

69061-12

6/3/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460

OFFICE OF
PREVENTION PESTICIDES
AND TOXIC SUBSTANCES

June 3, 2010

Megha-Shah Even
SIVAD Manufacturing and Packaging Inc
541 Proctor Avenue
Scottsdale, GA 30079

Subject Label Notification(s) for Pesticide Registration Notice 98-10
Primary Name Change

Dear Megha-Shah Even

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated May 13, 2010 for the following product(s)

Primary Name SIVAD 15% Pyrethrin Flea & Tick Shampoo EPA Reg No 69061-12
Primary Name Changed To SIVAD Flea & Tick Shampoo

The Registration Division (RD) has conducted a review of this request for applicability under PRN 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156 140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Regina Foushee'-Smith at 703-605-0780

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Gebken".

Richard J Gebken
Product Manager
Insecticide Branch
Registration Division (7505P)



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 69061-12	2 EPA Product Manager Richard Gebken	3 Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4 Company/Product (Name) SIVAD 15% Pyrethrin Flea & Tick Shampoo	PM# 10	
5 Name and Address of Applicant (Include ZIP Code) SIVAD Manufacturing and Packaging Inc 541 Proctor Avenue Scottsdale GA 30079 <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 NOTIFICATION Product Name JUN - 3 2010	

Section - II

<input type="checkbox"/> Amendment Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<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)

The primary brand name of the product has been changed to SIVAD Flea & Tick Shampoo and is reflected on the master label per PR Notice 98 10 Please confirm with Megha Shah Even meven@tsgusa.com or via fax (202) 872 0745

This notification is consistent with the provisions of PR Notice 98 10 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formulation for 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 terms of PR Notice 98 10 and 40 CFR 152.46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA

Section - III

1 Material This Product Will Be Packaged In				2 Type of Container	
Child Resistant Packaging <input type="checkbox"/> Yes <input checked="" 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	If "Yes" Unit Packaging wgt No per container		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Package wgt	No per container		
3 Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4 Size(s) Retail Container 12 fl oz (355 mL)		5 Location of Label Directions <input checked="" type="checkbox"/>	
6 Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued 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 Megha Shah Even Technology Sciences Group Inc		Title Regulatory Consultant		Telephone No (Include Area Code) (202) 828 8954	
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)
2 Signature 		3 Title Regulatory Consultant to SIVAD Manufacturing and Packaging Inc			
4 Typed Name Megha Shah Even		5 Date 5/13/10			



WASHINGTON

1150 18th Street NW
Suite 1000
Washington DC 20036
Telephone 202 223 4392
Fax 202 872 0745

May 13, 2010

Mr Richard Gebken
Office of Pesticide Programs
Antimicrobial Division (7505P)
Office of Pesticide Products
U S Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

SACRAMENTO

712 Fifth Street
Suite A
Davis CA 95616
Telephone 530 757 1298
Fax 530 757 1299

**RE SIVAD 15% Pyrethrin Flea & Tick Shampoo
(EPA Reg No 69061-12)
Notification for Label Changes per PR Notice 98-10**

Dear Mr Gebken

Technology Sciences Group Inc , on behalf of SIVAD Manufacturing and Packaging Inc , is submitting the enclosed notification to change the primary brand name of SIVAD 15% Pyrethrin Flea & Tick Shampoo to "SIVAD Flea & Tick Shampoo" on the master label The enclosed label includes the change identified above

You will find the following included with this submission

- 1) EPA Application Form,
- 2) One redline version of the revised label, and
- 3) Three clean copies of the revised label

CANADA

275 Slater Street
Suite 900
Ottawa Ontario
K1P 5H9
Telephone 613 247 6285
Fax 613 236 3754

Please do not hesitate to contact me directly with any questions and/ or concerns at (202) 828-8954 or via e-mail meven@tsgusa.com

Sincerely,

Megha Shah Even
Regulatory Agent for SIVAD Manufacturing and Packaging Inc

cc: [illegible]
cc: [illegible]
cc: [illegible]
cc: [illegible]
cc: [illegible]
cc: [illegible]

