



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

FEB 23 1994

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Marvin H. Alphin  
ABBOTT LABORATORIES  
CHEMICAL AND AGRICULTURAL PRODUCTS DIV.  
1401 Sheridan Road  
North Chicago, IL 60064

Subject: Label Amendment Submission of 07/06/93 in Response to PR Notice 93-7  
EPA Reg. No. 275-55  
DIPEL 10G GRANULAR

**IMPORTANT NOTICE:** This Letter Requires You to Submit a Notification to the Office of Compliance Monitoring within 20 Days.

Dear Registrant:

The labeling cited above and submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is accepted subject to the comments listed on the enclosed sheet. A copy of your proposed labeling stamped "ACCEPTED WITH COMMENTS" is enclosed.

**SERIOUS ERROR(S) ON SUBMITTED LABELING:**

EPA has determined that one or more of the errors on the labeling you submitted to the Agency is categorized as "serious" as defined in PR Notice 93-11. In general, serious errors are those that may create a potential for harm to workers, handlers, other persons, or the environment; or those that prevent the achievement of the basic goals of the Worker Protection Standard (WPS) or FIFRA.

**YOU MUST NOT SELL OR DISTRIBUTE (INCLUDING RELEASE FOR SHIPMENT) ANY PRODUCT BEARING THE SUBMITTED LABELING.** Sale or distribution of any product with the incorrect labeling is a violation of FIFRA that could result in initiation of an action for civil penalties and/or cancellation of your product. This matter has been referred to the Office of Compliance Monitoring (OCM) for further action.

**YOU MUST SUBMIT A NOTIFICATION TO THE OFFICE OF COMPLIANCE MONITORING WITHIN 20 DAYS OF THE DATE OF THIS LETTER.**



Recycled/Recyclable  
Printed with Soy/Canola Ink on paper that  
contains at least 50% recycled fiber

Each notification must include the following information:

1. Registrant's name and address.
2. EPA Registration number of the product for which the labeling was submitted.
3. Whether any product already has been sold or distributed (this includes released for shipment) bearing the submitted labeling.

In addition, the notification must include the following information, IF you have already sold or distributed any product bearing the submitted labeling:

1. Quantity of the product that has been sold or distributed.
2. EPA Producing Establishment number.
3. Location of the product, if known.
4. Proposed plan for assuring that product with the incorrect labeling in your control, as well as that in the hands of dealers/distributors/users, will be corrected. The plan must include your proposal for assuring that the labeling is corrected as soon as possible.

Submit the notification to:

Michael Wood, Director  
Compliance Division, (7203)  
Worker Protection Notification  
Office of Compliance Monitoring  
U.S. Environmental Protection Agency  
401 M Street SW  
Washington, DC 20460

Failure to submit a notification also may result in initiation of an action under FIFRA for civil penalties, if you sold or distributed (this includes released for shipment) product bearing the incorrect labeling.

**IN ADDITION, YOU SHOULD CONTACT IMMEDIATELY THE PERSONS TO WHOM YOU SOLD OR DISTRIBUTED YOUR PRODUCT AND INFORM THEM NOT TO SELL OR DISTRIBUTE ANY PRODUCT WITH THE INCORRECT LABELING.**

**WHAT THIS ACCEPTANCE MEANS:**

Based on your certification, the Agency has accepted the labeling changes that are necessary to comply with the WPS labeling requirements of 40 CFR part 156, subpart K, described in PR Notices 93-7 and 93-11. Any other labeling changes submitted in connection with this amendment application but not directly related to compliance with the WPS have neither been reviewed nor accepted by the Agency. If you wish to make such changes, you must submit a separate amendment application proposing them. If your product is currently suspended, the acceptance of this labeling amendment does not affect the suspension in any way.

**WHAT YOU NEED TO DO NEXT:**

Submit the required notification. Then by the next label printing make all the specified changes to your labeling. Send to EPA one (1) copy of the final printed labeling:

- **BEFORE** selling or distributing any product bearing the final printed labeling as amended

**AND**

- **WITHIN** one year from date of this acceptance.

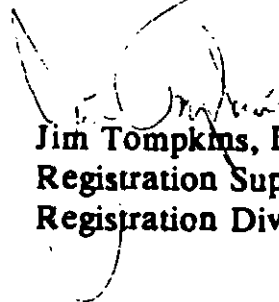
Submit the final printed labeling via the U.S. Postal Service to:

Document Processing Desk (FIN-LABEL)  
 Office of Pesticide Programs (7505C)  
 U.S. Environmental Protection Agency  
 401 M Street, SW  
 Washington, D.C. 20460-0001

Hand or courier deliveries of final labeling may be made to:

Document Processing Desk (FIN-LABEL)  
Office of Pesticide Programs  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Sincerely,



Jim Tompkins, Deputy Chief  
Registration Support Branch  
Registration Division (7505W)

Attachment

cc: Office of Compliance Monitoring

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division

Marvin H. Alphin  
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CHEMICAL AND AGRICULTURAL PRODUCTS DIV  
1401 SHERIDAN RD  
NORTH CHICAGO IL 60064

Comment for: EPA Reg Nr.275-55  
DIPEL 10G GRANULAR

The following specific comments pertain to your WPS  
labeling submission concerning the product  
cited above:

The glove requirement for early entry in the Agricultural  
Use Requirements box on your proposed labeling is missing or  
incorrect. Remove the incorrect requirement (if any) and  
add "Waterproof gloves". The exact location is shown in  
Sections F and G on Part 2 of the Product Worksheet in  
Supplement Three-A to PR Notice 93-7.

Correct the typographical errors circled on your proposed  
label.

Biological Insecticide

DIPEL® 10G  
Granules

ACTIVE INGREDIENT:

<i>Bacillus thuringiensis, var. kurstaki,</i>	
1600 International Units of Potency per mg.*	0.32%
Inert Ingredients:	99.68%
TOTAL	100.00%

\*This product contains 0.726 Billion IU/lb.

Potency units should not be used to adjust use rates beyond those specified in the Directions For Use Section.

KEEP OUT OF REACH OF CHILDREN  
CAUTION

ACCEPTED  
with COMMENTS  
In EPA Letter Dated

FEB 23 1994

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

275-55

EPA Reg. No. 275-55  
EPA Est. No. 33762-IA-1  
LIST NO. 5541-04-06

**STATEMENT OF PRACTICAL TREATMENT**

In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

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

Caution:  
Avoid inhalation or contact with eyes, skin or clothing.

**Personal Protective Equipment**

Some materials that are chemical resistant to this product are listed below.

Applicators and other handlers must wear:

- \* Long-sleeved shirt and long pants.
- \* Shoes plus socks.

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.

**User Safety Recommendations**

Users should:

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

**ENVIRONMENTAL HAZARDS**

Keep out of lakes, ponds, or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

**DIRECTIONS FOR USE**

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

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. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- \* Coveralls
- \* Shoes plus socks

**STORAGE AND DISPOSAL**

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

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: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**GENERAL INFORMATION**

DiPel 10G is a granular formulation of *Bacillus thuringiensis* variety *kurstaki*, designed specifically as a selective insecticide for control of certain leaf-eating caterpillars (Lepidoptera). For practical determinations of active ingredient, DiPel 10G can be expressed as a 10% formula of DiPel WP. The active ingredient in DiPel 10G is a



