

65331-1

9-23-2002

1/6



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 65331-1	2. EPA Product Manager Mr. Marion Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Frontline Spray Treatment	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) Merial Limited 3239 Satellite Blvd. Duluth, GA 30096 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION SEP 23 2002
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label revisions per PR-Notice 2001-6;
This notification is consistent with the guidance in PR-Notice 2001-6 and the requirements of EPA's regulations at 40 CFR 156.10 and 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula (CSF) of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the guidance of PR-Notice 2001-6 and requirements of 40 CFR 156.10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties or sections 12 and 14 of FIFRA.

Section - III

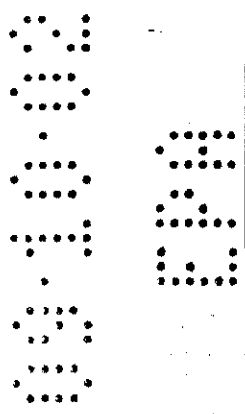
1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 8.5 and 17 fl. oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Timothy A. Dotson	Title Technical Director	Telephone No. (Include Area Code) 678-638-3713
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
Signature 	3. Title Technical Director	
4. Typed Name Timothy A. Dotson	5. Date 9/6/02	

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NOTIFICATION SEP 23 2002



Peel here to open/Press here to close



FRONTLINE

SPRAY TREATMENT

8.5 FL OZ (250 ml)

For Dogs, Puppies, Cats and Kittens
Long Lasting Control of
Fleas, Ticks and Chiggers Lice

ACTIVE INGREDIENT	0.28%
Inert Ingredients	99.72%
TOTAL	100.00%

CAUTION
KEEP OUT OF REACH
OF CHILDREN



PRECAUTIONS: Avoid contact with eyes, nose, mouth and skin. Wash hands thoroughly with soap and water after use. Do not use in areas where children and pets play. Do not use on animals with open wounds, cuts, or abrasions. Do not use on animals with known hypersensitivity to any of the ingredients. Do not use on animals with known or suspected flea or tick infestation. Do not use on animals with known or suspected chigger infestation. Do not use on animals with known or suspected flea or tick infestation. Do not use on animals with known or suspected chigger infestation. Do not use on animals with known or suspected flea or tick infestation. Do not use on animals with known or suspected chigger infestation.

STORAGE: Store unused product in original container out of reach of children and animals. Do not store in areas where children and animals play. Do not store in areas where children and animals play. Do not store in areas where children and animals play. Do not store in areas where children and animals play.

FLAMMABLE: Keep away from heat and open flame.

STORAGE & DISPOSAL: Do not contaminate water, food, or feed by storage and disposal. Do not store in areas where children and animals play. Do not store in areas where children and animals play. Do not store in areas where children and animals play. Do not store in areas where children and animals play.

PHYSICAL OR CHEMICAL HAZARDS: None known.

ENVIRONMENTAL HAZARDS: None known.

CONTAINER DISPOSAL: Recycle if possible. Do not burn. Do not use for any other purpose.

ACTIVE INGREDIENT 0.28%
INERT INGREDIENTS 99.72%
TOTAL 100.00%

HOW TO USE: Apply to the animal's back with the spray nozzle. Do not use on animals with open wounds, cuts, or abrasions. Do not use on animals with known hypersensitivity to any of the ingredients. Do not use on animals with known or suspected flea or tick infestation. Do not use on animals with known or suspected chigger infestation. Do not use on animals with known or suspected flea or tick infestation. Do not use on animals with known or suspected chigger infestation.

PRECAUTIONS: Avoid contact with eyes, nose, mouth and skin. Wash hands thoroughly with soap and water after use. Do not use in areas where children and pets play. Do not use on animals with open wounds, cuts, or abrasions. Do not use on animals with known hypersensitivity to any of the ingredients. Do not use on animals with known or suspected flea or tick infestation. Do not use on animals with known or suspected chigger infestation. Do not use on animals with known or suspected flea or tick infestation. Do not use on animals with known or suspected chigger infestation.

STORAGE: Store unused product in original container out of reach of children and animals. Do not store in areas where children and animals play. Do not store in areas where children and animals play. Do not store in areas where children and animals play. Do not store in areas where children and animals play.

FLAMMABLE: Keep away from heat and open flame.

STORAGE & DISPOSAL: Do not contaminate water, food, or feed by storage and disposal. Do not store in areas where children and animals play. Do not store in areas where children and animals play. Do not store in areas where children and animals play. Do not store in areas where children and animals play.

PHYSICAL OR CHEMICAL HAZARDS: None known.

ENVIRONMENTAL HAZARDS: None known.

CONTAINER DISPOSAL: Recycle if possible. Do not burn. Do not use for any other purpose.

Made in France
Merial Limited 3239 Satellite Blvd
Duluth, GA 30096-4640, USA

XXXXXX XXX

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Open here



Lot No:

XXXXXX XX

FRONTLINE

FRONTLINE (0.25% Fenitrothion, 0.50% Permethrin) is a topical flea and tick repellent and acaricide for dogs and cats. It kills fleas, ticks, and mites that cause flea infestations and tick-borne diseases. It also repels fleas, ticks, and mites, preventing them from reaching your pet.

Use **FRONTLINE** on dogs and cats to prevent flea infestations and tick-borne diseases. It is a repellent and acaricide, killing fleas, ticks, and mites that cause flea infestations and tick-borne diseases. It also repels fleas, ticks, and mites, preventing them from reaching your pet.

TO YOU AND YOUR PET, READ ENTIRE LABEL AND ATTACHED DIRECTIONS BEFORE EACH USE.

