

11556-138

9/11/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

SEP 11 2009

Subject: Notification(s) for Label Revisions under PRN 97-4, 97-5, 98-10
and 2007-4

Dear Dr. Spilker:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notices PRN 97-4, 97-5, 98-10 and 2007-4 dated, July 29, 2009 for:

EPA Registration 11556-138 CheckMite+ Bee Hive Pest Control Strip

The Registration Division (RD) has conducted a review of the request(s) for applicability under PRN 97-4, 97-5, 98-10 and 2007-4, and finds that the label changes requested fall within the scope PRN 97-4, 97-5, 98-10 and 2007-4. 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 me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,


A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

20911

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95

	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		

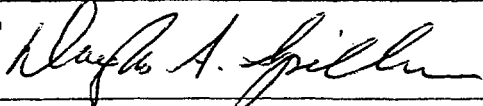
1. Company/Product Number 11556-138	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CheckMite+ Bee Hive Pest Control Strip	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <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"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.

NOTIFICATION
SEP 11 2009

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 See attachment, dated 7/29/2009.
 email: doug.spilker.b@bayer.com

Section - III					
1. Material This Product Will Be Packaged In:					
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	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <i>cardboard (outer)</i> <input checked="" type="checkbox"/> Other (Specify) <i>Foil (inner)</i>		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	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 <i>Box containing 10 or 100 strips</i>		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
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 Douglas A. Spilker, Ph.D.	Title Manager, EPA Regulatory Affairs	Telephone No. (Include Area Code) (913) 268-2751	
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 Manager, EPA Regulatory Affairs	
4. Typed Name Douglas A. Spilker, Ph.D.		5. Date <i>29 July 2009</i>	

ATTACHMENT FOR
APPLICATION FOR PESTICIDE REGISTRATION - Notification
July 29, 2009

Checkmite+ Bee Hive Pest Control Strip (EPA Reg. No. 11556-138)

Enclosed with this Application for Pesticide Notification is a draft label (5 copies) for Checkmite+ Bee Hive Pest Control Strip, dated July 28, 2009, which has been modified only to change those items (see highlighted copy) that fall under the scope of Pesticide Registration Notice (PRN) 97-4, PRN 97-5, PRN 98-10, PRN 2007-4 or may be accomplished as Non-notifications, and include:

1. Deletion of the long chemical name in the ingredient statement to only list common chemical name (coumaphos). This is allowed pursuant to PRN 97-5. See pages 1 and 2.
2. Revisions as required in EPA's NOTICE OF REGISTRATION for the product, dated January 24, 2008 (copy attached):
 - a. Replacement of the EPA File Symbol with the EPA Reg. No. See pages 1 and 2.
 - b. Revision of the first sentence of the HAZARDS TO HUMANS AND DOMESTIC ANIMALS. See Page 3.
 - c. Deletion of the skin sensitizer statement. See page 3.
 - d. Revision of the Warranty Statement. See page 7.
3. Revision of the emergency telephone numbers; we are transitioning to another medical service, but the previous telephone numbers will remain in effect for some time. The customer service statement was also revised. This is allowed pursuant to PRN 97-4. See page 3.
4. Revision of the CONDITIONS OF SALE section. See page 6.
5. Revision of the storage and disposal statements pursuant to PR Notice 2007-4. See page 6.

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This notification is consistent with the provisions of PR Notices 97-4, 97-5, 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been proposed for the labeling or the confidential statement of formula of this product. Bayer understands that it is a violation of 18 U.S. C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands 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 Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146 and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. Bayer understands that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands that if the amended label is not consistent with the requirements of 40 CFR §156.10, 156.140, 156.144, 156.146 and 156.156, this product may be in violation of FIFRA and Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

5011

Reason to Issue: Revise according to PRN 2007-4 and make other minor changes.

Date: 07/28/09
Supersedes: 11/20/2007
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Pouch

NOTIFICATION

SEP 11 2009



For Control of Varroa Mites and Small Hive Beetles in Honeybee Colonies

	<u>Percent by Weight</u>
Active Ingredient:	
Coumaphos	10%
Other Ingredients:	<u>90%</u>
Total	100%

KEEP OUT OF REACH OF CHILDREN

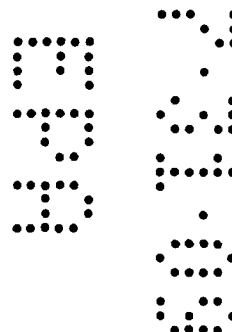
CAUTION

SEE BOX FOR DIRECTIONS FOR USE
AND PRECAUTIONARY STATEMENTS

NET CONTENTS: _____

Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201 U.S.A.

EPA Est. No. TBD
EPA Reg. No. 11556-138



leaf 11

Reason to Issue: Revise according to PRN 2007-4 and make other minor changes.

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Box



For Control of Varroa Mites and Small Hive Beetles in Honeybee Colonies

	<u>Percent by Weight</u>
Active Ingredient:	
Coumaphos	10%
Other Ingredients:	<u>90%</u>
Total	100%

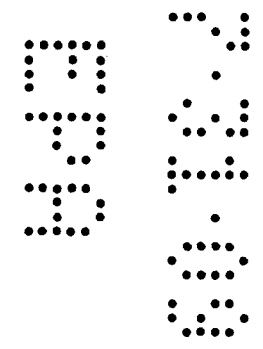
KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS: _____

Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201 U.S.A.

