STATE OF MAINE
DEPARTMENT OF AGRICULTURE, CONSERVATION AND FORESTRY
BOARD OF PESTICIDES CONTROL
28 STATE HOUSE STATION
AUGUSTA, MAINE 04333

PAUL R. LEPAGE
GOVERNOR

WALTER E. WHITCOMB
COMMISSIONER

TO: Board Members
FROM: Lebelle Hicks PhD DABT
RE: Review of VNT1 Protein in Potatoes
DATE: April 19, 2016

We have a request to register three new plant-incorporated protectants for late blight control in potatoes. These products are registered by J.R. Simplot Co and the varieties and EPA registration numbers are: Russet Burbank (W8), 8917-1 (J.R. Simplot 2016a), Ranger Russet (X17), 8917-2 (J.R. Simplot 2016b) and Atlantic (Y9) 8917-3 (J.R. Simplot 2016c) (attached). The gene, *Rpi-Vnt1* was taken from the wild tomato, *Solanum venturii* and the protein VNT1 inhibits the hyper sensitivity response in the fungi causing cell death (EPA 2016m).

In November 2016, J.R. Simplot submitted product characterization (description of the transformation process and the genetics of the product), and bioinformatics (protein similarities to allergens and plant toxins) to support waivers for toxicity testing.

In all three potato varieties, the gene expression was higher in the foliage (comparable to expression in the parent wild tomato) than in the tuber. The protein VNT1 was below the limit of quantitation in all plant materials for all cultivars. Due to the variation in the background level of expression, the conservative estimate of VNT1 in all tissues was set at < 100 ppb (ug/kg tissue) (EPA 2016m).

EPA granted the waivers for the entire battery of mammalian toxicity tests based on submitted data demonstrating that the gene and the VNT1 protein are very similar to 70 to 90% of genes found in widely consumed varieties of tomatoes that have no impacts on human health. In addition, no significant similarity between the VNT1 protein and known allergens or toxins was identified. It is highly unlikely that introduction of this gene into potatoes would represent a safety risk (EPA 2016m, EPA 2016n).

References Cited

EPA 2016m, Review of Product Characterization, Toxicity Waiver Requests, Allergenicity and Human Health Data for the Plant incorporated Protectant (PIP) X17 Ranger Russet, W8 Russet Burbank, and Y9 Atlantic Potato [EPA Reg No 8917-R, 8917-E, 8917-G] in support for a Sec 3 Registration and an exemption from tolerance [Petition 5F8425]

EPA 2016n, Federal Food Drug and Cosmetic Act (FFDCA) Considerations for VNT1 Protein in Potato

J.R. Simplot 2016a, W8 Late Blight Protection, EPA# 8917-1 containing < 1.0 x 5E-5% VNT1 protein from Plasmid pSIM1678 Federal label

J.R. Simplot 2016b, X17 Late Blight Protection, EPA# 8917-2 containing < 1.0 x 5E-5% VNT1 protein from Plasmid pSIM1678 Federal label

J.R. Simplot 2016c, Y9 Late Blight Protection, EPA# 8917-3 containing < 1.0 x 5E-5% VNT1 protein from Plasmid pSIM1678 Federal label

CAM LAY, DIRECTOR
32 BLOSSON LANE MARQUADT BUILDING

PHONE: (207) 287-2731
WWW.THINKFIRSTSPRAYLAST.ORG

Plant-Incorporated Protectant

W8 late blight protection

OECD Unique Identifier: SPS-ØØØW8-4

Active Ingredient:

The VNT1 protein product of the *Rpi-vnt1* gene from plasmid pSIM1678……<1.0x10^{-5} %*

*Percent VNT1 protein expressed in fresh potato tubers.

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACCEPTED
01/19/2017
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 8917-1

EPA Registration Number: 8917-1

EPA Establishment Number: 8917-ID-35

J.R. Simplot Company
5369 W. 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 W8 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, W8 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 W8 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.

W8 late blight protection is a patent-protected* product of the J.R. Simplot Company, Simplot Plant Sciences with unique genetic elements (*United States Patent No. 8,889,964).

