

11556-174

12/27/2012

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DEC 27 2012

Mr. Todd Frank
Bayer Healthcare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201

Dear Mr. Frank:

Subject: Application for Pesticide Notification (PRN 98-10)
Add Warranty and Limitation of Damages
Vapona Concentrate Insecticide
EPA Reg. No. 11556-174
Your submission dated November 8, 2012

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated November 8, 2012 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds 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.

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 regarding this letter, please contact Dana Pilitt, Ph.D. at (703) 305-7071 or via e-mail at pilitt.dana@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Suarez".

Mark Suarez
Product Manager 13
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 11556-174	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Vapona Concentrate Insecticide	PM# 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 <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: NOTIFICATION EPA Reg. No. _____ Product Name DEC 27 2012	

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.)

Notification to add the Warranty and Limitation of Damages statement as allowed per PR Notice 98-10.

E-mail Contact: todd.frank@bayer.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* 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 type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input 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 J. Todd Frank	Title Reg. Affairs Consultant	Telephone No. (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 (Stamped)
2. Signature 	3. Title Regulatory Affairs Consultant	
4. Typed Name J. Todd Frank	5. Date 11/08/2012	

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RESTRICTED USE PESTICIDE:

Due to **acute oral, acute dermal, 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

Vapona® Concentrate Insecticide

Controls Flies, Gnats, and Mosquitoes on Cattle and around Livestock and Poultry Premises

DO NOT SHIP OR USE THIS PRODUCT UNLESS DIRECTIONS FOR USE ARE ATTACHED.

Active Ingredient:	By Weight
Dichlorvos (CAS #62-73-7)	40.2%
Other Ingredients	59.8% *
Total	100.0%

* Contains petroleum hydrocarbons.

**For Agricultural/Commercial Use Only
Not For Use In Or Around Residential Sites**

DILUTE PRIOR TO USE

Keep Out of Reach of Children



**DANGER! POISON
PELIGRO**

TAKE TIME
OBSERVE LABEL DIRECTIONS

See inside panels for additional precautionary statements

Net Contents: XXXXX

NOTIFICATION

DEC 27 2012

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

EPA Reg. No. 11556-174

EPA Est. No. XXXXX

FIRST AID

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 eye.
- 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 this person.
- 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 by mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

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. You may also contact 1-800-422-9874 for emergency medical treatment information.

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NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage. Contains petroleum hydrocarbons – vomiting may cause aspiration pneumonia.

Poisoning Symptoms: Symptoms include weakness, headache, tightness in chest, blurred vision, non-reactive pinpoint pupils, salivation, sweating, nausea, vomiting, diarrhea, and abdominal cramps.

Treatment: Atropine is the specific therapeutic antagonist of choice against parasympathetic nervous stimulation. If there are signs of parasympathetic stimulation, Atropine Sulfate should be injected at 10-minute intervals in doses of 1 to 2 milligrams until complete atropinization has occurred. Pralidoxine chloride (2-PAM) may also be used as an effective antidote in addition to and while maintaining full atropinization. In adults, an initial dose of 1 gram of 2-PAM should be injected preferably as an infusion in 250cc of saline over a 15 to 30 minute period. If this is not practical, 2-PAM may be administered slowly by intravenous injection as a 5 percent solution in water over not less than two minutes. After about an hour, a second dose of 1 gram of 2-PAM will be indicated if muscle weakness has not been relieved. For infants and children the dose of 2-PAM is 0.25 grams. Morphine is an improper treatment. Clear chest by postural drainage. Oxygen administration may be necessary. Observe patient continuously for 48 hours. Repeated exposure to cholinesterase inhibitors may without warning cause prolonged susceptibility to very small doses of any cholinesterase inhibitor. Allow no further exposure until cholinesterase regeneration has been attained as determined by blood test.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER - POISON. Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Corrosive. Causes skin burns and irreversible eye damage. May be fatal if swallowed. Harmful if inhaled. Avoid breathing vapor, or spray mist. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