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[FRONT PANEL]

NOTIFICATION

JUN - 3 2010

SIVAD Flea & Tick Shampoo™

FOR DOGS, CATS AND HORSES

Kills fleas and ticks through contact

ACTIVE INGREDIENTS

Pyrethrins (CAS# 8003-34-7)	0 15%
Piperonyl Butoxide* (CAS# 51-03-6)	0 30%
N-Octyl bicycloheptene dicarboximide** (CAS # 113-48-4)	0 50%

OTHER INGREDIENTS

99 05%

TOTAL

100 00%

* (butyl carbityl) (6 propylpiperonyl) ether and related compounds

** MGK® 264 Insecticide Synergist

KEEP OUT OF REACH OF CHILDREN WARNING

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA REG NO 69061-12
EPA Est No 50591-GA-01

Manufactured by
Davis Manufacturing and Packaging Inc
541 Proctor Avenue
Scottdale GA 30079
800-292-2424
www.davismfg.com

Net Contents
Batch code /Lot No

[SIDE PANEL]

Sivad Flea & Tick Shampoo kills fleas and ticks on dogs and cats over 12 weeks of age and on horses. It cleans and conditions while leaving the coat shiny and smelling fresh.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

Causes substantial but temporary eye injury. Do not get in eyes. Wear goggles or face shield. Harmful if inhaled. Avoid breathing vapors or spray mist. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove and wash contaminated clothing before reuse. Wear long-sleeved shirt, long pants, socks plus shoes and chemical-resistant gloves.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

FIRST AID	
IF INHALED	<ul style="list-style-type: none"> • 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 treatment advice.
IF IN EYES	<ul style="list-style-type: none"> • 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 eyes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR ON CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing immediately. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for further treatment advice.
<p>Have a product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents) you may call 1-888-740-8712 or the National Pesticide Information Center at 1-800-858-7378.</p>	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

General Precautions and Use Restrictions

- Apply this product only as specified on this label
- Do not repeat treatment for 7 days
- Do not use on pets less than 12 weeks old
- Remove pets birds and cover fish aquariums before application
- Consult a veterinarian before applying this product on medicated debilitated aged pregnant or nursing animals Certain medications can interact with pesticides Consult a veterinarian before using on medicated animals
- Sensitivities may occur after using ANY pesticide for pets If signs of sensitivity occur bathe your pet with mild soap and water and rinse with large amounts of water If signs continue consult a veterinarian immediately

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS, CATS AND HORSES

USE ONLY IN A WELL VENTILATED AREA

HOW TO USE For use on dogs cats and horses for the control of fleas and ticks Wet the animal s coat for 2-3 minutes with warm water Apply shampoo on head and ears and lather Then repeat procedure with neck chest middle and hindquarters finishing with the legs last and paying special attention to the footpads (between the toes) and underbody areas Wash head and ear areas carefully making sure to keep shampoo out of the animal s eyes **NOTE** A drop of glycerin in each eye before bathing may prevent or reduce irritation if the shampoo gets in the animal s eyes Pay special attention to the base of the tail as it is a place frequented by fleas Fully lather animal and let lather remain for 5 minutes before rinsing thoroughly with water **NOTE** This final step is an important part of grooming procedure

For small dogs and cats less than 15 pounds wrapping the animal in a towel for several minutes to absorb moisture is advised This will also allow dying fleas and ticks to crawl off animal into towel before drying animal with towel or blow dryer

Flea and tick control on the animal is only part of the solution to the problem The inside of the house and the outdoor area used by the animal must also be treated for complete control

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage and disposal

Pesticide Storage Store in a cool dry place inaccessible to pets and children

Pesticide and Container Disposal **If empty** Nonrefillable container Do not reuse or refill this container Offer for recycling if available or place in trash **If partly filled** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions Never place unused product down any indoor or outdoor drain