Safety Data Sheet

According to OSHA HCS (29 CFR § 1910.1200(g)) as Published in the Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012

1 IDENTIFICATION

Product Identifier:

Product Name: W8 late blight protection
EPA Reg. No.: 8917-1
Synonyms: W8

Distributor Information:

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

Toll Free: 800.635.9444
Fax: 208.780.6027
Email: stewardship@simplot.com
Website: www.simplot.com

Emergency Phone Number: 208.780.6000
Recommended Use: This product is late blight-protected potato seed for use in potato production.
Use Restrictions: Use only according to label directions and precautionary statements.

2 HAZARDS IDENTIFICATION

Hazard Classification: This potato seed is not considered hazardous by the 2012 OSHA Communication Standard (29 CFR 1910.1200).
GHS Label Elements: N/A
Signal Word: This potato seed contains no substances which are, at their given concentration, considered to be hazardous to health.
Hazards Statements: None
Precautionary Statements:

Prevention: None
Response: None
Storage: Store according to typical practices for seed potato. No special pesticide handling precautions.
Disposal: Unwanted material may be disposed of by systemic herbicide treatment, disking, tillage, or hand picking, deep pit burial, autoclave (121 °C for 30 min), freezing, freeze-drying, grinding, composting, desiccating, crushing, or burning. Potato tuber storage bags, boxes, and containers may be cleaned, frozen, or autoclaved.

Hazards Not Otherwise Classified: N/A
Unknown Toxicity: None
Other Information: None
Interactions with Other Chemicals: Not classified.

3 COMPOSITION / INFORMATION ON INGREDIENTS

Active Ingredients: The VNT1 Protein and *Rpi-vnt1* gene necessary for production in potatoes. Potato seed contains $<1.0x10^{-5}$% VNT1 protein (as expressed in potato tubers).

4 FIRST-AID MEASURES

General Advice: No special first aid measures are necessary.
Eye Contact: If dust associated with the seed gets in the eye, remove with water.
Skin Contact: No known or anticipated hazards associated with handling of this product.
Inhalation: If any dust associated with the seed is inhaled, remove to fresh air.
Ingestion: This product is not toxic if swallowed.
Most Important Symptoms and Effects: N/A
Note to Physician: For additional information, call collect anytime day or night 208.780.6000.

5 FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Use measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable Extinguishing Media: N/A

Specific Hazards Arising from this Mixture: Not classified.
Hazardous Combustion Product(s): N/A
Sensitivity to Mechanical Impact: No
Sensitivity to Static Discharge: No
Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSHA (approved or equivalent) and full protective gear.

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: No special protective precautions are required when cleaning up spills.
Environmental Precautions: N/A
Containment Methods: Prevent further spillage if safe to do so.
Cleanup Methods: Pick up and transfer to properly labeled containers.

7 HANDLING AND STORAGE

Precautions for Safe Handling: Handle as any potato seed product.
Storage Recommendations: Keep containers closed in a cool, dry and well-ventilated place.
Incompatible Products: None known.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters - Exposure Guidelines: This product, as supplied, does not contain any hazardous material with occupational exposure limits established by the region specific regulatory bodies.
Appropriate Engineering Controls - Engineering Measures: None
Individual Protection Measures -Personal Protective Equipment:

Eye/Face: No specific protective equipment is needed.
Skin/Body: No specific protective equipment is needed.
Respiratory: Avoid breathing dusts. Use NIOSH approved respiratory protection equipment when airborne exposure is excessive (see below). Consult the respirator manufacturer to determine the appropriate type of equipment for given application. Observe respirator use limitations specified by NIOSH or the manufacturer. Respiratory protection programs must comply with 29 CFR 1910.134.

VENTILATION: No special requirement when used as recommended.
AIRBORNE EXPOSURE LIMITS:
COMPONENT: Late-blight protected potatoes
OSHA PEL: None established*
ACGIH TLV: None established
*OSHA has not established specific exposure limits for this material. However, OSHA has established limits for particulates not otherwise regulated (PNOR) respectively, which are the least stringent exposure limits applicable to dusts.
OSHA PEL: 15 mg/m3 (total dust) 8-hr TWA
5 mg/m3 (respirable) 8-hr TWA
Hygiene Measures: Handle in accordance with good industrial hygiene practices.

