

524-474

1-27-2000

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JAN 27 2000

Elizabeth D. Owens, Ph.D.
Regulatory Affairs Manager
Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

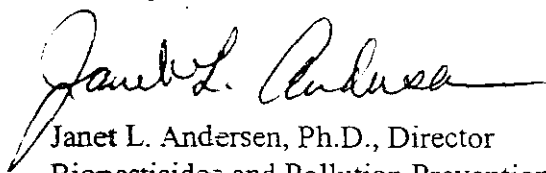
RE: Colorado Potato Beetle Control Protein
EPA Reg. No. 524-474
Product Label and Grower Guide

Dear Dr. Owens:

The labeling and product Grower Guide for this product is acceptable. A stamped copy of each are enclosed.

Per our letter dated 5/19/99, we requested that an annual report of the sales, research, monitoring/surveillance and grower compliance for this product be submitted. Although the registration of Colorado Potato Beetle Control Protein does not require the submission of such reports, we still encourage voluntary submission of an annual Insect Resistance Management Report, particularly as it relates to sales, monitoring and research for Colorado Potato Beetle Control Protein .

Sincerely,



Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution Prevention Division
7511C

CONCURRENCES							
SYMBOL							
SURNAME							
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Plant Pesticide Active Ingredient

Bacillus thuringiensis subsp. *tenebrionis*
Colorado Potato Beetle Control Protein

Pure form of the Plant Pesticide, *Bacillus thuringiensis* subsp. *tenebrionis*, delta endotoxin protein as expressed in potato cells.

Active Ingredients:

Bacillus thuringiensis CryIII(A) delta endotoxin and the genetic material necessary for its production..... 0.2% - 0.01% *

Inert Ingredients:..... 0.02-0.01% *

*Percent of total protein on a dry weight basis.

Keep Out of Reach of Children

CAUTION

Precautionary Statements

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

EPA Registration Number 524-474

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

ACCEPTED
with COMMENTS
In EPA Letter Dated

JAN 27 2000

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

524-474

Directions for Use

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

These potatoes have been genetically modified to produce the *Bacillus thuringiensis* CryIII(A) delta endotoxin protein for the control of the Colorado potato beetle, *Leptinotarsa decemlineata* (CPB).

Insect Resistance Management techniques are required to be employed in using this product. Potato varieties containing B.t.t. CPB controlling protein (CryIII(A)) should not be planted to cover more than 80% of the planted acres. At least 20% of the acres must be planted as a "refuge", i.e. potato varieties which will allow CPB feeding and survival. Growers must read and follow the specific guidance and instructions for the location and management of the refuge set forth in the product grower guide.

Transformed potatoes for planting must be accompanied by informational material, which contains the following:

- 1) These potatoes produce the insecticidal protein *Bacillus thuringiensis* CryIII(A) delta endotoxin and the genetic material necessary for its production from EPA registration number 524-474.
- 2) Routine applications of insecticides to control Colorado potato beetle are unnecessary when potatoes containing the *B.t.t.* delta endotoxin protein are planted.
- 3) Instruction for growers to read the product grower guide prior to planting, for information on planting, production and required insect resistance management.

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NatureMark
Grower Guide

September 30, 1999

NewLeaf® potatoes contain a gene for the Bt (*Bacillus thuringiensis*) protein making them 100% effective against Colorado potato beetle (CPB). Thus NewLeaf potatoes offer an alternative to conventional chemical insecticides used to control this insect.

However, all crop protection inputs require appropriate management practices to maintain effectiveness against this beetle. The CPB has been known to develop resistance to every insecticide used against it. By following the NatureMark® "Best Management Practices" outlined below, you can extend the life of Bt potatoes by reducing the potential for CPB to develop resistance.

Preventing insect resistance is much more effective than trying to manage the problem after it occurs. To prevent the development of CPB resistance, take the following steps when planting, managing, and harvesting your crop. Your participation is essential to maintain the utility of NewLeaf potatoes and Bt for future seasons.

A

NewLeaf Best Management Practices:

1) Use NewLeaf potatoes in rotation to reduce CPB on your farm.

Colorado potato beetle do not survive or reproduce on NewLeaf potatoes, so these plants can be used to reduce the overwintering CPB population on your farm. Plant NewLeaf near known overwintering sites, or where your CPB pressure is heaviest. In fields where CPB is not as troublesome, such as in areas where you planted NewLeaf last year, plant non-Bt varieties as a "refuge" (see #2 below).

2) Plant and Manage "Refuges" for Susceptible Insects on Your Farm.

The onset of resistance is less likely when susceptible insects greatly outnumber rare resistant ones. Therefore, it is important to provide "refuges"—plantings where Colorado potato beetles are never exposed to Bt—where some susceptible beetles can survive. Nobody wants to harbor pest insects on their farm, but don't worry..."refuge" areas can be protected through normal production practices without incurring damage from potato beetles.

NatureMark® REQUIRES the following:

- Do not plant your entire potato acreage to NewLeaf potato varieties, but maintain at least 20% of the total potato acreage as "refuge": potato varieties which do not contain Bt. By doing so, the requirement for CPB refuge in NatureMark's Technology Agreement will be met. (For a copy of NatureMark's Technology Agreement call 1-800-3-TATERS.)
- Do not use a foliar Bt application for CPB control on refuge acres. You may treat CPB in the refuge with insecticides to prevent damage. However, it is

B

recommended that you use foliar insecticides only when populations reach damaging levels, according to local IPM recommendations. (No insecticide is 100% effective when applied to the foliage, so some CPB will survive treatment.) Allowing a low level of CPB to survive in your field will help prevent resistance to NewLeaf potatoes.

For placement of your refuge, NatureMark **RECOMMENDS** either of the following two options:

- **OPTION 1:** Plant every NewLeaf potato field within ½ mile or less of the appropriate current year refuge (minimum 20% non-Bt potatoes, as described above).
- **OPTION 2:** Plant every NewLeaf potato field within ½ mile of land that was the designated refuge (non-Bt potatoes) *last year*. This will provide a source of susceptible CPB from overwintering sites, and will help control the worst CPB problems on your farm. Note: If following OPTION 2, you must also plant a current year 20% refuge, but it may be located as desired within your farming unit.

3) Use Every Available Method to Reduce CPB Populations

- Rotate your production so potatoes are not grown in the same field every year.
- If necessary, use methods other than insecticides to reduce CPB such as propane flaming, trench trapping, or overwintering habitat destruction. Talk to your extension specialist for recommendations about how to apply these methods.

4) Monitor for Survival of CPB

NewLeaf potatoes are so effective, no CPB larvae have ever been found to survive in NewLeaf potato fields. Although you may occasionally see adult beetles that have moved into the crop from elsewhere, you should **NEVER** see CPB larvae on NewLeaf foliage.

- Scout your NewLeaf potatoes regularly for the presence of CPB.
- If you see damaged plants or surviving larvae in your NewLeaf potatoes at *any time* during the season, call NatureMark Technical Support at 1-800-3-TATERS.