

SAFETY DATA SHEET

Version Date: 01 April 2013 Supersedes: 05 March 2013

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Fipronil (10%)/S-methoprene (12%) Spot-On Solution for Cats and

Kittens

Trade Name(s): FRONTLINE COMBO

FRONTLINE COMBO - GATOS FRONTLINE COMBO CATS

FRONTLINE COMBO PARA GATOS Y GATITOS

FRONTLINE COMBO SPOT ON CATS

FRONTLINE COMBO SPOT ON CATS SOL. AD US. VET.

FRONTLINE COMBO SPOT ON CHAT

FRONTLINE COMBO SPOT ON MACSKA A.U.V.

FRONTLINE COMP FRONTLINE PLUS FRONTLINE PLUS CAT FRONTLINE PLUS KEDI

FRONTLINE PLUS PARA GATOS FRONTLINE TOP SPOT CATS

The following information is intended to give general health and safety guidance on the manufacturing, storage and transport of the mixture. Professional and non-professional users should consult label and package inserts for the proper use, storage and disposal of this mixture.

Chemical Family: Mixture: phenylpyrazole, terpenoid

Chemical Name: Mixture - NA

Synonyms: NA **Formula:** None

Product Use: Fipronil (10%)/S-methoprene (9%) Spot-On Solution is used in veterinary

medicine for the treatment and prevention/control of fleas, ticks and

biting lice infestation on cats and kittens.

COMPANY ADDRESS Merial Limited

3239 Satellite Boulevard Duluth, Georgia 30096-4640

EMERGENCY INFORMATION:

HEALTH INFORMATION 1-888-637-4251, option 3 (U.S.A. and Canada) SPILL INFORMATION CHEMTREC® (In the U.S.A.): 1-800-424-9300

CHEMTREC® (International): 1-703-527-3887 (call collect)

2. HAZARDS IDENTIFICATION

Danger!

Emergency Overview

Flammable liquid and vapor. Harmful if swallowed. May be harmful in contact with skin. Causes mild skin irritation. Causes eye irritation. Causes damage to central nervous system through single or prolonged/repeated exposure. Very toxic to aquatic life. Do not eat, drink, or smoke when handling this mixture. Wash hands thoroughly after handling.

Risk phrase(s):

R10	Flammable
R21	Harmful In Contact With Skin
R36	Irritating To Eyes
R38	Irritating To Skin
R48	Danger Of Serious Damage To Health By Prolonged Exposure
R25	Toxic If Swallowed
R50	Very Toxic To Aquatic Organisms

Safety Phrase(s):

S2	Keep Out Of The Reach Of Children
S7/9	Keep Container Tightly Closed And In A Well-Ventilated Place
S16	Keep Away From Sources Of Ignition - No Smoking
S29	Do Not Empty Into Drains
S33	Take Precautionary Measures Against Static Discharges
S24	Avoid Contact With Skin
S28	After Contact With Skin, Wash Immediately With Plenty Of Water
S25	Avoid Contact With Eyes
S26	In case Of Contact With Eyes, Rinse Immediately With Plenty Of Water And Seek
	Medical Advice
S46	If Swallowed, Seek Medical Advice Immediately And Show The Container Or Label
S60	Avoid Release To The Environment

The following three boxes are relevant to GHS classification and are not labeling guides.

Physical Hazard (GHS Classification)	Category	Pictogram	Signal Word	Hazard Statement
Flammable liquid	3		Warning	Flammable liquid and vapor (H226)

Health Hazard (GHS Classification)	Category	Pictogram	Signal Word	Hazard Statement
Acute Oral Toxicity	4	No Symbol	Warning	Harmful if swallowed (H302)

