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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 27, 2014

Todd Frank Regulatory Affairs Consultant Bayer HealthCare, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390

Subject:

Label Notification per PRN 98-10 -Add Label Clarifications

Product Name: Ravap® E. C. Livestock, Poultry & Premise Insecticide Spray

EPA Registration Number: 11556-162 Application Date: August 05, 2014

Decision Number: 494171

Dear Mr. Frank:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, you may contact Driss Benmhend by phone at (703) 308-9525, or via email at Benmhend.driss@epa.gov.

Sincerely,

Mark Suarez, Product Manager 13

Insecticide Branch

Registration Division (7505P) Office of Pesticide Programs

Enclosure

Ples read instructions on reverse before a ling form.	Form Approved			
United States Environmental Protection A Washington, DC 20460	Registration OPP Identifier Number			
Application for	r Pesticide - Section I			
1. Company/Product Number 11556-162	2. EPA Product Manager Mark Suarez 3. Proposed Classification			
4. Company/Product (Name) Ravap E.C. Livestock, Poultry & Premise Insecticide Spray	PM# X None Restricted Team Number 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	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			
Check if this is a new address	Product Name			
S	ection - II			
Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below.	Final printed labels in response to Agency letter dated "Me Too" Application. Other - Explain below.			
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification to add dog kennel directions that were on previously EPA accepted label dated 01/07/2008. This update is being made at the request of the Agency. E-mail Contact: todd.frank@bayer.com				
S	ction - III			
1. Material This Product Will Be Packaged In:				
Yes Yes No. per If	Yes Metal Plastic Glass Paper Container Co			
3. Location of Net Contents Information 4. Size(s) Retail Co	tainer 5. Location of Label Directions			
Label Container 6. Manner in Which Label is Affixed to Product Lithograph	On Labeling accompanying product Other			
Paper glued Stencifed Section - IV				
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Title	Affairs Consultant Telephone No.c(Include Area Code) 913-268-2585			
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 (Staniped)				
2. Signature 3. Tit Regular Re	atory Affairs Consultant			
4. Typed Name 5. Da				

Bayer HealthCare

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mark Suarez, Team 13

August 5, 2014

Subject:

Ravap E.C. Livestock, Poultry & Premise Insecticide Spray

(EPA Reg. No. 11556-162)
Application for Notification

Dear Mr. Suarez,

Bayer HealthCare LLC Animal Health is submitting an application to revise the subject label per the Agency's request (per K. Ballard). The direction for use section for dog kennels has been updated to match the text previously accepted that was removed.

Thank you for your assistance with this notification process, and please contact me at (913) 268-2585 or todd.frank@bayer.com if you have any questions or need further information.

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 formula 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 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.

Regards,

BAYER HEALTHCARE LLC ANIMLAL HEALTH DIVISION

J. Todd Frank

Regulatory Affairs Consultant

Cc: Kelly Ballard, Chemical Review Manager, USEPA (email)

Cc: Bruce Bernard, Consultant, SRA International (email)

Cc: Douglas Spilker, Bayer HealthCare

Bayer HealthCare LLC P.O. Box 390 Shawnee Mission, KS

66201-0390

Date: Supersedes:

Page 1 of 8

08/05/2014 01/31/2014 4/1

RESTRICTED USE PESTICIDE:

Due to primary eye and primary dermal toxicity.

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification

Ravap® E.C. Livestock, Poultry & Premise Insecticide Spray

RECOMMENDED FOR AGRICULTURAL/COMMERICAL USE ONLY. NOT FOR SALE FOR ANY OTHER USES.

ACTIVE INGREDIENTS:

Tetrachlorvinphos (CAS# 22248-79-9)	23.0%*
Dichlorvos (CAS# 62-73-7)	5.3%**
OTHER INGREDIENTS:	<u>.71.7%</u> ***
TOTAL:	100.0%

*RABON® Insecticide

**VAPONA® Insecticide

NOTIFICATION

*** Contains Petroleum Distillates.

This product contains the toxic inert ingredient phenol

AUG 2 7 2014

EPA Reg.No. 11556-162

EPA Est. No. XXXXX

Manufactured For:
Bayer HealthCare, LLC
Animal Health Division
PO Box 390
Shawnee Mission, KS 66201 USA

KEEP OUT OF REACH OF CHILDREN

DANGER --



-- POISON

PELIGRO

Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes (including animals), on skin, or on clothing.

See Side Panel for Complete First Aid and Precautionary Statements

Date: Supersedes: Page 2 of 8 08/05/2014 01/31/2014 5/11

DANGER -- PELIGRO

FIRST AID

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.

