



SAFETY DATA SHEET

Version Date: 05 March 2013
Supersedes: 18 May 2011

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Fipronil (10%)/S-methoprene (9%) Spot-On Solution for Dogs and Puppies

Trade Name(s): 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
FRONTLINE PLUS KOPEK
FRONTLINE PLUS PARA PERROS

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 dogs and puppies.

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		Warning	Harmful if swallowed (H302)
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.

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.

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 ENVIRONMENTAL EFFECTS Some ingredients of this mixture are very toxic to aquatic life. 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	9	-	R50
Ethanol	64-17-5	8	-	R10
Non Hazardous		73	-	

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 AND EXPLOSION HAZARDS: Prevent 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 FIREFIGHTERS: Fire fighters should wear approved/certified positive pressure self-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.

Component	OSHA PEL (TWA)		ACGIH TLV® (TWA)	
	ppm	mg/m ³	ppm	mg/m ³
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 PROTECTION:	Wear approved/certified respirator when cleaning up spills. For normal use, ensure adequate exhaust ventilation.
GENERAL HYGIENE CONSIDERATIONS:	Do not eat, drink, or smoke while using this mixture. Wash hands thoroughly after use.
OTHER:	Provide emergency shower and eyewash facility in close proximity to use. Remove contaminated clothing and launder before reuse or discard.

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/v
Upper Explosive Limit:	15% v/v
Autoignition Temperature:	190°C
Decomposition Temperature:	No data
Vapor Pressure:	No data
Vapor 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 – 5.50 (ingredients) (computer generated)
Partition Coefficient (n-octanol/Air):	Log K _{oa} 3.379 – 11.463 (ingredients) (computer generated)
Soil Partition Coefficient:	Log K _{oc} 0.034 – 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 PRODUCTS:	When heated to decomposition may produce oxides of carbon and nitrogen as well as other uncharacterized decomposition products.
HAZARDOUS POLYMERIZATION:	Will not occur.

11. TOXICOLOGICAL INFORMATION

POTENTIAL EXPOSURE ROUTES:	This mixture may be encountered through skin contact, eye contact or ingestion.
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ACUTE TOXICITY DATA: *The following toxicity data are derived from the mixture.*

Parameter	Result	Comments
Acute Oral (LD₅₀)	750 mg/kg (rat)	
Acute Dermal (LD₅₀)	>5000 mg/kg (rat)	
Acute Inhalation (LC₅₀)	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.
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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:

IMDG Class: 3
 UN Number: 1170
 Label: 3
 Packaging Group: III
 EMS Number: F-E, S-D
 Marine Pollutant: Yes
 Proper Shipping Name: Ethanol Solution (Ethyl Alcohol Solution)

Land Transport ADR/RID: (cross-border)

ADR/RID Class: 3
 Danger Code (Kemler): 30
 UN Number: 1170
 Packaging Group: III
 Proper Shipping Name: Ethanol Solution (Ethyl Alcohol Solution)

Land Transport ADG7

Class: 3
 UN Number: 1170
 Packaging Group: III
 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.
 Incompatible stowage: Do not stow with DG of Class 1, Class 2.3, Class 4.2, Class 5.1, Class 5.2 or Class 7

USDOT Regulations:

Hazard Class: 3
 Identification Number: 1170
 Packing Group: III
 Proper Shipping Name: Ethanol Solution (Ethyl Alcohol Solution)
 (technical name)

*Merial Ships Under SP9275

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
GHS Precautionary Phrases - Prevention:	H400	Very toxic to aquatic life with long lasting effects
	P280	Wear protective gloves/protective clothing/eye protection/face protection
GHS Precautionary Phrases - Response:	P313/P316 P313 + P312	Call a POISON CENTER or doctor/physician if you feel unwell.
	P303 + P361 + P353	If on skin (or hair): Remove/Take off immediately all 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
PA = Pennsylvania

NJ = New Jersey
MA = Massachusetts

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
- NC = Not Classified (study results do not meet the requirements for classification)
- 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: Revised carcinogenicity statement (Section 11).

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.