4-9-96

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

APR 9 1996

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Danielle Larochelle
Rhone-Poulenc AG Company
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, N.C. 27709-2014

Re: Iprodione

Dear Ms. Larochelle:

At our March 13, 1996 meeting, Rhone-Poulenc agreed to amend product labels, implement label changes immediately upon approval and conduct a residue chemistry study on peaches. These actions were taken to address EPA's concern that dietary exposure to Iprodione posed excessive cancer risks. Thank you for submitting your revised labels so promptly. On March 18, 1996, EPA approved amendments to the Iprodione registrations as follows: for stonefruit, eliminate post-harvest applications, reduce the number of applications from 5 to 4 and increase the PHI from 0 to 7 days; for grapes, increase PHI from 0 to 7 days; for peanuts, add a feeding restriction on peanut hay; and eliminate the use of Iprodione on cowpeas. These changes are intended to reduce dietary exposure to Iprodione residues from the consumption of peaches, grapes and milk.

On March 18, 1996, EPA also granted a one-year tolerance for the Iprodione residues on cotton and conditionally registered the use of Iprodione on cotton. As agreed at the meeting, the cotton tolerance is conditioned upon label amendments to reduce Iprodione residues in or on peaches, grapes and milk and other actions to reduce the overall dietary risk of Iprodione to negligible levels. Now that the amendments are approved, we need to follow-up on the other items that we agreed to at our meeting to make sure that they are completed.

Peach Processing Study. We have scheduled a meeting for April 11, 1996 to discuss the design of this study. Timeframes for submitting the study will be set at this meeting.

Existing stocks date. At our meeting, you agreed that Iprodione products released for shipment from registered establishments on or after the date of the amendment approval (i.e., March 18, 1996) would bear the revised labels.

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Re-labeling of Iprodione Products in Channels of Trade. Your March 14, 1996 letter outlined your plans for notifying dealers, distributors and other parties of these label amendments. Your letter of April 1, 1996 to Jon Jacobs in OECA provided additional information concerning your program for re-labeling existing stocks that are already in the channels of trade in California, including the text of the sticker and a list of distributors where the relabeling will be performed. We are unsure whether you plan to conduct relabeling programs outside of California. We believe that all Iprodione products in the channels of trade should be re-labeled so that the risk mitigation measures can go into effect this growing season. As explained in the Enclosure, the Agency will permit re-labeling to occur in non-registered establishments (i.e., dealerships and distributerships) provided that adequate records are kept. We expect that you will be able to complete your re-labeling program by April 30, 1996, and have inserted this date in the enclosed guidance. Products not bearing the new labeling after April 30, 1996 will be considered misbranded. In your response, you may propose an alternative compliance date if April 30, 1996 is not feasible. Please notify us that you agree to follow the procedures specified in the enclosure. Please respond by April 12, 1996.

If you have any questions, please call Vivian Prunier, the Review Manager for Iprodione, at 703-308-8034. If she is unavailable, please call me at 703-308-8163.

Sincerely,

Jack E. Housenger, Chief
Special Review Branch
Special Review and
Reregistration Division

Enclosure

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Enclosure

Provisions Permitting Relabeling of Existing Stocks
By Persons Other than the Registrant

The provisions described below are intended to permit the relabeling of existing stocks in the channels of trade of affected Iprodione products by persons other than the registrant. The products covered by this provision are ROVRAL Fungicide (EPA Reg. No. 264-453), ROVRAL 4 Flowable Fungicide (EPA Reg. No. 264-482) and ROVRAL WG Fungicide (EPA Reg. No. 264-524). This provision will be in effect until April 30, 1996.

The Agency will permit relabeling of affected Iprodione products to occur by persons other than the registrant provided that those persons are acting under the supervision of the registrant. Supervision by the registrant does not have to be on the site where relabeling is occurring. However, where relabeling is performed, it must be supervised by a person authorized in writing by the registrant. The registrant will remain responsible and liable for the proper relabeling of the product. Additionally, for the purposes of this relabeling program, any such person acting on behalf of the registrant will be considered for the purposes of FIFRA to be an agent of the registrant of the product being relabeled.

The relabeling may also be conducted at facilities that are not EPA registered establishments under FIFRA §7, provided that the registrant complies with the following recordkeeping requirements. The registrant must keep lists of all persons authorized to supervise relabeling, and must submit this list to each EPA regional pesticide branch in that region where relabeling occurs (see attached list). The registrant must also keep records of the person or company that performed the relabeling; the registration number(s) of the product that was relabeled; the address of the facility where relabeling took place; the date(s) on which the relabeling took place; and, for each registration number, the quantity of product relabeled. Such records are to be maintained by the registrant for 2 years.

Failure to comply with the recordkeeping requirements contained herein will be considered, among other things, a violation of FIFRA §12(a)(1)(E) and §12(a)(2)(L).

Attachment

Region 1:

Marvin Rosenstein, Chief
Pesticides, Toxics and Radiation Branch
EPA
John F. Kennedy Federal Building
Boston, MA 02203-0001

Region 2:

Fred Kozak, Chief
Pesticides and Asbestos Section
EPA
2890 Woodbridge Avenue
Edison, NJ 08837-3679

Region 3:

Don Lott, Chief
Pesticides Branch
EPA
841 Chestnut Building
Philadelphia, PA 19107

Region 4:

Beverly Spragg, Chief
Pesticides and Toxic Substances Branch
EPA
345 Courtland Street, N.E.
Atlanta, GA 30365

Region 5:

Phyllis Reed
Pesticides and Toxic Substances Branch
EPA
77 West Jackson Boulevard
Chicago, IL 60604-3507

Region 6:

Van P. Kozak, Chief
Pesticides Section
EPA
~~Fountain Place 12th Floor Suite 1200~~
1445 Ross Avenue
Dallas, TX 75202-2733

Region 7:

Luetta Fluornoy, Chief
Pesticides Branch
EPA
726 Minnesota Avenue
Kansas City, KS 66101

Region 8:

Dallas Miller (8P2-TX)
Pesticides Branch
EPA
Suite 500
999 18th Street
Denver, CO 80202-2466

Region 9:

Katherine Taylor, Chief
Pesticides and Toxics Branch
EPA
75 Hawthorne Street
San Francisco, CA 94105

Region 10:

Marie Jennings, Chief
Pesticides Unit
EPA
1200 Sixth Avenue
Seattle, WA 98101