

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 8, 2017

Walid Al-Akhdar, Ph.D. Manager, Regulatory & Government Affairs – Biologicals BASF Corporation 26 Davis Drive Research Triangle Park, NC 27709

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation

Amendment – Update the Ingredient Percentages on the Basic Confidential Statement of Formula (CSF) and Labeling and Make Other Changes (Including Those Requested by the EPA) to Both the Basic CSF and Labeling (e.g., Updating the Respirator Statement)

Product Name: Nogall

EPA Registration Number: 62388-1 Application Date: 02/26/2015 OPP Decision Number: 502481

Dear Dr. Al-Akhdar:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

• Basic CSF dated 08/08/2017

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

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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 Environmental Protection Agency (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 these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Alex Boukedes by phone at (703) 347-0305 or via email at boukedes.alexandra@epa.gov.

Sincerely,

Jeannine Kausch, Product Manager 92
Microbial Postioides Propel

Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)

Office of Pesticide Programs



Nogall®

For Biological Control of Crown Gall Disease

FOR USE ON NON-FOOD OR NON-FOOD BEARING PLANTS ONLY

Active Ingredient:

 Agrobacterium radiobacter (strain K1026)*
 37.50%

 Other Ingredients:
 62.50%

 Total:
 100.00%

* Contains not less than 1 x 10⁹ colony-forming units (cfu) per gram of moist peat medium. When mixed as directed, it will provide a suspension of not less than 2.64 x 10⁷ cfu per milliliter in the dip solution.

EPA Reg. No. 62388-1

EPA Est. No. 62388-AUS-001

CAUTION/PRECAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See back panel and insert for complete First Aid, Precautionary Statements, Directions For Use, and Conditions of Sale and Warranty.

You may contact BASF Corporation for emergency medical treatment information at 1-800-832-HELP (4357).

Net Weight:

Batch Number: [Located on side panel]

Not for sale or use after [Located on side panel; date stamped is 6 months after the date of manufacture].

BASF Corporation 26 Davis Drive, Research Triangle Park, NC 27709

ACCEPTED

11/08/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2000 2011

62388-1

FIRST AID	
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact BASF Corporation for emergency medical treatment information: 1-800-832-HELP (4357).

Precautionary Statements

Hazards to Humans & Domestic Animals

Caution: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixers/loaders and applicators must wear a NIOSHapproved particulate respirator with any N, R, or P filter with NIOSH approval number prefix TC-84A; or a NIOSHapproved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

DO NOT apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. **DO NOT** contaminate water when disposing of equipment washwater or rinsate.

Directions For Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **DO NOT** apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any

requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

DO NOT enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water) is:

- coveralls
- shoes plus socks
- waterproof gloves

STORAGE AND DISPOSAL

DO NOT contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Store at refrigeration temperature (35-40°F) and use before the date stamped on the side panel of this box. **DO NOT** store cartons where they can be punctured or crushed by sharp or heavy objects. **DO NOT** store part of an opened packet as it may deteriorate through contamination. Store Nogall® separate from other pesticides, fertilizer, food, and feed to prevent cross contamination. Maximum period of storage is 6 months from the date of manufacture. The date of expiration is printed on the side panel of this box. If the foil or plastic pouch in the carton is ruptured accidentally or spilled, sweep the spilled contents into a dust pan, place the contents in a tied plastic bag and discard in the garbage. Rinse the area of the spill with several rinses of water.

Pesticide Disposal

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling

Nonrefillable container. DO NOT reuse or refill this container. Completely empty foil or plastic pouch by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then, offer for recycling if available or dispose of empty foil or plastic pouch in a sanitary landfill, by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If outer carton is contaminated, dispose of it in the same manner as required for the foil or plastic pouch.

In Case of Emergency

In case of large-scale spill of this product, call:

• CHEMTREC 1-800-424-9300

BASF Corporation 1-800-832-HELP (4357)

In case of medical emergency regarding this product, call:

Your local doctor for immediate treatment

Your local poison control center (hospital)

BASF Corporation 1-800-832-HELP (4357)

Product Information

Nogall® is a living culture that must be protected against sunlight and extremes of temperature. DO NOT use with any other pesticides, fertilizers or chemicals that may harm the bacteria. Mix only with clean, chlorine-free water, using clean containers and utensils. DO NOT wash treated stock prior to planting. Nogall is used to dip or spray (inoculate) germinating seeds, roots and stems, and cuttings of non-food (gall free) or non-food bearing (gall free) almond, apricot, caneberry, cherry, euonymus, nectarine, peach, pecan, plum, rose and walnut. Plant material should be inoculated at each transfer stage, if possible.

