

JAN 27 2000

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

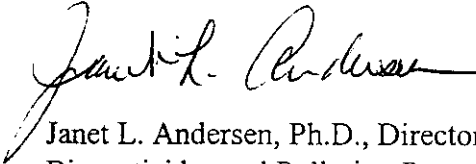
RE: New Leaf Plus Potatoes
EPA Reg. No. 524-498
Product Label and Grower Guide

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 New Leaf Plus Potatoes 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 New Leaf Plus Potatoes.

Sincerely,



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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

**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**

JAN 27 2000
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* CryIII(A) delta
endotoxin for the control of Colorado potato beetle (CPB).

Insect Resistance Management techniques are required to be employed in using this product. Potato varieties containing the B.t.t. Colorado potato beetle (CPB) control protein (CryIII(A)) must 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 potato for planting must be accompanied by the product notice, which contains the following:

- 1) 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 (CPB) from EPA registration number 524-498.
- 2) Routine applications of insecticides to control transmission of PLRV by aphids and the feeding by Colorado potato beetle might be unnecessary.
- 3) Instructions for growers to read the product grower guide prior to planting, for information on planting, production and Insect Resistance Management.