07/9/2013



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

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Mr. J. Todd Frank Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390

JUL - 9 2013

Subject: Label Notification(s) for Pesticide Registration Notice 98-10.

Dear Mr. Frank:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 June 27, 2013 for the following product(s):

CO-Ral 1% Livestock Dust

Alternate Brand Name

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 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.

CO-Ral Animal Insecticide EPA Reg. No. 11556-14 1% Bulk Dust

If you have any questions, please contact Linda A. DeLuise at 703-305-5428.

Sincerely,

Let A De de

Richard J. Gebken Product Manager (10) Insecticide Branch Registration Division (7504P)

Concerning Concer				
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Environmental Protection Agency Wahngton, DC 20490 Application for Pesticide - Section I Amendment Amendment Application for Pesticide - Section I CompanyProduct Number SS6-14 CompanyProduct Summer SS6-14	ese reed instructions on reverse before comple. / form.	Form Approved, d.	No. 2070-0060	PrintForm
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Bayer HealthCare Animal Health

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: Richard Gebken, Team 10

June 27, 2013

Subject:

CO-RAL (Coumaphos) Animal Insecticide 1% Bulk Dust EPA Reg. No. 11556-14 Application for Notification

Dear Mr. Gebken,

Please find enclosed, for the Agency's acceptance, an Application for Pesticide Notification, one copy of the highlighted label, and three copies of the unhighlighted labels for the subject product.

As allowed by PR Notice 98-10 Bayer HealthCare LLC Animal Health is adding an Alternate Brand Name an correcting minor typographical errors. No other changes have been made to the label.

Thank you for your assistance with this notification process, and please contact me at (913) 268-2585 or <u>todd.frank@bayer.com</u> 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

fitree /4

J. Todd Frank Regulatory Affairs Consultant

Bayer HealthCare LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201

Add Alternate Brand Name. Correct minor typographical errors.

Date: 06/27/2013 Supersedes: 08/27/09 Page 1 of 7

Co-Ral®

NOTIFICATION

JUL - 9 2013

Animal Insecticide

1% Bulk Dust

Control of Horn Flies and Lice on Beef and Dairy Cattle, Reduction of Face Flies on Beef and Dairy Cattle, Control of Lice on Swine

[Atternate Brand Name: Co-Ral 1% Livestock Dust]

Use in Dust Bag or Shaker Can

		Percent by Weight
Active Ingredient:		
coumaphos		1%
Other Ingredients	••••••••••••••••	99%
TOTAL		100%
EPA Reg. No. 11556-14	EPA Est. No. T	BD

Keep Out of Reach of Children

CAUTION

Harmful if swallowed, absorbed through the skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, and clothing.

See Side Panel for First Aid and Other Precautionary Statements

NET CONTENTS: 12.5 [2] POUNDS

Manufactured for Bayer HealthCare LLC, Animal Health Division PO Box 390 نورية دولية Shawnee Mission, Kansas 66201

Add Alternate Brand Name. Correct minor typographical errors.

Date: 06/27/2013 Supersedes: 08/27/09 Page 2 of 7

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

FIRST AID			
Contains an organophosphate that inhibits cholinesterase.			
If swallowed:	 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 told to do so by the 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. 		
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. 		
Note To Physician: Prolonged exposure will result in cholinesterase depression.			
-	jection is antidotal. 2-PAM is also antidotal and may be		

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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Add Alternate Brand Name. Correct minor typographical errors.

Date: 06/27/2013 Supersedes: 08/27/09 Page 3 of 7

CAUTION

PERSONAL PROTECTIVE EQUIPMENT

Some materials that are chemical-resistant to this product are rubber or waterproof material. If you want more options, follow the instructions for Category A on an EPA chemical-resistance category selection chart.

Loaders, applicators and others handlers must wear long-sleeve shirt and long pants, chemical-resistant gloves, shoes plus socks, chemical-resistant apron, and a NIOSH-approved dust/mist respirator, with MSHA/NIOSH approval number prefix TC21C or a NIOSH-approved respirator with any N, R, P, or HE filter.

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 the other laundry.

User Safety Recommendations

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

Users should remove clothing 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 toxic to mammals, birds, fish and aquatic invertebrates. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

Add Alternate Brand Name. Correct minor typographical errors.

Date: 06/27/2013 Supersedes: 08/27/09 Page 4 of 7

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label and Conditions of Sale before using this product.

