

PM03

239-2536

7/31/98

178

JUL 31 1998

Mr. Frank Kamienski  
The SOLARIS Group of Monsanto  
P.O. Box 5006  
San Ramon, CA 94583-0906

Subject: Submission # 259286 for amended labeling  
(1) to respond to PR Notice 96-6  
(2) revise storage and disposal and environmental hazard statements for homeowner products to comply with Agency LRM and.  
(3) revise precautionary and first aid statements to reflect the acute toxicity data.

Date of Submission: January 6, 1998

Product #: 239-2536

Product Name: ORTHO Pet, Flea & Tick Spray Formula II

Dear Mr. Kamienski:

The Agency has completed reviewing the Solaris Group of Monsanto's Application for Pesticide Amendment referenced above, and has concluded the following, as outlined in the attached inter-office Memorandum.

1. The proposed labeling amendments addressing PR Notice 96-6 are adequate.
2. The proposed storage and disposal, and environmental hazard statements are adequate.
3. The proposed precautionary and first aid statements are not acceptable. A previous Agency review dated 1/15/86 indicates that a number of studies (referenced as accession numbers) were not reviewed, but that the following projected toxicity categories were established "based upon the formulation": (copy enclosed)

Study	Toxicology Category	Accession Numbers*
Acute Oral LD50	IV	246722
Acute Dermal LD50	III	246719
Acute Inhalation LC50	IV	246723, 222006, 238529, 50570, 50571
Primary Eye Irritation	III	246721
Primary Dermal Irritation	IV	246720
Dermal Sensitization	No	230692

\* These studies are identified as Accession Numbers which the Agency has since converted to MRID numbers as noted below:

Accession Number	MRID number(s)
246722	00094803
246719	00094800
246723	00094804
222006	00086125
238529	00110070
50570	00086125
50571	00086125
246721	00094802
246720	00094801
230692	00057851, 00058255, 00107537, 00111967

However, Solaris Group of Monsanto has stated (letter dated January 6, 1998) that: "The data show that this product is in EPA toxicity Category IV for oral and inhalation toxicity and eye and skin irritation. The data also show that the dermal toxicity of this product is greater than 2,000 mg/kg, the highest dose tested." The Agency currently **does not have** any toxicology studies on the end use product referenced above. In order to change the toxicology status of this product, Solaris Group of Monsanto must present new acceptable studies to update the Agency's files and subsequent toxicology profile.

**Based on the above referenced Agency toxicology categories, the following labeling is required:**

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if symptoms persist.

The Agency will determine the adequacy of the existing toxicological data base for this product and the above referenced studies during Phase V of the Agency's Reregistration process.

If you have any questions, you may contact Richard J. Gebken. at (703) 305-6701.

Sincerely,

Marion Johnson  
Product Manager 03  
Insecticide Branch  
Registration Division (7505C)

enclosures

**Pet, Flea & Tick Spray Formula II, EPA Reg. No. 239-2536**  
[ABN: Flea-B-Gon® Pet Flea & Tick Killer]

[ICON] [FOR] INDOOR & OUTDOOR USE  
[ICON] WATER BASED

Kills Fleas on Contact  
Kills on Contact

[Kills] - Household Insects: Exposed adult and pre-adult fleas, ants, ticks, cockroaches, clover mites, crickets, flies, earwigs, spiders, mosquitoes, gnats, firebrats, small flying moths, sowbugs (pillbugs), millipedes and & silverfish.

For Use on Dogs and/& Cats, and Areas They Inhabit to Control Fleas & Ticks  
Freshly Scented - Leaves animal/your pet smelling fresh

Non-staining  
Non-damaging

For use in kitchens, bathrooms, basements, storage areas, garages, & on floors/floor coverings (carpets, rugs, tile, vinyl & wood).

For use on floor coverings and other indoor areas including kitchens, bathrooms, basements, storage areas, garages.

Ready-To-Use  
No Mixing [Necessary]

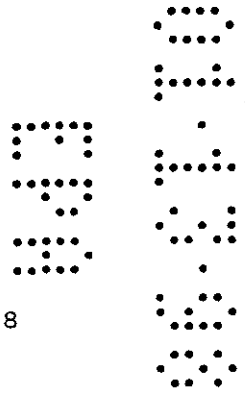
Active Ingredients	
Pyrethrins.....	0.1%
*Piperonyl Butoxide, Technical.....	1.0%
Inert Ingredients.....	98.9%
*Equivalent to 0.8% (butylcarbityl)	
(6-propylpiperonyl) ether and 0.2% related compounds.	

KEEP OUT OF REACH OF CHILDREN  
CAUTION

See back panel/booklet for additional precautionary statements.