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 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. Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

Call a poison control center or doctor immediately for treatment advice.

Do not give any liquid to the person.

Do not induce vomiting unless told to by a poison control center or doctor.

Do not give anything by mouth to an unconscious person

HOTLINE NUMBER

Contains an organophosphate that inhibits cholinesterase.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-422-9874 or CHEMTREC at 1-800-424-9300, 24 hours per day, 7 days per week.

NOTE TO PHYSICIAN

This product is a cholinesterase inhibitor. If symptoms of cholinesterase inhibition are present, atropine sulfate by injection is antidotal. 2-PAM is also antidotal and may be administered, but only in conjunction with atropine. Contains petroleum distillates. Product may cause aspiration pneumonia. Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER - POISON

Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes (including animals), on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco or using toilet. Remove contaminated clothing and wash clothing before reuse.

FOR CHEMICAL EMERGENCY. Spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

Date: Supersedes: Page 3 of 8 08/05/2014 01/31/2014 /u

PERSONAL PROTECTIVE EQUIPMENT

Applicators and other handlers must wear:

- Wear protective eyewear (goggles, face shield, or safety glasses).
- Wear coveralls over long sleeved shirt and long pants, socks, chemical resistant footwear, and chemical resistant gloves (Barrier laminate or Viton, selection category G).
- When mixing, loading, or cleaning equipment wear a chemical resistant apron.

USER SAFETY REQUIREMENTS

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

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. 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. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in adjacent areas. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or when disposing of equipment wash waters or rinsate.

PHYSICAL AND CHEMICAL HAZARDS

Combustible. Do not use, pour, spill or store near heat or open flame. Do not use with thermal foggers or heat-generating devices.

DIRECTIONS FOR USE – Read the entire label prior to use.

RESTRICTED USE PESTICIDE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For Agricultural/Commercial Use Only. This product is suitable for use in conventional power or low pressure knapsack sprayers and in livestock backrubbers. Follow the Use Directions for the proper dilution needed for specific insect control.

Use Restrictions

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. Do not enter or allow others to enter the treated areas until sprays have dried. Must be diluted with water except for backrubber use.

Livestock Use Directions: Do not make direct application to livestock more

frequently than once per day.

Toquerity	than once per	Dilution•Ravap	<u> </u>
Use	Insect	In Water	Remarks
Livestock Spray (Beef Cattle)	Horn Flies, Lice, Including Tail Lice, and aids in control of Face Flies	1 gal. in 75 gal. or 5 oz. in 3 gal.	Dilute in water as indicated and spray directly on the animal only to the point of runoff. Use between ½ to 1 gallon of diluted spray solution per animal depending on size and hair coat. Do not treat more often than every 10 days. Do not apply to calves under six months of age. Brahman and Brahman-cross cattle should not be treated as they may show hypersensitivity to organophosphate pesticides. Do not apply in combination with other dermal organo-phosphate pesticides (e.g. trichlorofon). There is no withholding period from last application to slaughter.
	Horn Flies, Lone Star Ticks	1 gal. in 200 gal. or 2 oz. in 3 gal	Apply as above. For severe tick infestations, dilution may be increased to 1 gallon in 50 gallons water
Livestock Spray (Lactating Dairy Cattle	Horn Flies, Lice, Lone Star Ticks, and aids in control of Face Flies	1 gal. in 200 gal or 2 oz. in 3 gal.	Dilute in water as indicated. Direct spray to cover thoroughly with up to ½ gallon of the dilution per animal. Repeat as necessary. Do not apply to calves under six months of age. No milk discard is required. Care should be taken that the spray does not come in direct contact with the lactating dairy cow's teats unless they are washed with an approved cleansing solution and dried before milking. Apply the spray at least 20 minutes prior to milking or after milking has been completed.

Update Kennel Directions per EPA request.

Date:

08/05/2014 01/31/2014

Supersedes: Page 5 of 8

Backrubber Use Directions

Use	Insect	Dilution•Ravap In Oil	Remarks
Backrubber or Facerubber (Beef and Dairy Cattle	Horn Flies, and aids in control of Face Flies	1 gal, in 25 gal or 5 oz. in 1 gal	Mix with any approved backrubber base oil. Pour diluted solution into oil reservoir of mechanical rubbing devices or pour one gallon per 20 linear feet on burlap or rope backrubbers. Keep backrubber or facerubber charged.