Co-Ral 1% Bulk Dust [Alternate Brand Name] may be used to fill cattle dust bags or it may be applied directly to cattle, swine or swine bedding by use of a shaker can. When used as recommended, Co-Ral 1% Dust [Alternate Brand Name] controls horn flies and lice on beef and dairy cattle and lice on swine. Co-Ral 1% Dust [Alternate Brand Name] will also reduce face fly populations on cattle; however, as face flies are able to travel over an area of several miles, best reduction of face fly populations is achieved when Co-Ral 1% Dust [Alternate Brand Name] is used on an area-wide basis.

APPLICATION RESTRICTIONS

The use of mechanical dusters is prohibited.

For external insecticidal use only on specified animals. Do not contaminate feed, troughs, water or water utensils. Provide thorough ventilation while dusting. Do not apply to sick, stressed or convalescent animals.

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.

Individuals must limit the number of animals they can treat per day with shaker can to no more than 25 and the area of swine bedding they can treat per day to 1,000 sq. ft.

Do not treat areas such as drinking cups, mangers, or troughs where livestock feed. Do not contaminate food, feedstuffs, food or feed handling equipment or milk or meat handling equipment.

Entry restrictions: Do not enter treated areas or allow contact with treated animals until dusts have settled.

Add Alternate Brand Name. Correct minor typographical errors.

Date: 06/27/2013 Supersedes: 08/27/09 Page 5 of 7

INSTALLATION OF DUST BAGS:

Suspend the bags by inserting rope, chain or wire through the grommets at the top of the bag and attaching to an overhead structure or by hooking the grommets into hooks fastened to a stationary overhead 2 x 4 board at the heights recommended for louse and horn fly or face fly control. In areas of frequent or heavy rainfall Co-Ral 1% Cattle Duster should be protected from the weather.

Install as many Co-Ral 1% Cattle Dusters as necessary to lanes or other openings to assure proper dusting of the animals. After the bags are in place, pull the rip cord to allow the insecticide to fall into the bottom of the bag. When dust bags are provided on a free-choice basis, allow one 12.5-pound Co-Ral 1% Duster per 25 animals.

ANIMAL	PARASITE	REMARKS
Beef and	Horn Flies	DUST BAG: Place contents of this package in any
Dairy Cattle	Lice	commercially available dust bag. Suspend bags in areas
	Face Flies	frequented by cattle or in gateways or lanes through
		which the animals pass daily for water, feed or minerals.
		Bags may also be suspended in loafing sheds or in front
		of protected mineral feeders. For lactating dairy cows
		bags may be suspended in the exit through which cows
		leave the milking barn. In all cases the bags should be
		adjusted so that the bottom of the bag will hang four to
		six inches below the topline of the cattle. For reduction
		of face flies: (1) The bottom of the bags should be 18 to
		24 inches from the ground to insure that the faces of the
		cattle will be dusted. (2) The bags must be located so the
		animals will be forced to use them daily.
		•
	Horn Flies	DIRECT APPLICATION: Co-Ral 1% Dust [Alternate
	Lice	Brand Name] may be applied by use of a shaker can.
		Animals should be thoroughly dusted using not more
		than 2 oz.* (6 level tablespoonfuls) of dust per animal
		per treatment. Treat no more than 12 times per year. Do
		not make applications less than 10 days apart.
L	ł	Continued)

APPLICATION RATES

CoRail%BulkDust B.doc

Add Alternate Brand Name. Correct minor typographical errors.

Date: 06/27/2013 Supersedes: 08/27/09 Page 6 of 7

APPLICATION RATES

ANIMAL	PARASITE	REMARKS
Swine	Lice	DIRECT APPLICATION: Apply not more than 1 oz.* (3 level tablespoonfuls) per head as a uniform coat to the head, shoulders and back by use of a shaker can. Treat no more than 6 times per year. Do not make applications less than 10 days apart.
		<u>BEDDING TREATMENT</u> : Apply 2 oz.* (6 level tablespoonfuls) uniformly over 30 square feet of fresh, dry bedding by use of shaker can. Treat no more than 6 times per year. Do not make applications less than 10 days apart.
		DIRECT APPLICATION AND BEDDING <u>TREATMENT</u> : In severe infestations both individual animals and the bedding may be treated as directed above.
No interval is of milk as feed	•	n treatment and slaughter or between treatment and use

*Note: 1 oz of this material equals approximately three level tablespoonfuls.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool, dry place.

PESTICIDE DISPOSAL: Wastes 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. Completely empty the container by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Offer for recycling, if available. Dispose of bags in a sanitary landfill of by incineration if allowed by state and local authorities.

Add Alternate Brand Name. Correct minor typographical errors.

Date: 06/27/2013 Supersedes: 08/27/09 Page 7 of 7

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 HealthCare LLC. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

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.

CoRal1%BuikDust B.doc