9 PHYSICAL AND CHEMICAL PROPERTIES

Auto-ignition temperature:	N/A	Partition coefficient: n-octanol/water:	N/A
Color:	typical of potato seed	pH:	N/A
Decomposition temperature:	N/D	Physical state:	Solid
Evaporation rate:	N/A	Relative density:	N/D
Flammability (solid, gas):	N/A	Solubility(ies):	No
Flash point:	N/A	Upper/lower explosive limits:	N/A
Freezing point:	N/D	Upper/lower flammability limits:	N/A
Initial boiling point and range:	N/A	Vapor pressure:	N/A
Melting point:	N/A	Viscosity:	N/A
Odor:	typical of potato seed	N/A = Not Applicable	N/D = Not Determined

10 STABILITY AND REACTIVITY

Reactivity: Not classified.
Chemical Stability: Considered comparable to proteins.
Possibility of Hazardous Reactions: None
Hazardous Polymerization: Does not occur.
Conditions to Avoid: None known.
Incompatible Materials: None known.
Hazardous Decomposition Products: N/A

11 TOXICOLOGICAL INFORMATION

No toxicological data are available.

Product Information:
- **Inhalation:** N/A
- **Eye Contact:** N/A
- **Skin Contact:** N/A
- **Ingestion:** N/A

Information on Toxicological Effects: Not classified.
Delayed and immediate effects as well as chronic effects from short and long-term exposure:
- **Sensitization:** Not classified.
- **Mutagenic Effects:** Not classified.
- **Carcinogenicity:** Contains no ingredient listed as a carcinogen.
- **Reproductive Toxicity:** Not classified.
- **STOT-single exposure:** Not classified.
- **STOT-repeated exposure:** Not classified.
- **Chronic Toxicity:** No known effect based on information supplied.
- **Target Organ Effects:** None known.
- **Aspiration Hazard:** Not classified.

Numerical Measures of Toxicity – Product Information:
The following value is calculated based on Chapter 3.1 of the GHS document: N/A

12 ECOLOGICAL INFORMATION (NON-MANDATORY)

Adverse effects to non-target organisms, including birds, wild mammals, freshwater and marine/estuarine fish, invertebrates, insects, honey bees, soil invertebrates, and terrestrial and aquatic plants, are not anticipated. Horizontal gene transfer, gene flow, and the development of weediness are also not anticipated.

For additional information on this product or the protein, contact Simplot at stewardship@simplot.com or 800.635.9444.

Persistence and Degradability: Not classified.
Bioaccumulation: Not classified.
Other Adverse Effects: Not classified.

13 DISPOSAL CONSIDERATIONS (NON-MANDATORY)

Disposal Methods: This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional or local regulations for additional requirements.

If treated with a seed treatment, dispose of any remaining product per container disposal instructions.

Contaminated Packaging: Dispose of contents/containers in accordance with local regulations.

14 TRANSPORT INFORMATION (NON-MANDATORY)

The data provided in this section is for information only. Please apply the appropriate regulations to properly classify your shipment for transportation.

15 REGULATORY INFORMATION (NON-MANDATORY)

International Inventories:

TSCA: N/A	DSL: All components are listed either on the DSL or NDSL
TSCA: United States Toxic Substances Control Act Section 8(b) Inventory; DSL/NDSL: Canadian Domestic Substances List/Non-Domestic Substances List	

U.S. Federal Regulations:
SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (“SARA”). This product does not contain any chemicals that are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 313.312 Hazard Categories:

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (Clean Water Act): This product does not contain any substances regulated as pollutants pursuant to the CWA (40 CFR 122.21 and 122.42).

CERCLA (Comprehensive Environmental Response Compensation and Liability Act): This material does not contain any substances regulated as hazardous under CERCLA (40 CFR 302).

SARA (Superfund Amendments and Reauthorization Act): This material does not contain any substances regulated as hazardous under SARA (40 CFR 355). There may be specific requirements at the local, regional or state level pertaining to releases of this material.