POISONOUS IF SWALLOWED, INHALED OR ABSORBED THROUGH THE SKIN AND EYES. RAPIDLY ABSORBED THROUGH SKIN. REPEATED INHALATION OR SKIN CONTACT MAY WITHOUT SYMPTOMS, PROGRESSIVELY INCREASE SUSCEPTIBILITY TO DICHLORVOS (DDVP) POISONING. Do not swallow or get in eyes, on skin or on clothing. Do not breathe vapor. Do not contaminate food or feed products. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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CALIFORNIA ONLY: When used in enclosed structures, do not enter or allow worker entry during the Restricted Entry Interval (REI) of 24 hours.

Personal Protective Equipment (PPE):

Some materials that are chemical-resistant to this product are listed below. If you want more options follow the instructions of category "C" on an EPA chemical-resistance category selection chart in the Worker Protection Standard.

Applicators and other Handlers Must Wear:

- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves such as Barrier Laminate, Butyl Rubber, Nitrile Rubber, Neoprene Rubber, Polyvinyl Chloride or Viton.
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant headgear for overhead exposure
- Chemical-resistant apron required for mixing/loading and cleaning equipment
- Respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P, or HE prefilter.

USER SAFETY RECOMMENDATIONS

User should wash hands before, eating, drinking, chewing gum, using tobacco, or using the toilet.

User 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.

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. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to fish, birds and aquatic invertebrates. 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 disposing of equipment wash-waters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

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

DIRECTIONS FOR USE**RESTRICTED USE PESTICIDE**

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

This product must be mixed with water or diesel oil, depending on use, prior to using. It is suitable for use in conventional power or low pressure knapsack sprayers, mist blowers or non-thermal foggers. Select the specific site, method of use and insect problem, then dilute as directed. Follow the remarks for the safe use and best results in using this product. Do not store diluted product. Prior to use, read the Precautionary Statements elsewhere on this product label.

NOTIFICATION: Before the start of application, post fumigant warning signs at all entrances to the building. The signs must bear the skull and crossbones symbol and state: (1) DANGER/PELIGRO, (2) Building under fumigation, DO NOT ENTER/NO ENTRE, (3) the date and time of fumigation, (4) Dichlorvos Fumigant in use, and name, address, and telephone number of the applicator. The signs must be located prominently at each entrance, using a sign size and letter size that makes the sign clearly legible. All signs must be removed after the ventilation is complete and before routine entry by unprotected persons is permitted.

Entry by any person – other than a correctly trained and equipped handler who is performing a task related to ventilation or air concentration monitoring and who is wearing the personal protective equipment required for handlers – is **PROHIBITED** in the entire enclosed structure/building from the start of application until ventilation is complete. Ventilation is complete either when 24 hours have elapsed following application and the building has been opened and aired or when a direct-indication short term monitoring device (e.g. Draeger tube) indicates that the Dichlorvos air concentration is equal to, or less than 0.050 ppm (50% of the OSHA PEL).

NOT FOR USE IN OR AROUND RESIDENTIAL SITES.

This product can be used on lactating dairy cattle and requires only 1-day withdrawal period when used on beef cattle.

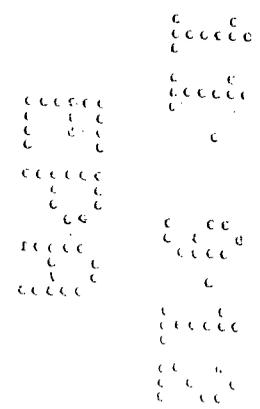
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Livestock Use Directions – Dilute In Water Only

For direct application to beef and dairy cattle (including lactating). Do not make direct application to livestock more frequently than once per day.

MUST BE DILUTED PRIOR TO APPLICATION.

