U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
☒Registration
☐Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
8917-4	1/21/2020

Term of Issuance:
Unconditional

Name of Pesticide Product:
Z6 Late Blight Protection

Name and Address of Registrant (include ZIP Code):

J.R. Simplot Company
5369 W. Irving Street
Boise, ID 83706

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you comply with the following terms:

1. Submit and/or cite all data required for registration or registration review of Z6 late blight protection when the EPA requires all registrants of similar products to submit such data.

2. Before the final label is printed, change “8917-U” to “8917-4”.

Signature of Approving Official:

Alan Reynolds, Team Leader
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division (7511P)

Date:
1/21/2020

3. The subject registration will be limited to VNT1 and the genetic material necessary for its production (pSIM1678 T-DNA) in Z6 late blight protection (OECD Unique Identifier: SPS-∅∅∅Z6-5) in potato and will expire January 31, 2022.

4. Under this registration, Z6 late blight protection may be used for conventional breeding with non-PIP potatoes not regulated by the EPA to develop new potato varieties containing VNT1 and the genetic material necessary for its production (pSIM1678 T-DNA)

5. This plant-incorporated protectant may be combined through conventional breeding with registered PIPs that are similarly approved for use in combination, through conventional breeding, with registered PIPs to produce new potato varieties with combined pesticidal traits.

6. Implement the following Resistance Management (RM) Program for Z6 late blight protection:

a. Integrated Pest Management Stewardship Program

1) J.R. Simplot must implement an Integrated Pest Management (IPM)-based stewardship program for Z6 late blight protection. This program will be designed to reduce selection pressure for late blight resistance and prolong trait durability. Key components of the stewardship program are appropriate fungicide use in conjunction with the late blight protection trait and use of Best Management Practices (BMPs). Implementation of the IPM strategy can include grower education initiatives and outreach to extension and consultant groups.

   J.R. Simplot will develop a Late Blight IPM Guide that will set forth recommended late blight fungicide use on potatoes with Z6 late blight protection and recommend BMPs for late blight. Examples of appropriate BMPs include:

   - Using certified seed
   - Crop rotation (including avoidance of planting to fields with infected potato volunteers)
   - Sanitizing seed-cutting equipment
   - Monitoring late blight alerts
   - Scouting for late blight lesions
   - Killing vines prior to harvest if the crop will be stored
   - Destroying all cull piles

   The Late Blight IPM Guide will also include instructions for how growers can contact J.R. Simplot if they observe late blight damage on fields with Z6 late blight protection. J.R. Simplot will distribute the Late Blight IPM Guide to all licensed growers of potatoes with Z6 late blight protection.

2) Annually, J.R. Simplot must submit a report to the EPA documenting activities conducted under the IPM stewardship program. This report will include:

   - An assessment of the level of IPM adoption for potatoes with the Z6 late blight protection
   - The estimated late blight fungicide reduction from the use of potatoes with Z6 late blight protection

b. Resistance Monitoring: Investigation of Performance Inquiries

1) J.R. Simplot must investigate late blight performance from growers of potatoes with Z6 late blight protection. The investigation will begin with confirming the symptoms are significant. Significant late blight symptoms are defined as sporulating foliar lesions or defoliation on otherwise healthy potato plants, and do not include symptoms on senescing plants or tuber blight.

   Infected plant material and the late blight isolate from the field will be collected to confirm:

   - The disease causing the symptoms is Phytophthora infestans;
   - The affected plants contain Z6 late blight protection; and
   - The late blight isolate is a labeled strain (i.e., US-8, US-22, US-23, or US-24).

   Cases with Z6 late blight protection potato plants meeting the above criteria are defined as "unexpected damage (UDX) cases."