U.S. State Regulations:
California Proposition 65: This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations: N/A

International Regulations:
Mexico National Occupational Exposure Limits: N/A

Canada WHMIS Class: Not Determined

FIFRA Statement
This potato seed is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under Federal pesticide law. These requirements differ from the classification criteria and hazard information required for Safety Data Sheets ("SDS") and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including Directions for Use.

16 OTHER INFORMATION

NFPA:	Health Hazards:	0	Flammability:	0	Instability:	0	Physical and Chemical Hazards-Personal Protection:	No
HMIS:	Health Hazards:	0	Flammability:	0	Instability:	0	Physical and Chemical Hazards-Personal Protection:	No

SDS Information:
Date Prepared: 01/17/2017
Version: 1

DISCLAIMER

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, process, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific designated material and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Plant-Incorporated Protectant

X17 late blight protection

OECD Unique Identifier: SPS-ØØX17-5

Active Ingredient:

The VNT1 protein product of the *Rpi-vnt1* gene from plasmid pSIM1678……<1.0x10^{-5} %*

*Percent VNT1 protein expressed in fresh potato tubers.

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACCEPTED
01/19/2017
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 8917-2

EPA Registration Number: 8917-2

EPA Establishment Number: 8917-ID-35

J.R. Simplot Company
5369 W. 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 X17 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, X17 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 X17 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.

X17 late blight protection is a patent-protected* product of the J.R. Simplot Company, Simplot Plant Sciences with unique genetic elements (*United States Patent No. 8,889,964).

Safety Data Sheet

According to OSHA HCS (29 CFR § 1910.1200(g)) as Published in the Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012

1 IDENTIFICATION

Product Identifier:

Product Name: X17 late blight protection
EPA Reg. No.: 8917-2
Synonyms: X17

Distributor Information:

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

Toll Free: 800.635.9444
Fax: 208.780.6027
Email: stewardship@simplot.com
Website: www.simplot.com

Emergency Phone Number: 208.780.6000
Recommended Use: This product is late blight-protected potato seed for use in potato production.
Use Restrictions: Use only according to label directions and precautionary statements.

2 HAZARDS IDENTIFICATION

Hazard Classification: This potato seed is not considered hazardous by the 2012 OSHA Communication Standard (29 CFR 1910.1200).
GHS Label Elements: N/A
Signal Word: This potato seed contains no substances which are, at their given concentration, considered to be hazardous to health.
Hazards Statements: None
Precautionary Statements:
Prevention: None
Response: None
Storage: Store according to typical practices for seed potato. No special pesticide handling precautions.
Disposal: Unwanted material may be disposed of by systemic herbicide treatment, disking, tillage, or hand picking, deep pit burial, autoclave (121 °C for 30 min), freezing, freeze-drying, grinding, composting, desiccating, crushing, or burning. Potato tuber storage bags, boxes, and containers may be cleaned, frozen, or autoclaved.
Hazards Not Otherwise Classified: N/A
Unknown Toxicity: None
Other Information: None
Interactions with Other Chemicals: Not classified.

3 COMPOSITION / INFORMATION ON INGREDIENTS

Active Ingredients: The VNT1 Protein and *Rpi-vnt1* gene necessary for production in potatoes. Potato seed contains $<1.0x10^{-5}$% VNT1 protein (as expressed in potato tubers).

4 FIRST-AID MEASURES

General Advice: No special first aid measures are necessary.
Eye Contact: If dust associated with the seed gets in the eye, remove with water.
Skin Contact: No known or anticipated hazards associated with handling of this product.
Inhalation: If any dust associated with the seed is inhaled, remove to fresh air.
Ingestion: This product is not toxic if swallowed.
Most Important Symptoms and Effects: N/A
Note to Physician: For additional information, call collect anytime day or night 208.780.6000.

5 FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Use measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable Extinguishing Media: N/A

Specific Hazards Arising from this Mixture: Not classified.
Hazardous Combustion Product(s): N/A
Sensitivity to Mechanical Impact: No
Sensitivity to Static Discharge: No
Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSHA (approved or equivalent) and full protective gear.