Health Hazard (GHS Classification)	Category	Pictogram	Signal Word	Hazard Statement
Acute Dermal Toxicity	5	No Symbol	Warning	May be harmful in contact with skin (H313)
Dermal Irritation	3	No Symbol	Warning	Causes mild skin irritation (H316)
Ocular Irritation	2B	No Symbol	Warning	Causes eye irritation (H320)
SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:	1		Danger	Causes damage to organs (CNS) (H370)
SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:	1		Danger	Causes damage to organs (CNS) through prolonged or repeated exposure (H372)

Environmental Hazard (GHS Classification)	Category	Pictogram	Signal Word	Hazard Statement
Acute Aquatic Hazard	1	***	Warning	Very toxic to aquatic life (H400)

POTENTIAL HEALTH EFFECTS

The following potential human health effects are the results of the exposure to the mixture or extrapolated from the individual ingredients of the mixture.

EYE: The mixture is irritating to the eyes.

SKIN: The mixture produces mild skin irritation. The mixture is not

anticipated to produce skin sensitization.

INHALATION: The mixture is not anticipated to produce vapors in a sufficient

quantity that would be irritating to eyes, skin, nose and/or

throat.

INGESTION: The mixture is harmful if swallowed.

CHRONIC EFFECTS: The mixture is not anticipated to be carcinogenic, mutagenic, a

reproductive toxin or a developmental toxin.

SIGNS AND SYMPTOMS OF

EXPOSURE:

Signs and symptoms of exposure may include sweating, nausea, vomiting, headache, abdominal pain, dizziness, agitation,

weakness and/or tonic-clonic seizures.

MEDICAL CONDITIONS

AGGRAVATED BY EXPOSURE:

None known.

POTENTIAL	Some ingredients of this mixture are very toxic to aquatic life.
ENVIRONMENTAL EFFECTS	Avoid release to the environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No.	Proportion % w/v	Cut off conc. for classification %	Risk phrases
Fipronil	120068-37-3	10	10	R20/21/25/36/38/48/50
S-methoprene	65733-16-6	12	-	R50
Ethanol	64-17-5	8	-	R10
Non Hazardous		70	-	

4. FIRST AID MEASURES

EYE CONTACT: In case of contact or if eyes become irritated during administration,

immediately flush eyes with plenty of water for at least 15 minutes.

If ocular irritation persists, seek medical attention.

SKIN CONTACT: If skin or hair contact occurs, remove contaminated clothing and

shoes and flush skin and/or hair with plenty of water for at least 15 minutes. Launder contaminated clothing before reuse. If skin irritation develops and persists or recurs, seek medical attention.

INHALATION: If inhaled, remove from contaminated area. Administer artificial

respiration if not breathing. If lungs become irritated or breathing is difficult during use of the product, move to fresh air and seek

medical attention.

INGESTION: If swallowed, do NOT induce vomiting and seek immediate medical

attention.

5. FIRE FIGHTING MEASURES

UNUSUAL FIRE ANDPrevent accumulation of vapors. When heated to decomposition, may produce oxides of carbon and nitrogen.

EXTINGUISHING MEDIA: Carbon dioxide, dry chemical extinguishers, foam, water fog or

spray. Large fires with "alcohol"-type foam extinguishers. Use extinguishing media appropriate for surrounding materials.

Contain contaminated fire-fighting water.

PROTECTION OF Fire fighters should wear approved/certified positive pressure self-

FIREFIGHTERS: contained breathing apparatus and full protective equipment.

6. ACCIDENTAL RELEASE MEASURES

For transportation-related and large spills call CHEMTREC at 1-800-424-9300. If outside the U.S.A., call CHEMTREC collect at 1-703-527-3887.

For small spills, use protective equipment as prescribed in Section 8. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material in sealed container as waste according to Section 13.

PERSONAL PRECAUTIONS: Evacuate unnecessary personnel and eliminate all sources of

ignition. Follow protective measures provided under Personal

Protection in Section 8.

ENVIRONMENTAL PRECAUTIONS:

Avoid release to the environment.

METHODS FOR CLEANING

UP:

For small spills, soak up with absorbent materials and place in

properly labeled containers.