Use	Insects Controlled	Dilution Vapona In Water	Remarks
Dairy Cattle (including lactating), Beef Cattle	Horn Flies, Face Flies, Stable Flies, House Flies, Mosquitoes	1 gal. in 50 gal. or 5 oz. in 2 gal. (1% Dilution)	Apply 1 to 2 fl. oz. of diluted solution (do not exceed 2 oz.) per animal daily as a fine mist spray. Be sure to cover all parts of animal for best results. Do not apply in combination with other dermal organophosphate pesticides (e.g. trichlorfon). Brahman and Brahman cross cattle should not be treated as they may show hypersensitivity to organophosphates. Do not wet the hide. Do not apply to calves under 6 months of age. One day withdrawal is required on beef cattle.



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Indoor Premise/Area Use Directions – Dilute in Water Only
For indoor application to livestock facilities.

Use	Insects Controlled	Dilution Vapona In Water	Remarks
Dairy Barns, Poultry Houses, Swine Barns, Other Animal Buildings	Flies, Gnats, Mosquitoes, Roaches, Sowbugs, Ants	1 gal. in 100 gal. or 2 oz. in 1.5 gal. (0.5% Dilution)	Apply as a space spray mist to open air space at the rate of 1 quart (32 oz.) of diluted solution per 8,000 cubic feet or as a coarse wet spray to indoor surfaces at the rate of 1 quart of diluted solution per 1,000 sq. ft. Before applying reduce air movement as much as possible by closing doors, windows, and other openings. Do not use this solution in areas where animals have received a direct organophosphate pesticide application within eight hours. If animals are present, ventilate treated area immediately following spray application. Do not contaminate water, feed, or foodstuffs, milk or milking utensils.
		1 gal. in 50 gal. or 5 oz. in 2 gal. (1.0% Dilution)	Apply as above at the rate of 1 pint (16 oz.) per 8,000 cubic feet or 1 pint (16 oz.) per 1,000 sq. ft. when a reduced quantity of water is desired and equipment can adequately provide coverage of area to be treated.
Manure Piles	Fly Maggots	1 gal. in 100 gal. or 2 oz. in 1.5 gal. (0.5% Dilution)	Apply as above at the rate of 1 to 2 qts. of solution per 100 sq. ft. of manure once a week.

Outdoor Area Use Directions – Dilute in Water (Misting) or Diesel Oil (Fogger)

For outdoor area treatment of livestock holding facilities.

Use	Insects Controlled	Dilution Vapona In Diluent	Remarks
Cattle Feedlots, Stockyards, Holding Pens, Corrals	Flies, Gnats, Mosquitoes	1 gal. in 100 gal. or 1 qt. in 25 gal. (0.5% Dilution)	Apply at an overall application rate of approximately 5 gallons of diluted solution per acre. Fog or mist during the time insects are most active, usually late afternoon and when there is little wind. Particular attention should be given to areas where flies congregate such as around feed bunks, fences, and walls of buildings. Avoid direct application to exposed feed and water. Animals may be present during treatment.

USE RESTRICTIONS:

Do not enter or allow others to enter until sprays have dried.

Do not apply this product in a way that will contact workers on other persons, either directly or through drift. Only handlers wearing specified PPE may be in the area during application.

Use in hand held fogger or hand held smoke generator equipment is prohibited.

Use in residential sites as a crack and crevice or space spray is prohibited.

Use on Lawns, turf or ornamentals is prohibited.

STORAGE AND DISPOSAL:

Not for use or storage in or around the home.

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

Pesticide Storage: Store in original container only. Store in a safe place where children or animals cannot reach the product or its diluted emulsion. Protect from freezing.

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.

Pesticide Disposal: Pesticide wastes are acutely hazardous. 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.

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.

WARRANTY AND LIMITATION OF DAMAGES:

Seller warrants that this material conforms to its 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. Seller makes no other express or implied warranty, including any other express or implied warranty of Fitness or of Merchantability, and no agent of Seller is authorized to do so except in writing and with specific reference to this warranty. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.