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: No special protective precautions are required when cleaning up spills.
Environmental Precautions: N/A
Containment Methods: Prevent further spillage if safe to do so.
Cleanup Methods: Pick up and transfer to properly labeled containers.

7 HANDLING AND STORAGE

Precautions for Safe Handling: Handle as any potato seed product.
Storage Recommendations: Keep containers closed in a cool, dry and well-ventilated place.
Incompatible Products: None known.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters - Exposure Guidelines: This product, as supplied, does not contain any hazardous material with occupational exposure limits established by the region specific regulatory bodies.
Appropriate Engineering Controls - Engineering Measures: None
Individual Protection Measures -Personal Protective Equipment:

Eye/Face: No specific protective equipment is needed.
Skin/Body: No specific protective equipment is needed.
Respiratory: Avoid breathing dusts. Use NIOSH approved respiratory protection equipment when airborne exposure is excessive (see below). Consult the respirator manufacturer to determine the appropriate type of equipment for given application. Observe respirator use limitations specified by NIOSH or the manufacturer. Respiratory protection programs must comply with 29 CFR 1910.134.

VENTILATION: No special requirement when used as recommended.
AIRBORNE EXPOSURE LIMITS:
COMPONENT: Late-blight protected potatoes
OSHA PEL: None established*
ACGIH TLV: None established
*OSHA has not established specific exposure limits for this material. However, OSHA has established limits for particulates not otherwise regulated (PNOR) respectively, which are the least stringent exposure limits applicable to dusts.
OSHA PEL: 15 mg/m3 (total dust) 8-hr TWA
5 mg/m3 (respirable) 8-hr TWA
Hygiene Measures: Handle in accordance with good industrial hygiene practices.

9 PHYSICAL AND CHEMICAL PROPERTIES

Auto-ignition temperature:	N/A	Partition coefficient: n-octanol/water:	N/A
Color:	typical of potato seed	pH:	N/A
Decomposition temperature:	N/D	Physical state:	Solid
Evaporation rate:	N/A	Relative density:	N/D
Flammability (solid, gas):	N/A	Solubility(ies):	No
Flash point:	N/A	Upper/lower explosive limits:	N/A
Freezing point:	N/D	Upper/lower flammability limits:	N/A
Initial boiling point and range:	N/A	Vapor pressure:	N/A
Melting point:	N/A	Viscosity:	N/A
Odor:	typical of potato seed	N/A = Not Applicable	N/D = Not Determined

10 STABILITY AND REACTIVITY

Reactivity: Not classified.
Chemical Stability: Considered comparable to proteins.
Possibility of Hazardous Reactions: None
Hazardous Polymerization: Does not occur.
Conditions to Avoid: None known.
Incompatible Materials: None known.
Hazardous Decomposition Products: N/A

11 TOXICOLOGICAL INFORMATION

No toxicological data are available.

Product Information:
- **Inhalation:** N/A
- **Eye Contact:** N/A
- **Skin Contact:** N/A
- **Ingestion:** N/A

Information on Toxicological Effects: Not classified.
Delayed and immediate effects as well as chronic effects from short and long-term exposure:
- **Sensitization:** Not classified.
- **Mutagenic Effects:** Not classified.
- **Carcinogenicity:** Contains no ingredient listed as a carcinogen.
- **Reproductive Toxicity:** Not classified.
- **STOT-single exposure:** Not classified.
- **STOT-repeated exposure:** Not classified.
- **Chronic Toxicity:** No known effect based on information supplied.
- **Target Organ Effects:** None known.
- **Aspiration Hazard:** Not classified.

Numerical Measures of Toxicity – Product Information:
The following value is calculated based on Chapter 3.1 of the GHS document: N/A

12 ECOLOGICAL INFORMATION (NON-MANDATORY)

Adverse effects to non-target organisms, including birds, wild mammals, freshwater and marine/estuarine fish, invertebrates, insects, honey bees, soil invertebrates, and terrestrial and aquatic plants, are not anticipated. Horizontal gene transfer, gene flow, and the development of weediness are also not anticipated.