2) For UDX cases, J.R. Simplot must take the following actions:
   - Review with the grower their late blight management practices. Make late blight management recommendations to the grower for the affected field and any nearby fields with the same trait. Rotation to a non-host crop will be strongly encouraged.
   - Conduct a necessary bioassay to assess whether potatoes with Z6 late blight protection are protected against the *P. infestans* isolate collected from the field with UDX. The bioassay will assess the VNT1 efficacy from Z6 late blight protection to labeled late blight strains.
   - In the case of complete lack of late blight foliar protection from VNT1 to a labeled strain as confirmed in the bioassay (i.e., EPA-defined "resistance"), J.R. Simplot will notify the EPA within 30 days.

3) Annually, J.R. Simplot must submit a report to the Agency with the total number of UDX cases and results of the subsequent bioassay, as follows:
   - Number of UXD cases with complete lack of VNT1 protection to a labeled strain, including state and county information.
   - Number of cases with labeled protection from VNT1.
   - Number of cases with intermediate responses between labeled and complete lack of protection from VNT1.

c. Annual Reporting Requirements

1) IPM Stewardship Program: Activities conducted under the IPM stewardship program, including an assessment of the level of IPM adoption for potatoes with Z6 late blight protection and the estimated late blight fungicide reduction from the use of potatoes with Z6 late blight protection, on or before June 1st each year, beginning in 2021.
2) Unexpected Damage (UDX) Investigations: Activities related to the investigations of UDX, including the total number of UDX cases and results of the subsequent bioassay(s), on or before June 1st each year, beginning in 2021.
3) Sales Data: J.R. Simplot must maintain records of annual commercial sales of Z6 late blight protection seed sold to growers (pounds of commercial tuber seed sold per state) and make this information available to the EPA within three months of the Agency's request.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If you fail to satisfy these terms, the EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e).

A stamped copy of the label is enclosed for your records. A Confidential Statement of Formula dated March 22, 2019 is on file for this product.

If you have any questions, please contact Matt Weiner by phone at (703) 347-0333 or via email at weiner.matthew@epa.gov.

Sincerely,

Alan Reynolds, Team Leader
Emerging Technologies Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Plant-Incorporated Protectant

Z6 late blight protection

OECD Unique Identifier: SPS-ØØØZ6-5

Active Ingredient:

The VNT1 Protein and *Rpi-vnt1* gene from plasmid pSIM1678……<5.0x10^{-5} %*

*Percent VNT1 protein as expressed in fresh potato tubers.

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACCEPTED
01/21/2020
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 8917-4

EPA Registration Number: 8917-U

EPA Establishment Number: 008917-ID-035

J.R. Simplot Company
5369 West Irving St.
Boise, ID 83706

DIRECTIONS FOR USE

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

Potatoes with Z6 late blight protection have been transformed to express the *Rpi-vnt1* gene product, the VNT1 protein, for protection against foliar late blight caused by *Phytophthora infestans*. Controlled *P. infestans* strains include US-8, US-22, US-23, and US-24.

Under this registration, Z6 late blight protection may be used for conventional breeding with non-PIP potatoes not regulated by EPA to develop new potato varieties containing VNT1 and the genetic material necessary for its production (pSIM1678 T-DNA).

This plant-incorporated protectant may be combined through conventional breeding with registered PIPs that are similarly approved for use in combination with registered PIPs to produce new potato varieties with combined pesticidal traits.

INTEGRATED PEST MANAGEMENT

Best management practices are recommended when using Z6 late blight protection. Examples of appropriate BMPs include:

- using certified seed;
- crop rotation, including avoidance of planting to fields with infected potato volunteers;
- sanitizing seed-cutting equipment;
- monitoring late blight alerts;

- scouting for late blight lesions;
- killing vines prior to harvest if the crop will be stored; and
- destroying cull piles.

In order to prolong trait durability, late blight fungicide use may be recommended. Read the Late Blight Integrated Pest Management Guide for Innate® Generation 2 Varieties and follow the recommended number of fungicide applications.

Z6 late blight protection is a protected variety developed by the J.R. Simplot Company, Simplot Plant Sciences with unique genetic elements.