EPA Est. No. TBD
EPA Reg. No. 11556-138



70811

Reason to Issue: Revise according to PRN 2007-4 and make other minor changes.

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Box

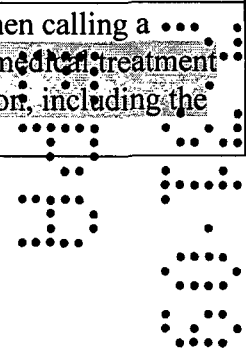
PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if ~~swallowed or~~ absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking chewing gum, using tobacco, or using the toilet. Wear chemical-resistant gloves made of rubber or any waterproof material (thickness equal to or greater than 14 mils) when applying strips.

FIRST AID	
Contains organophosphates that inhibits cholinesterase.	
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call 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 eye. • Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none"> • Call 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 instructed to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious or convulsing person.
Note to Physician: This product contains cholinesterase inhibitors. If symptoms of cholinesterase inhibition are present, atropine sulfate, by injection, is antidotal. 2-PAM is also antidotal and may be administered in conjunction with atropine.	
HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment call 1-800-422-9874. For customer service or to obtain product information, including the MSDS, call 1-800-633-3796.	



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Box

PERSONAL PROTECTIVE EQUIPMENT (PPE)

When using strips, applicators and other handlers must wear:

- long sleeved shirt and long pants
- shoes and socks
- chemical-resistant gloves made of rubber or any waterproof material (thickness equal to or greater than 14 mils).

USER SAFETY REQUIREMENTS

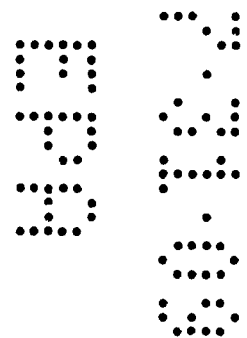
Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washable exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to birds, fish and aquatic invertebrates. Do not apply directly to any body of water. Do not contaminate water when disposing of used strips.



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Directions for Use

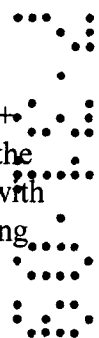
It is a violation of Federal law to use this product in a manner inconsistent with its label.

Treatments may be applied at any time – during honey flow or not during honey flow. Just before application, remove the required number of CheckMite+ Strips from the pouch. Unused strips should remain in original package.

CheckMite+ is not recommended for use in honeybee colonies that are used as cell builders for producing queens. Do not treat more than twice a year for varroa mites nor more than four times a year for the small hive beetle.

For Varroa Treatment: To control varroa mite, remove honey supers before application of CheckMite+ Strips. Use one strip for each five combs of bees in each brood chamber (Langstroth deep frames or equivalent in other sizes). Hang the strips in separate spaces between the combs as near the center of the bee/brood cluster as possible. If two deep brood chambers are used for the brood nest, hang the CheckMite+ Strips in both the top and bottom brood chambers. Treat all infested colonies within the yard. The treatment is most effective when brood rearing is lowest. Effective control may be achieved by treating hives in the spring before the first honey flow and in the fall after the last honey flow. For maximum efficacy leave the strips in the hive for at least 42 days (six weeks). **Do not leave the strips in hive for more than 45 days. Do not treat more than twice a year for varroa mites. Should infected hives need strip treatment during honey flow, the honey supers may be replaced on brood chambers for collection of honey while the strips are present in brood chamber.**

For Small Hive Beetle Treatment: To control the small hive beetle, remove honey supers before the application of CheckMite+ Strips. Prepare a piece of corrugated cardboard approximately 4x4 inches by removing one side. Remove one CheckMite+ Strip. Cut strip in half crossways and staple the two pieces to the corrugated side of the cardboard. Tape over the smooth side of the cardboard (the side opposite the strips) with duct tape, shipping tape or similar tape to prevent the bees from chewing and removing



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Box

the cardboard. Or use one sided plastic corrugated sheets. Place cardboard as near the center of the bottom board as possible with the strips down. Make sure the bottom board is clean and the strips lay flat on the bottom board. For maximum efficacy leave the strips in the hive for at least 42 days (six weeks). **Do not leave the strips in hive for more than 45 days. Do not treat more than four times per year for the small hive beetle. Should infected hives need strip treatment during honey flow, the honey supers may be replaced on brood chambers for collection of honey while the strips are present in brood chamber.**

STORAGE AND DISPOSAL

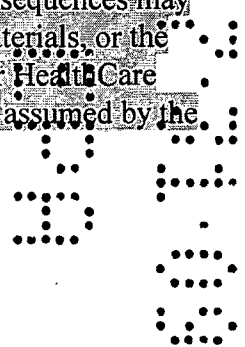
Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in cool place in original container.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: ~~Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available, or~~ dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

Conditions of Sale: The directions on this label are believed to be adequate and must be followed carefully. This product has been tested under different environmental conditions similar to those that are ordinary and customary for use of the product. However, it is impossible to eliminate all risks associated with the use of this product. Failure to follow label directions may cause injury to animals, humans and damage to the environment. Insufficient control of pests, injury or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer Health Care LLC. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.



110911

Reason to Issue: Revise according to PRN 2007-4 and
make other minor changes.

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Box

Limited Warranty and Limitation of Damages: Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. ~~TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL,~~ and no agent of Bayer is authorized to make or modify any warranties beyond those contained herein. Any damages arising from breach of this warranty shall be limited to direct damages and shall not include special, incidental or consequential damages resulting from the use of handling of this product.