7. HANDLING AND STORAGE

HANDLING: No smoking, eating, or drinking while using this mixture. Keep

container tightly closed when not in use. Provide for adequate ventilation to prevent accumulation of vapors. Avoid prolonged or repeated exposure. Do not get in eyes, on skin or clothing. Keep

away from incompatible materials (see Section 10).

PROTECTION AGAINST EXPLOSION AND FIRES:

Keep ignition sources away. Do not smoke. Protect against electrostatic charges. Ground/bond container and receiving

equipment. Use explosion-proof electrical, ventilating, and/or

lighting equipment. Use only non-sparking tools.

STORAGE: Store in a well-ventilated place. Keep cool. Store locked up.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION (INDUSTRIAL)

The following ingredient(s) has exposure limits.

	OSHA PE	L (TWA)	ACGIH TLV [®] (TWA)	
Component	ppm	mg/m³	ppm	mg/m³
Fipronil (CAS No.120068-37-3)	-	-	-	-
S-methoprene (CAS No. 65733-16-6)	-	-	-	-
Ethanol (CAS No. 64-17-5)	1000	1900	1000	-

ENGINEERING CONTROLS: Use local exhaust ventilation to prevent accumulation of vapors.

EYE / FACE PROTECTION: Wear chemical splash goggles when cleaning spilled mixture or if

the potential for eye contact exists, wear safety glasses with side

shields for normal handling.

SKIN PROTECTION: Wear butyl rubber, neoprene, vinyl or other chemical resistant

impervious gloves.

RESPIRATORY Wear approved/certified respirator when cleaning up spills. For

PROTECTION: normal use, ensure adequate exhaust ventilation.

GENERAL HYGIENE Do not eat, drink, or smoke while using this mixture. Wash hands

CONSIDERATIONS: thoroughly after use. Wear protective clothing.

OTHER: Provide emergency shower and eyewash facility in close proximity

to use. Remove contaminated clothing and launder or clean before

reuse.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid

Color: Light amber **Odor:** Alcohol-like

pH: 5.2
Melting/Freezing Point: No data
Boiling Point: 172°C

Flash Point: 38°C (Closed Cup) **Flammability:** Liquid, flammable

Lower Explosive Limit:1.2% v/vUpper Explosive Limit:15% v/vAutoignition Temperature:190°CDecomposition Temperature:No dataVapor Pressure:No dataVapor Density:No data

Solubility in Water: Forms milky white precipitate

Specific gravity: 1.02 g/cc **Viscosity:** <10 cps

Partition Coefficient (n-octanol/Water): Log K_{ow} -0.54 to 4 (ingredients)

(computer generated)

Partition Coefficient (n-octanol/Air): Log K_{oa} 3.379 to 11.463 (ingredients)

(computer generated)

Soil Partition Coefficient: Log K_{oc} 0.034 to 4.002 (ingredients)

(computer generated)

10. STABILITY AND REACTIVITY

STABILITY: Stable under normal conditions.

CONDITIONS TO AVOID: Avoid exposure to heat, sparks, or flame.

MATERIALS TO AVOID: Avoid strong oxidizing agents

HAZARDOUS DECOMPOSITION

When heated to decomposition may produce oxides of carbon and nitrogen as well as other uncharacterized decomposition products.

PRODUCTS:

HAZARDOUS Will not occur.

POLYMERIZATION:

11. TOXICOLOGICAL INFORMATION

POTENTIAL EXPOSURE

This mixture may be encountered through skin contact, eye

ROUTES: contact or ingestion.

ACUTE TOXICITY DATA: The following toxicity data are derived from the mixture.

Parameter	Result	Comments
Acute Oral (LD ₅₀)	750 mg/kg (rat)	
Acute Dermal (LD ₅₀)	>5000 mg/kg (rat)	
Acute Inhalation (LC ₅₀)	NE	
Ocular Irritant	Yes (Category 2B; GHS)	
Dermal Irritant	Yes (Category 3; GHS)	
Dermal Sensitizer	Non-sensitizing	

NE = Not Established

The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the final mixture.

