



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

MAY 19 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Russell P. Schneider, Ph.D.
Director, Regulatory Affairs
Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear Dr. Schneider:

Subject: New Leaf Plus Potato
Amendment of Insect Resistance Management Language to Label and Grower
Guide
EPA Reg. No. 524-498

The amendments referred to above, submitted in connection with registration under FIFRA, are conditionally acceptable. The changes as requested below should be made prior to the next growing season. A revised label and grower guide should be submitted at that time in addition to an annual report of the sales, research, monitoring/surveillance, and grower compliance for this product.

The Agency has reviewed the language and noted the following changes which would better address the issue of Colorado potato beetle (CPB) resistance management:

To the product label you should:

1. Delete the word "siting" and replace with "location"
2. Colorado Potato Beetle should be written as Colorado potato beetle (CPB)

To the grower guide you should: Refer to the section entitled "Plant and Manage "Refuges" for Susceptible Insects on Your Farm."

3. Delete such words as "unimproved" or "standard" potatoes and replace with the phrase "non-Bt" potatoes. Example:

“Do not plant your entire potato acreage to NewLeaf varieties, but maintain at least 20% as standard, non-Bt potatoes (required in NatureMark’s Technology Agreement). These non-Bt potato acres may be treated for potato beetles with non-Bt insecticides as needed. Treat CPB as refuge acres only when population reach damaging levels according to local IPM recommendations.”

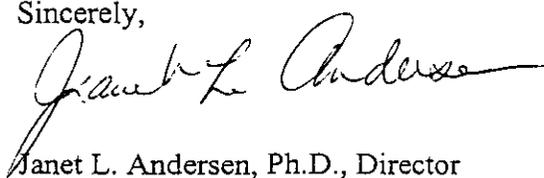
3. Provide detail as to the proximity of the refuge. Example:

“Plant NewLeaf as far as possible (greater than 0.5 miles away) from the previous year’s NewLeaf fields.

“Plant your non-Bt potato variety ‘refuge’ on farm ground that is contiguous (i.e. continuous adjacent land) and under your control. The “refuge” should also be planted as close as possible, but must be within 0.5 miles, to your current year’s NewLeaf acreage.”

Per the changes requested above, the major concerns with the future grower guide is to ensure that the appropriate language is included which specifies that treatment of the refuge does not include Bt foliar insecticides and that the proximity/location of the refuge is planted as close as possible, but within 0.5 miles, to the Bt potato fields.

Sincerely,



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

**Plant Pesticide Active Ingredient
End Use Product**

NewLeaf® Plus Potatoes

Active Ingredients:

Potato Leaf Roll Virus Resistance Gene (also known as *orf1/orf2* gene)
.....< 0.03% (w/w)

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

Inert Ingredients:..... 99.8% (w/w)

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- 498

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

ACCEPTED
with COMMENTS
In EPA Letter Dated

MAY 19 1999

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

524-498

Directions for Use

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

NewLeaf Plus potato has been transformed to express the PLRV resistance gene
for the control of Potato Leaf Roll Virus and *Bacillus thuringiensis* CryII(A) delta
endotoxin for the control of Colorado Potato Beetle.

Transformed potato for planting must be accompanied by the product notice, which contains the following:

The PLRV Resistance gene provides resistance to the Potato Leaf Roll Virus and the CryIII(A) delta endotoxin provides resistance for the control of feeding by the Colorado Potato Beetle.

Routine applications of insecticides to control transmission of PLRV by aphids and the feeding by Colorado Potato Beetle might be unnecessary.

Resistance management techniques are required to be employed for use of this product. The product grower guide shall contain language which instructs the user to plant and manage a refuge for susceptible Colorado Potato Beetles. Potato varieties containing B.t.t. CPB controlling protein should not be planted to cover more than 80% of the planted acres. At least 20% of the acres must be devoted to varieties susceptible to Colorado Potato Beetle feeding, i.e. a refuge. The specific instructions for the siting and management of the refuge shall be provided in the product grower guide.

Growers are instructed to read the product grower guide prior to planting; for information on planting, production, and required insect resistance management.