NET-CONTENTS— 24 FL OZ (1 PT 8 FL OZ ) 709 ml

**ACCEPTED**  
with COMMENTS  
In EPA Letter Dated:  
**JUL 31 1998**  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
239-2536



~~Kills fleas and ticks on dogs and cats. Spray contains a fragrance that leaves animal smelling fresh. For use on dogs, cats, pet bedding, floor coverings, basements, garages, and pet areas. [Moved to another section of label text].~~

~~Peel open for use directions and further information~~

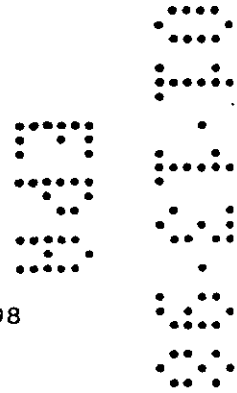
~~CAUTION: Harmful if swallowed. SEE ADDITIONAL PRECAUTIONARY STATEMENTS AND DIRECTIONS INSIDE BOOKLET.~~

~~PULL HERE TO OPEN LABEL PRESS TO RESEAL~~

~~Medical Information call 1-800-454-2333  
Product Information call 1-800-225-2883~~

~~Trademark of Monsanto Company  
Monsanto Company~~

~~The Solaris Group of  
Monsanto Company  
P.O. Box 5008  
San Ramon CA 94583-0808  
Form R6831-A  
Product 5557  
EPA Reg. No. 239-2536  
EPA Est. 239-1A-3  
Made in USA~~



Open Resealable Label for Directions & Precautions

PRESS TO RESEAL

Kills fleas and/& ticks on dogs and cats. Spray contains a fragrance that leaves animal/your pet smelling fresh. Also use on pet bedding & floors/floor coverings (rugs, carpets, tile, vinyl & wood).

[OR]

For use on dogs & cats in homes, apartments, attics, garages, basements and storage areas. Non-staining, non-damaging to floors/floor coverings (carpets, rugs, vinyl, tile & wood) and baseboards. [Will not damage or stain floors/floor coverings (carpets, rugs, tile, vinyl or wood)]. Kills insects on contact.

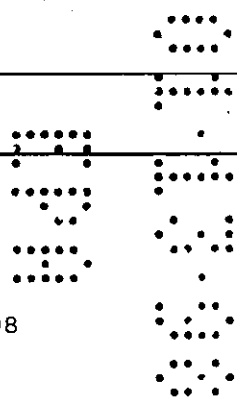
[OR]

[optional text]

PRODUCTS FACT TABLE

<u>Product Facts</u>	
<u>KILLS</u>	• Fleas (adult & pre-adult) & Ticks
<u>BUGS/INSECTS/PESTS</u>	• Roaches, Ants, Clover Mites, Crickets, Earwigs, Firebrats, Sowbugs (Pillbugs), Millipedes, Silverfish & Spiders • Flying Insects: Flies, Mosquitoes, Small Flying Moths, Gnats
<u>WHERE TO USE</u>	• On Dogs & Cats • On Indoor & Outdoor Surfaces including: <u>Floor coverings / Floors (carpets, rugs, tile, vinyl &amp; wood) &amp; baseboards</u> <u>Pet bedding [resting quarters]</u> <u>Cracks &amp; crevices</u> <u>Window &amp; door frames</u> <u>Garbage cans</u> <u>Under &amp; behind sinks, stoves, refrigerators &amp; cabinets</u> <u>Around plumbing</u> <u>Around outdoor lights</u>
<u>☎ Questions, Comments or Medical Information</u> call 1-800-225-2883 <a href="http://www.ortho.com">http://www.ortho.com</a>	

Specially formulated for residential use.



DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL BEFORE EACH USE. THE ONLY ANIMALS THIS PRODUCT CAN BE USED ON ARE DOGS & CATS. USE STRICTLY IN ACCORDANCE WITH LABEL PRECAUTIONARY STATEMENTS AND DIRECTIONS

~~For use in homes, apartments, attics, garages, basements and storage areas. Non-staining, non-damaging to carpets, rugs, floors and baseboards. Kills insects on contact.~~

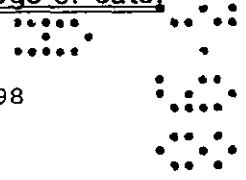
HOW TO USE: Shake well before use. ~~using. Fold back protective hinged tab exposing nozzle. Snap in place on sprayer top.~~ Adjust spray nozzle to deliver a spray or fine stream for cracks and crevices or a spray for other areas. ~~treatment.~~ Hold ~~sprayer container~~ 12 inches from the insect, animal or surface to be being sprayed/treated. [May be used indoors or outdoors]. Hold container upright and spray until barely wet. Do not spray desirable plants. [Do not spray upholstery, furniture, or drapes]. Thoroughly wash dishes and food handling utensils with soap and water if contacted by spray, they become contaminated by application of this product. Do not apply/spray of this product in conduits, motor housings, junction and switch boxes or other electrical equipment because of possible shock hazard. ~~Do not use in edible products areas of food processing plants, restaurants or other areas where food is commercially prepared. Repeat treatment as needed.~~