For additional information on this product or the protein, contact Simplot at stewardship@simplot.com or 800.635.9444.

Persistence and Degradability: Not classified.
Bioaccumulation: Not classified.
Other Adverse Effects: Not classified.

13 DISPOSAL CONSIDERATIONS (NON-MANDATORY)

Disposal Methods: This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional or local regulations for additional requirements.

If treated with a seed treatment, dispose of any remaining product per container disposal instructions.

Contaminated Packaging: Dispose of contents/containers in accordance with local regulations.

14 TRANSPORT INFORMATION (NON-MANDATORY)

The data provided in this section is for information only. Please apply the appropriate regulations to properly classify your shipment for transportation.

15 REGULATORY INFORMATION (NON-MANDATORY)

International Inventories:

TSCA: N/A	DSL: All components are listed either on the DSL or NDSL
TSCA: United States Toxic Substances Control Act Section 8(b) Inventory; DSL/NDSL: Canadian Domestic Substances List/Non-Domestic Substances List	

U.S. Federal Regulations:
SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (“SARA”). This product does not contain any chemicals that are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 313.312 Hazard Categories:

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (Clean Water Act): This product does not contain any substances regulated as pollutants pursuant to the CWA (40 CFR 122.21 and 122.42).

CERCLA (Comprehensive Environmental Response Compensation and Liability Act): This material does not contain any substances regulated as hazardous under CERCLA (40 CFR 302).

SARA (Superfund Amendments and Reauthorization Act): This material does not contain any substances regulated as hazardous under SARA (40 CFR 355). There may be specific requirements at the local, regional or state level pertaining to releases of this material.

U.S. State Regulations:
California Proposition 65: This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations: N/A

International Regulations:
Mexico National Occupational Exposure Limits: N/A

Canada WHMIS Class: Not Determined

FIFRA Statement
This potato seed is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under Federal pesticide law. These requirements differ from the classification criteria and hazard information required for Safety Data Sheets ("SDS") and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including Directions for Use.

16 OTHER INFORMATION

NFPA:	Health Hazards:	0	Flammability:	0	Instability:	0	Physical and Chemical Hazards-Personal Protection:	No
HMIS:	Health Hazards:	0	Flammability:	0	Instability:	0	Physical and Chemical Hazards-Personal Protection:	No

SDS Information:
Date Prepared: 01/17/2017
Version: 1

DISCLAIMER

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, process, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific designated material and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Plant-Incorporated Protectant

Y9 late blight protection

OECD Unique Identifier: SPS-ØØØY9-7

Active Ingredient:

The VNT1 protein product of the *Rpi-vnt1* gene from plasmid pSIM1678……<1.0x10^{-5} %*

*Percent VNT1 protein expressed in fresh potato tubers.

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACCEPTED
01/19/2017
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 8917-3

EPA Registration Number: 8917-3

EPA Establishment Number: 8917-ID-35

J.R. Simplot Company
5369 W. 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 Y9 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, Y9 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 Y9 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.

Y9 late blight protection is a patent-protected* product of the J.R. Simplot Company, Simplot Plant Sciences with unique genetic elements (*United States Patent No. 8,889,964).

Safety Data Sheet

According to OSHA HCS (29 CFR § 1910.1200(g)) as Published in the Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012

1 IDENTIFICATION

Product Identifier:

Product Name: Y9 late blight protection
EPA Reg. No.: 8917-3
Synonyms: Y9

Distributor Information:

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

Toll Free: 800.635.9444
Fax: 208.780.6027
Email: stewardship@simplot.com
Website: www.simplot.com

Emergency Phone Number: 208.780.6000
Recommended Use: This product is late blight-protected potato seed for use in potato production.
Use Restrictions: Use only according to label directions and precautionary statements.