Nogall helps protect infection sites against the crown gall disease organism (*Agrobacterium tumefaciens*) and should be used when highly susceptible plant material is transferred and/or subjected to wounding, such as when taking cuttings, germinating seeds, re-potting, field lifting, and replanting, etc. Successful control of crown gall disease in the above hosts is largely due to the production of the antibiotic agrocin 84 and root colonization by *Agrobacterium radiobacter* strain K1026 contained in Nogall. Control of sensitive pathogenic agrobacteria is most effective with correctly applied Nogall. Where pathogenic bacteria are resistant to agrocin 84, however, then control can be considerably reduced.

Nogall is shipped as packs of either 3.5 oz (100 g) or 17.6 oz (500 g) of concentrated, moist peat bacterial cultures.

Use Limitations

Chemigation: DO NOT apply this product through any type of irrigation system.

Application Instructions

Germinating Seed Application to almond, apricot, cherry, nectarine, peach, pecan, plum and walnut: Dip 15 pounds of seed into a suspension of Nogall prepared by adding 3.5 oz (100 g) of Nogall to 1 gallon of clear, unchlorinated water in a clean container. The surface of the seed must be thoroughly wet. Remove the seed from the suspension, drain off excess liquid and sow immediately. DO NOT ALLOW THE SEED TO COMPLETELY DRY BEFORE SOWING.

Root and Stem Application to non-food bearing almond, apricot, caneberry, cherry, nectarine, peach, pecan, plum and walnut and non-food euonymus and rose: Treat seedlings of stone fruit trees, nut trees, spindle trees and roses with Nogall within 2 hours of lifting, root pruning or other handling operations that damage plant tissue and before and after cold storage. Dip or spray bare rootstock with Nogall suspension (3.5 oz (100 g) of **Nogall** to 1 gallon of clear, unchlorinated water) until root surfaces and the stem above the bud or graft union are completely wet, or spray these tissues to runoff. Replace treatment suspension after treating the equivalent of 1,000 plants/gallon of suspension or sooner when larger trees are dipped or when the suspension becomes excessively dirty. Larger plants may require 10-15 gallons of suspension per 5,000 plants. Protect treated plants from direct sunlight and excessive drying by storing in a cool, humid area or heeled-in clean, moist material such as sphagnum or sawdust. Treated plants must be protected from drying during transport to the planting site and during the planting operation.

Cutting Application to non-food bearing almond, apricot, caneberry, cherry, nectarine, peach, pecan, plum and walnut and non-food euonymus and rose: Treat cuttings by dipping clean basal ends in a suspension of Nogall prepared by adding 3.5 oz (100 g) of Nogall to 1 gallon of clear, unchlorinated water in a clean container. Treated cuttings must be protected from drying and direct sunlight by storing in a cool, humid area until they are placed in rooting media. When using alcohol-based rooting compounds, dip cuttings in accordance with directions, allow to dry for 2 hours and then treat with Nogall. Treat cuttings with Nogall before and after cold storage.

MIXING INSTRUCTIONS

Stir vigorously and periodically stir solution during use. A 3.5 oz (100 g) or 17.6 oz (500 g) pack properly mixed in water will treat 1,000 and 5,000 bare root seedlings (1/4 inch caliper), respectively. **DO NOT HOLD DILUTED SUSPENSION FOR MORE THAN 8 HOURS.**

Conditions of Sale and Warranty

The **Directions For Use** of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as the presence of other or untested or unapproved materials, seed of low quality or low vigor or low germination, use of the product in a manner inconsistent with its labeling, misapplication of this product, or weather conditions at planting or environmental conditions during seed storage, all of which are beyond the control of BASF CORPORATION ("BASF") or the Seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

BASF warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions For Use**, subject to the inherent risks, referred to above.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BASF MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S EXCLUSIVE REMEDY AND BASF'S EXCLUSIVE LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE, SHALL BE LIMITED TO REPAYMENT OF THE PURCHASE PRICE OF THIS PRODUCT.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BASF AND THE SELLER DISCLAIM ANY LIABILITY FOR CONSEQUENTIAL, EXEMPLARY, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

BASF and the Seller offer this product, and the Buyer and User accept it, subject to the foregoing **Conditions of Sale and Warranty** that may be varied only by agreement in writing signed by a duly authorized representative of BASF.

Nogall is a registered trademark of BASF.

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