CARCINOGENICITY:

Fipronil is classified at a Group C Possible Human Carcinogen based on laboratory animal studies (increased thyroid tumors in male and female rats). Based on known species sensitivity differences between rat and human, the rat thyroid tumors are not regarded for human health risk assessment. None of the remaining ingredients in the mixture are considered to be carcinogenic.

MUTAGENICITY:

None of the ingredients in the mixture are considered to be mutagenic.

REPRODUCTIVE EFFECTS:

None of the ingredients in the mixture are considered to be reproductive toxins.

TERATOGENICITY/ DEVELOPMENTAL EFFECTS: None of the ingredients in the mixture are considered to be teratogenic or developmental toxins at the dose rate and frequency stated on the packaging for this mixture.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE: Based on the concentration of fipronil in the mixture, the specific target organ toxicity – single exposure classification is a Category 1. Animal studies and human pharmacovigilance reports identify fipronil as a neurotoxicant. Signs and symptoms include: sweating, nausea, vomiting, headache, abdominal pain, dizziness, agitation, weakness and/or tonic-clonic seizures.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE: Based on the concentration of fipronil in the mixture, the specific target organ toxicity – repeated exposure classification is a Category 1. Animal studies and human pharmacovigilance reports identify fipronil as a neurotoxicant. Signs and symptoms include: sweating, nausea, vomiting, headache, abdominal pain, dizziness, agitation, weakness and/or tonic-clonic seizures.

INTERACTIONS WITH OTHER CHEMICALS WHICH ENHANCE TOXICITY:

None known

12. ECOLOGICAL INFORMATION

The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the mixture.

TOXICITY: LC_{50}/EC_{50} ranged from 0.009 to >100 mg/L for freshwater fish,

invertebrates and plants. Based on test results for the most sensitive species (freshwater invertebrates) and mathematical modeling, the mixture is considered a Category 1 Acute Aquatic

Hazard (GHS standards).

PERSISTENCE AND DEGRADABILITY:

Based upon biodegradation testing, computer modeling and physico-chemical characteristics of the ingredients in the mixture, the mixture is considered inherently biodegradable in the

environment.

BIOACCUMULATION POTENTIAL:

Based on the K_{ow} of the ingredients in the mixture, some of the ingredients have the potential for bioaccumulation. However, fugacity modeling and biodegradation testing suggest that the potential for bioaccumulation of those ingredients is low. Therefore, it is considered that the mixture will not persist in the

environment.

MOBILITY IN SOIL: Based on the K_{oc} of the ingredients in the mixture and fugacity

modeling, the mixture is not considered to have a high probability

of mobility through the soil.

13. DISPOSAL CONSIDERATIONS

Responsibility for proper waste disposal is with the owner of the waste. Dispose of all waste mixture and containers in accordance with national, regional, state and local regulations.

SPECIAL PRECAUTIONS: As the active ingredient is highly toxic to aquatic organisms, great

care is need to ensure that the product does not reach a drain,

waterway or unpaved soil.

PREFERRED METHOD OF

DISPOSAL:

Individual used ampoules / phials may be disposed of by wrapping in absorbent paper and disposal to household garbage. For the disposal of the clean-up materials from a significant spill or leak,

negotiate with the EPA responsible for the jurisdiction. Incineration may be permitted by local authority; otherwise secure

landfill should be used, if approved by local authority.