Follow all directions and necessary precautions carefully. Use only on dogs and cats. Do not use on any other animals. To kill fleas, tick, call a veterinarian for treatment. Do not use **FRONTLINE** on dogs, cats, puppies, or kittens. Do not use on dogs, cats, puppies, or kittens. Do not use on dogs, cats, puppies, or kittens. Do not use on dogs, cats, puppies, or kittens. Do not use on dogs, cats, puppies, or kittens.

FRONTLINE

0.25% Fenitrothion

0.50% Permethrin

TOTAL

CAUTION

KEEP OUT OF REACH

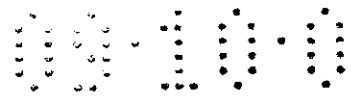
OF CHILDREN



Made in France

Merial Limited 3239 Satellite Blvd

Duluth, GA 30096-4640 USA



NOTIFICATION

SEP 23 2002

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed or absorbed through the skin. May cause severe eye irritation. Avoid breathing spray. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Persons applying this product must wear household latex gloves.

HAZARDS TO DOMESTIC ANIMALS. For external use only. May cause severe eye irritation. Take care not to spray in the animal's eyes or facial area. Do not use on kittens and puppies under 8 weeks. Individual sensitivities, while rare, may occur after using any pesticide product for pets. If signs persist or become more severe, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing animals.

Call 1-800-660-842 for 24 hr. assistance.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE. Keep away from heat and open flame.

STORAGE AND DISPOSAL

Store in original container. Do not use if container is damaged or leaking. Do not use if contents are empty. Do not use if contents are expired.

disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL: If empty, do not reuse this container. Place in trash or offer for recycling if available.

XXX XXXXX

FRONTLINE®

SPRAY TREATMENT

17 fl oz (500 ml)

For Dogs, Puppies, Cats and Kittens
Long Lasting Control of
Fleas, Ticks and Chewing Lice

ACTIVE INGREDIENT	
flipronil	0.29%
INERT INGREDIENTS	99.71%
TOTAL	100.00%

CAUTION
KEEP OUT OF REACH
OF CHILDREN



FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

WARRANTY

Merial Limited warrants that the product is free from adulteration and contains the amount of active ingredient stated on the label. This warranty is void if the product is used in violation of the label directions. Merial Limited does not warrant the product for any other purpose. Merial Limited is not responsible for the actions of third parties. Merial Limited is a registered proprietor of Merial.

EPA Reg. No. 65331-1
EPA Est. 65331-FR-2

Made in France
Merial Limited 3239 Satellite Blvd.
Duluth, GA30096-4640, USA

Peel here to open/Press here to close



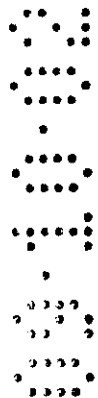
4/10

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SEP 2 3 2002

NOTIFICATION

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FRONTLINE®
SPRAY TREATMENT
EVAL (500 ml)

ACTIVE INGREDIENT
Sipronylipropyl 0.29%

INERT INGREDIENTS
99.71%

TOTAL
100.00%

CAUTION
KEEP OUT OF REACH
OF CHILDREN

MERIAL

Made in France
Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096-4640, USA

DIRECTIONS FOR USE:
Use only on dogs and cats. Do not use on rabbits. Do not use on any other animals. To kill fleas, and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may transmit Lyme disease) and chewing lice, apply to dogs cats purposes in dilutions as follows:
Press down on the lock button located at the top of the trigger pump.

PREVENT HARM TO YOU AND YOUR PET: READ ENTIRE LABEL AND ATTACHED DIRECTIONS BEFORE EACH USE.
Follow all directions and precautionary statements carefully. Use only on dogs and cats. Do not use on rabbits. Do not use on any other animals. To kill fleas, and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may transmit Lyme disease) and chewing lice, apply to dogs cats purposes in dilutions as follows:
Press down on the lock button located at the top of the trigger pump.

FRONTLINE spray will kill fleas, ticks and chewing lice for at least 30 days. Studies have shown **FRONTLINE** spray most effective for up to 90 days.

CAUTION: Use only on dogs and cats. Do not use on rabbits. Do not use on any other animals. To kill fleas, and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may transmit Lyme disease) and chewing lice, apply to dogs cats purposes in dilutions as follows:
Press down on the lock button located at the top of the trigger pump.



Lot No:

6/16



Timothy A. Dotson, M.S.
Technical Director
Regulatory Affairs North America
Tel: 678-638-3713
Fax: 678-638-3715

3239 Satellite Blvd.
Duluth, GA 30096
Tel: 678 638 3000

September 6, 2002

Ms. Ann Sibold
Team 3, Insecticide Branch
Registration Division (H7505C)
Document Processing Desk (NOTIF)
Office of Pesticide Programs
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

SUBJECT: Frontline® Spray Treatment, EPA Reg. No. 65331-1
NOTIFICATION of Label Revisions Per PR-Notice 2001-6

Dear Ms. Sibold:

Please find enclosed a NOTIFICATION per PR-Notice 2001-6 for revision of pesticide disposal statements for Frontline® Spray Treatment, EPA Reg. No. 65331-1. Since Merial chose to adopt the exact wording set forth in this notice, the label is submitted by NOTIFICATION only. Enclosed is a copy of EPA Form 8570-1 along with a highlighted copy of the revised label for both the 250-ml and 500-ml bottles (Exhibit 1). Please note the printed facsimile labels may not be actual size.

Thank you for your assistance. Please call me at 678-638-3713 (email at timothy.dotson@merial.com) if you have any questions regarding this submission.

Sincerely,

Timothy A. Dotson, M.S.
Technical Director
Regulatory Affairs NA

www.merial.com



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