2 HAZARDS IDENTIFICATION

Hazard Classification: This potato seed is not considered hazardous by the 2012 OSHA Communication Standard (29 CFR 1910.1200).
GHS Label Elements: N/A
Signal Word: This potato seed contains no substances which are, at their given concentration, considered to be hazardous to health.
Hazards Statements: None
Precautionary Statements:
Prevention: None
Response: None
Storage: Store according to typical practices for seed potato. No special pesticide handling precautions.
Disposal: Unwanted material may be disposed of by systemic herbicide treatment, disking, tillage, or hand picking, deep pit burial, autoclave (121 °C for 30 min), freezing, freeze-drying, grinding, composting, desiccating, crushing, or burning. Potato tuber storage bags, boxes, and containers may be cleaned, frozen, or autoclaved.
Hazards Not Otherwise Classified: N/A
Unknown Toxicity: None
Other Information: None
Interactions with Other Chemicals: Not classified.

3 COMPOSITION / INFORMATION ON INGREDIENTS

Active Ingredients: The VNT1 Protein and *Rpi-vnt1* gene necessary for production in potatoes. Potato seed contains $<1.0x10^{-5}$% VNT1 protein (as expressed in potato tubers).

4 FIRST-AID MEASURES

General Advice: No special first aid measures are necessary.
Eye Contact: If dust associated with the seed gets in the eye, remove with water.
Skin Contact: No known or anticipated hazards associated with handling of this product.
Inhalation: If any dust associated with the seed is inhaled, remove to fresh air.
Ingestion: This product is not toxic if swallowed.
Most Important Symptoms and Effects: N/A
Note to Physician: For additional information, call collect anytime day or night 208.780.6000.

5 FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Use measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable Extinguishing Media: N/A

Specific Hazards Arising from this Mixture: Not classified.
Hazardous Combustion Product(s): N/A
Sensitivity to Mechanical Impact: No
Sensitivity to Static Discharge: No
Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSHA (approved or equivalent) and full protective gear.

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: No special protective precautions are required when cleaning up spills.
Environmental Precautions: N/A
Containment Methods: Prevent further spillage if safe to do so.
Cleanup Methods: Pick up and transfer to properly labeled containers.

7 HANDLING AND STORAGE

Precautions for Safe Handling: Handle as any potato seed product.
Storage Recommendations: Keep containers closed in a cool, dry and well-ventilated place.
Incompatible Products: None known.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters - Exposure Guidelines: This product, as supplied, does not contain any hazardous material with occupational exposure limits established by the region specific regulatory bodies.
Appropriate Engineering Controls - Engineering Measures: None
Individual Protection Measures -Personal Protective Equipment:

Eye/Face: No specific protective equipment is needed.
Skin/Body: No specific protective equipment is needed.
Respiratory: Avoid breathing dusts. Use NIOSH approved respiratory protection equipment when airborne exposure is excessive (see below). Consult the respirator manufacturer to determine the appropriate type of equipment for given application. Observe respirator use limitations specified by NIOSH or the manufacturer. Respiratory protection programs must comply with 29 CFR 1910.134.

VENTILATION: No special requirement when used as recommended.
AIRBORNE EXPOSURE LIMITS:
COMPONENT: Late-blight protected potatoes
OSHA PEL: None established*
ACGIH TLV: None established
*OSHA has not established specific exposure limits for this material. However, OSHA has established limits for particulates not otherwise regulated (PNOR) respectively, which are the least stringent exposure limits applicable to dusts.
OSHA PEL: 15 mg/m3 (total dust) 8-hr TWA
5 mg/m3 (respirable) 8-hr TWA
Hygiene Measures: Handle in accordance with good industrial hygiene practices.

9 PHYSICAL AND CHEMICAL PROPERTIES

Auto-ignition temperature:	N/A	Partition coefficient: n-octanol/water:	N/A
Color:	typical of potato seed	pH:	N/A
Decomposition temperature:	N/D	Physical state:	Solid
Evaporation rate:	N/A	Relative density:	N/D
Flammability (solid, gas):	N/A	Solubility(ies):	No
Flash point:	N/A	Upper/lower explosive limits:	N/A
Freezing point:	N/D	Upper/lower flammability limits:	N/A
Initial boiling point and range:	N/A	Vapor pressure:	N/A
Melting point:	N/A	Viscosity:	N/A
Odor:	typical of potato seed	N/A = Not Applicable	N/D = Not Determined

10 STABILITY AND REACTIVITY

Reactivity: Not classified.
Chemical Stability: Considered comparable to proteins.
Possibility of Hazardous Reactions: None
Hazardous Polymerization: Does not occur.
Conditions to Avoid: None known.
Incompatible Materials: None known.
Hazardous Decomposition Products: N/A

11 TOXICOLOGICAL INFORMATION

No toxicological data are available.