14. TRANSPORT INFORMATION

Air Transport ICAO-TI and IATA-DGR:

ICAO/IATA Class: 3 UN/ID Number: 1170 Label: 3 Packing Group: III

Proper Shipping Name: Ethanol Solution (Ethyl Alcohol Solution)

Maritime Transport IMDG Class: 3 IMDG: UN Number: 1170

> Label: 3 Packaging Group: IIIF-E, S-D EMS Number:

Marine Pollutant: Yes

Proper Shipping Name: Ethanol Solution (Ethyl Alcohol Solution)

Land Transport ADR/RID Class: 3 ADR/RID: Danger Code (Kemler): 30 (cross-border) UN Number: 1170 Packaging Group:

> Proper Shipping Name: Ethanol Solution (Ethyl Alcohol Solution)

Land Transport Class: ADG7 **UN Number:** 1170

Packaging Group:

Proper Shipping Name: Ethanol Solution (Ethyl Alcohol Solution)

Special precautions: SP144 SP184

Hazchem Code: 2[Y]

Labelling: Transport packaging to comply with ADG

Code labeling requirements for Class 3 PG

III DG.

Do not stow with DG of Class 1, Class 2.3, Incompatible stowage:

Class 4.2, Class 5.1, Class 5.2 or Class 7

USDOT Regulations: Hazard Class: 3

> Identification Number: 1170 Packing Group: III

*Merial Ships Under SP9275 Proper Shipping Name: Ethanol Solution (Ethyl Alcohol Solution)

(technical name)

15. REGULATORY INFORMATION

GHS Hazard Phrase: H226 Flammable liquid and vapor

> H302 Harmful if swallowed

H313 May be harmful in contact with skin

H316 Causes mild skin irritation

H320 Causes eye irritation

H370 Causes damage to organs (CNS)

H372 Causes damage to organs (CNS) through prolonged

or repeated exposure

H400 Very toxic to aquatic life with long lasting effects

GHS Precautionary Phrases - Prevention:

P280 Wear protective gloves/protective clothing/eye

protection/face protection

Call a POISON CENTER or doctor/physician if you feel **GHS Precautionary** P313/P316

Phrases - Response: P313 + P312 unwell. P303 + P361 If on skin (or hair): Remove/Take off immediately all + P353

contaminated clothing. Rinse skin with water/shower.

P391 Collect spillage.

GHS Precautionary Phrases - Disposal: P501 Dispose of contents/container to in accordance with

local/regional/national/international regulation.

United States:

This mixture is exempt from classification under Environmental Protection Agency (EPA) Superfund Amendments and Reauthorization Act (SARA), Hazardous Substances List or Toxic Substances Control Act (TSCA)

STATE RIGHT-TO-KNOW STATUS:

Component	CA	NJ	PA	MA
Fipronil	Not listed	Not listed	Not listed	Not listed
S-methoprene	Not listed	Not listed	Not listed	Not listed
Ethanol	Listed	Listed	Listed	Listed

CA = California Proposition 65 NJ = New Jersey

MA = Massachusetts PA = Pennsylvania

Canada:

This mixture is exempt from classification under WHMIS Requirements of the Hazardous Products Act and Controlled Products Regulations.

16. OTHER INFORMATION

Information contain within this document was based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (a.k.a. Purple Book).

KEY/LEGEND USED: NE = Not Established

LD50 = The median lethal dose where 50% mortality is noted

LC50 = The median lethal concentration (in air or solution) where 50%

mortality is noted

CNS = central nervous system TWA = Time Weighted Average

OSHA PEL = Occupational Safety and Health Association Permissible

Exposure Limits

ACGIH TLV = American Conference of Governmental Industrial

Hygienists Threshold Limit Values

REVISION: New trade name added.

DISCLAIMER: The requirements or recommendations of any relevant site or working

procedure, system or policy in force or arising from any risk assessment involving the substance or mixture should take precedence over any of the guidance contained in this safety data sheet where there is a

difference in the information given.

To the best of our knowledge, the information provided in this safety data sheet is accurate at the date of publication and will be updated as and when appropriate. However, neither Merial nor any of its subsidiaries or parents assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards may be described herein, Merial cannot guarantee that these are the only hazards that exist.