ROACHES, ANTS, CLOVER MITES, CRICKETS, EARWIGS, FIREBRATS, SOWBUGS (PILLBUGS), MILLIPEDES, SILVERFISH AND SPIDERS - Apply to/spray surfaces where insects hide including: Thoroughly apply under and & behind sinks, stoves, refrigerators & cabinets; around plumbing; along baseboards; ~~where insects hide, including dark corners of rooms & cabinets; and cracks and & crevices in walls and floors. Repeat as necessary.~~

ANTS - Apply directly to ants. Spray directly on ants and ant trails or wherever these pests may gain entrance. ~~May be used indoors or outdoors.~~

**FLEAS AND/ & TICKS ON DOGS AND CATS:**

Start spraying at the animal's head. Avoid ~~avoiding~~ the eyes, nose, mouth and genital areas as you spray. Make sure the animal's entire body is covered, including legs and tail. While spraying, fluff the hair so that spray will reach ~~penetrate to the skin. Make sure spray wets thoroughly.~~ Do not use on animals under 12 weeks of age/younger than 12 weeks. [Spray contains a fragrance that leaves animal/your pet smelling fresh.] Repeat as necessary but not more than once a week. Contact a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing dogs or cats.



Sensitivities may occur after using any pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

IN PET AREAS:

Spot spray/treat infested surfaces including: floors/floor coverings (carpets, rugs, tile, vinyl & wood) & baseboards &/ (molding); pet bedding [& resting quarters]; cracks & crevices; and window & door frames. Concurrent treatment of dogs & cats is recommended. Repeat as needed.

~~To control fleas and brown dog ticks on premises: Spray infested areas, pet bedding, resting quarters, nearby cracks, and crevices, along and behind baseboards, molding, window and door frames, and localized areas of floor and floor covering. Concurrent treatment of animals is recommended. Repeat treatment as needed.~~

FLYING INSECTS - FLIES, MOSQUITOS, SMALL FLYING MOTHS, GNATS:

Spray directly on insects/pests and surfaces where these insects alight or congregate including: window screens &/ frames; screen doors; garbage cans; and around outdoor lights.

~~Spray directly on pests or on surfaces, especially around window screen and frames, screen doors, around outdoor lights, garbage cans and other places where these insects alight or congregate.~~

STORAGE AND DISPOSAL

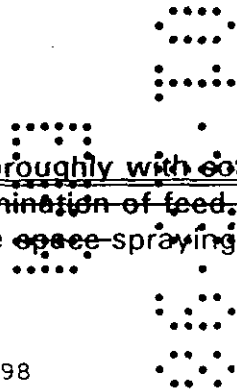
~~STORAGE: (For storage, reseal by replacing tab closure over spray nozzle.) To store, rotate nozzle to closed position. Store in original container in a safe place. Keep pesticide in original container. Do not put concentrate or dilute into food or drink containers. Avoid contamination of feed and foodstuffs. Store in a cool, dry place, preferable in a locked storage area.~~

~~DISPOSAL: Do not reuse container. Securely wrap partially filled or empty container in newspaper and put in trash. PRODUCT Partially filled bottle may be disposed of by securely wrapping original container in several layers of newspaper and discard in trash. CONTAINER Do not reuse empty bottle. Wrap bottle and put in trash.~~

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Harmful if swallowed. Avoid contamination of feed and foodstuffs. Remove pets, birds and cover fish aquarium before space spraying or surface applications.



FIRST AID: IF ON SKIN: Wash with plenty of soap and water. Call a physician if irritation persists. ~~IF SWALLOWED: Drink one or two glasses of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Call a physician immediately. Do not induce vomiting or give anything by mouth to an unconscious person.~~ ~~IF INHALED: Remove victim to fresh air. Apply artificial respiration if indicated.~~ ~~IF ON SKIN: Remove contaminated clothing and wash affected areas with soap and water.~~ Note to Physicians: Emergency Information call 1-800-225-2883 454-2333.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water. ~~lakes, ponds, streams, tidal marshes or estuaries.~~ Do not contaminate water when disposing of equipment washwaters or rinsate. ~~by cleaning of equipment or disposal of wastes.~~

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

Questions, Comments or Medical Information ?  
Call 1-800-225-2883      <http://www.ortho.com>

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Manufactured for  
The SOLARIS Group of  
Monsanto Company  
P.O. Box 5008  
San Ramon CA 94583-0808  
Form  
EPA Reg. No. 239-2536  
EPA Est. 239-IA-3  
Made in USA