Product Information:
- **Inhalation:** N/A
- **Eye Contact:** N/A
- **Skin Contact:** N/A
- **Ingestion:** N/A

Information on Toxicological Effects: Not classified.
Delayed and immediate effects as well as chronic effects from short and long-term exposure:
- **Sensitization:** Not classified.
- **Mutagenic Effects:** Not classified.
- **Carcinogenicity:** Contains no ingredient listed as a carcinogen.
- **Reproductive Toxicity:** Not classified.
- **STOT-single exposure:** Not classified.
- **STOT-repeated exposure:** Not classified.
- **Chronic Toxicity:** No known effect based on information supplied.
- **Target Organ Effects:** None known.
- **Aspiration Hazard:** Not classified.

Numerical Measures of Toxicity – Product Information:
The following value is calculated based on Chapter 3.1 of the GHS document: N/A

12 ECOLOGICAL INFORMATION (NON-MANDATORY)

Adverse effects to non-target organisms, including birds, wild mammals, freshwater and marine/estuarine fish, invertebrates, insects, honey bees, soil invertebrates, and terrestrial and aquatic plants, are not anticipated. Horizontal gene transfer, gene flow, and the development of weediness are also not anticipated.

For additional information on this product or the protein, contact Simplot at stewardship@simplot.com or 800.635.9444.

Persistence and Degradability: Not classified.
Bioaccumulation: Not classified.
Other Adverse Effects: Not classified.

13 DISPOSAL CONSIDERATIONS (NON-MANDATORY)

Disposal Methods: This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional or local regulations for additional requirements.

If treated with a seed treatment, dispose of any remaining product per container disposal instructions.

Contaminated Packaging: Dispose of contents/containers in accordance with local regulations.

14 TRANSPORT INFORMATION (NON-MANDATORY)

The data provided in this section is for information only. Please apply the appropriate regulations to properly classify your shipment for transportation.

15 REGULATORY INFORMATION (NON-MANDATORY)

International Inventories:

TSCA: N/A	DSL: All components are listed either on the DSL or NDSL
TSCA: United States Toxic Substances Control Act Section 8(b) Inventory; DSL/NDSL: Canadian Domestic Substances List/Non-Domestic Substances List	

U.S. Federal Regulations:
SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (“SARA”). This product does not contain any chemicals that are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 313.312 Hazard Categories:

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (Clean Water Act): This product does not contain any substances regulated as pollutants pursuant to the CWA (40 CFR 122.21 and 122.42).

CERCLA (Comprehensive Environmental Response Compensation and Liability Act): This material does not contain any substances regulated as hazardous under CERCLA (40 CFR 302).

SARA (Superfund Amendments and Reauthorization Act): This material does not contain any substances regulated as hazardous under SARA (40 CFR 355). There may be specific requirements at the local, regional or state level pertaining to releases of this material.

U.S. State Regulations:
California Proposition 65: This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations: N/A

International Regulations:
Mexico National Occupational Exposure Limits: N/A

Canada WHMIS Class: Not Determined

FIFRA Statement
This potato seed is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under Federal pesticide law. These requirements differ from the classification criteria and hazard information required for Safety Data Sheets ("SDS") and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including Directions for Use.

16 OTHER INFORMATION

NFPA:	Health Hazards:	0	Flammability:	0	Instability:	0	Physical and Chemical Hazards-Personal Protection:	No
HMIS:	Health Hazards:	0	Flammability:	0	Instability:	0	Physical and Chemical Hazards-Personal Protection:	No

SDS Information:
Date Prepared: 01/17/2017
Version: 1

DISCLAIMER

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, process, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific designated material and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.