Poultry Use Directions

Foultry Use		Dilution•Ravap	
Use	Insect	In Water	Remarks
Caged	Lice &	1 gal. in 50 gal	Apply 1 gal. of dilution/100 birds
Chickens	Mites	or	under high pressure (no less than
		5 oz. in 2 gal	100-125 psi) to the vent and fluff
		,	areas from below. Repeat when
			necessary; however, not more
	ĺ		often than every 14 days. For
		<u>}</u>	individual bird treatment, apply 1
	l		ounce of dilution per bird.
Chickens	Lice &	1 gal. in 50 gal	Apply 1-2 gal. of dilution/1000 sq.
On Litter	Mites	or	ft. evenly with penetration of litter
		5 oz. in 2 gal	surface. Also apply thoroughly to
			walls, roosts, cracks and crevices.
		•	Spray birds as above. Treat
			roosters carefully to avoid
Dooot	Lice &	1 gal in 25 gal	reinfestation of breeding flocks. Apply 1 pt. of dilution/100 ft. of
Roost	Mites	1 gal. in 25 gal or	roost area with brush or spray.
Paint	MILES	5 oz. in 1 gal	roost area with brush of spray.
Poultry	Fowl Tick	1 gal. in 25 gal	Apply 1 gal. of dilution/100-150
Buildings	(Blue Bug)	or	sq. ft. to thoroughly cover walls,
Dunungs	(Dide Dug)	5 oz. in 1 gal	ceilings, floors, cracks and
		J UZ. III I Yal	crevices using high pressure
		,	
		<u> </u>	spray.

Date: Supersedes: Page 6 of 8 08/05/2014 01/31/2014 9/11

Premise Use Directions for Poultry and Livestock Facilities

		Dilution•Ravap	
Use	Insect	In Water	Remarks
Residual	Flies,	1 gal. in 25 gal	Apply 1 gal. of dilution/500-1000
Surface	Gnats,	or	sq. ft. Thoroughly cover walls,
Spray	Litter	5 oz. in 1 gal	ceilings or other areas where
	Beetles,	,	pests rest or congregate in dairy
_	Mosquitoes,		barns, horse barns, poultry
}	Spiders,	•	houses, swine buildings, livestock
	Wasps -		sheds and other farm buildings.
			Extreme infestations may
			necessitate increasing the diluted
			spray to one gallon per 12-1/2 gal.
			or 10 oz. per 1 gal. of water.
Larvicide	Maggots	1 gal. in 25 gal	Apply 1 gal. of dilution/100 sq. ft.
	(fly larvae)	or	of droppings as a coarse spray.
		5 oz. in 1 gal	Repeat at 7-10 day intervals until
		·	droppings begin to cone up, then
			treat only "hot spots" (small areas
			found to have large number of
İ		,	maggots). Do not spray manure
			where runoff to soil or water can
			occur. Do not spray animals
			directly with this concentration.

Kennel Use Directions

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Use	Insect	Dilution•Ravap In Water	Remarks
Residual Surface Spray – Kennels	Ticks, Fleas	1 gal. in 50 gal or 5 oz. in 2 gal	Apply 1 gal. of solution / 500-1000 sq. ft. as a spot treatment only once per year. Thoroughly treat infested kennel, outside runways and along woody borders of kennels. Do not allow pets or people to return to treated areas until sprays have thoroughly dried. Thoroughly ventilate kennels to remove any vapors.

Date: Supersedes: Page 7 of 8 08/05/2014 01/31/2014 10/11

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store product in its original container in a cool, dry place in an area inaccessible to children and animals.

PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available, for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONDITIONS OF SALE:

The directions on this label were determined through research to be appropriate for the correct use of this product. This product has been tested under different environmental conditions both indoors and outdoors similar to those that are ordinary and customary where the product is to be used. Insufficient control of pests or plant injury may result from the occurrence of extraordinary or unusual conditions, or from failure to follow label directions. In addition, failure to follow label directions may cause injury to animals, man, and damage to the environment. To the extent permitted by applicable law, Bayer offers, and the buyer accepts and uses, this product subject to the conditions that extraordinary or unusual environmental conditions, or failure to follow label directions are beyond the control of Bayer and are, therefore, the responsibility of the buyer.

Reason to Issue:

Update Kennel Directions per EPA request.

Date: Supersedes:

Page 8 of 8

08/05/2014 01/31/2014 11/11

WARRANTY AND LIMITATION OF DAMAGES:

Seller warrants that this material conforms to the chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTIES THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Seller is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law, Seller's liability for any breach of warranty shall not exceed the purchase price of the material as to which a claim is made.

RAVAP® is a trademark of Bayer.