907/2006 for Conditions of re-

striction

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

E1

P<sub>5</sub>c

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 HAZARDS

100 t

200 t

P5c

FLAMMABLE LIQUIDS

5.000 t

50.000 t

Water contaminating class

(Germany)

WGK 3 highly water endangering

TA Luft List (Germany) : Total dust:

Not applicable

Inorganic substances in powdered form:

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

Not applicable

Inorganic substances in vapour or gaseous form:

Not applicable Organic Substances: portion Class 1: 10 %

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) Volatile organic compounds (VOC) content: 73 %, 744,6 g/l

VOC content excluding water

Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Volatile organic compounds (VOC) content: 73 %, 744,6 g/l VOC content valid only for coating materials used on wood

surfaces

#### Other regulations:

The product is subject to the supply restrictions of the Ordinance on the Prohibition of Chemicals.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

REACH : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

**Fipronil** 

(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoic

acid 1-methylethyl ester

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

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

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**

H225 : Highly flammable liquid and vapour.

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

H331 : Toxic if inhaled.

H372 : Causes damage to organs through prolonged or repeated

exposure.

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 Flam. Liq. : Flammable liquids

STOT RE : Specific target organ toxicity - repeated exposure

DE TRGS 900 : Germany. TRGS 900 - Occupational exposure limit values.

DE TRGS 900 / AGW : Time Weighted Average

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx -Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx -Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No

according to Regulation (EC) No. 1907/2006



## Frontline Combo®, liquid (finished product)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.02.2018

 4.0
 23.04.2018
 000000049050
 Date of first issue: 11.04.2017

Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### **Further information**

Training advice : Provide adequate information, instruction and training for op-

erators.

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

from the previous version.

Sources of key data used to

compile the Safety Data

Sheet

The specifications are based on own tests and/or literature

Classification procedure:

data.

#### Classification of the mixture:

		<u>-</u>
Flam. Liq. 3	H226	Based on product data or assessment
Acute Tox. 4	H302	Based on product data or assessment
STOT RE 1	H372	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

DE / EN