



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

April 4, 2019

Kevin Staska  
Field Development Manager  
Plant Health Care, Inc.  
2626 Glenwood Avenue, Ste. 350  
Raleigh, North Carolina 27608

Subject: Pesticide Registration Improvement Act (PRIA) Labeling Amendment (B680) – Submission of an Acute Inhalation Toxicity Study and Storage Stability and Corrosion Characteristics Studies to Support Revised Labeling and Request to Add Sweet Corn as a Use Site to the Product Label  
Product Name: PHC-620 (Containing 0.26% Harpin  $\alpha\beta$  Protein)  
EPA Registration Number: 71771-11  
Application Dates: September 12, 2018 and October 1, 2018  
OPP Decision Number: 545430

Dear Mr. Staska:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable for the following two amendment requests:

- Storage Stability and Corrosion Characteristics of the End-Use Product PHC-620: The submitted studies were rated “acceptable” and support the revised product labeling. This submission also satisfies the registration term imposed in the April 23, 2018 registration notice for PHC-620 to submit storage stability and corrosion characteristics data (Guidelines 830.6317 and 830.6320) within 18 months of registration.
- Request to add sweet corn as a use site to the product label.

However, the submitted Acute Inhalation Toxicity study was not acceptable to support revised inhalation precautionary statements on the product label. This request was unacceptable for the following reasons:

EPA’s science review of the submitted Acute Inhalation Toxicity Study concluded: “PHC-620 end-use product (EP) is a powder protein substance thus, inhalation is a relevant route of exposure. The presented study is a non-guideline study because it lacks the appropriate controls and the test substance exceeded the target MMAD set forth in the guideline. However, the study was classified as supplemental because it did provide some information on the effect of inhalation exposure to the EP. A toxicity category for acute inhalation toxicity could not be assigned.” Therefore, the Agency cannot approve reducing the inhalation precautionary language

and personal protective equipment from the product label at this time. A copy of the Agency's science review is enclosed for your records.

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.

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 U.S. 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 Stephanie Kelly by phone at (703) 347-0598 or via email at [kelly.stephanie@epa.gov](mailto:kelly.stephanie@epa.gov).

Sincerely,



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

Enclosures:

- 1) U.S. EPA, 2018. Post Registration Review of Acute Inhalation Toxicity Study, Storage Stability, and Corrosion Characteristics of the End-Use Product PHC-620 (Containing 0.26% Harpin  $\alpha\beta$  Protein) and Request to Add Sweet Corn as a New Use Site. Memorandum from Wiebke T. Striegel, through John L. Kough, to Stephanie Kelly, February 13, 2019.
- 2) Product label stamped "Accepted"

# PHC-620™

[Alternate Brand Names: OUTFRONT, QUALIFY, STANDOUT, STANDFAST, STANDCOUNT, FASTAND, HM-1734]

## Combination BioChemical Seed Treatment/ Seed Lubricant

A Biochemical Pesticide Seed Treatment and Seed Lubricant (a proven Talc/Graphite Replacement) that: Improves stand establishment; Suppresses nematode egg production; Lubricates Seed in Corn and Soybean Planters

**FOR USE ONLY AS SEED TREATMENT IMMEDIATELY PRIOR TO PLANTING**

### Dry Seed Treatment Formulation

**ACTIVE INGREDIENT:**

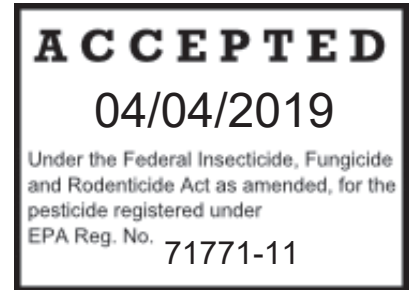
Harpin αβ Protein: ..... 0.26%

**OTHER INGREDIENTS:** ..... 99.74%

Total: ..... 100.0%

EPA Reg. No. 71771-XX

EPA Est. No. XXXXX-XX-XXX



**KEEP OUT OF REACH OF CHILDREN**

### CAUTION PRECAUCIÓN

See additional precautionary statements elsewhere on this label.

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.)

**PLANT HEALTH CARE, INC.**  
2626 Glenwood Avenue, Suite 350  
Raleigh, NC 27608  
1-800-421-9051  
[www.planthealthcare.com](http://www.planthealthcare.com)

**NET WEIGHT: XXX**

Read the entire label before using this product. Read WARRANTY AND DISCLAIMER before buying or using. If terms are not acceptable, return at once unopened.

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### CAUTION

Harmful if swallowed. Harmful if inhaled. Avoid breathing dust. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
<b>If Inhaled</b>	<ul style="list-style-type: none"> <li>▪ Move person to fresh air.</li> <li>▪ If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>▪ Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If Swallowed</b>	<ul style="list-style-type: none"> <li>▪ Call a poison control center or doctor immediately for treatment advice.</li> <li>▪ Have person sip a glass of water if able to swallow.</li> <li>▪ Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>▪ Do not give anything to an unconscious person</li> </ul>

<b>If on Skin</b>	<ul style="list-style-type: none"> <li>▪ Take off contaminated clothing</li> <li>▪ Rinse skin immediately with plenty of water for 15 – 20 minutes</li> <li>▪ Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If in Eyes</b>	<ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ Call a poison control center or doctor for treatment advice.</li> </ul>
<p><b>HOT LINE NUMBER</b></p> <p><b>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, call the National Pesticide Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time, seven days a week. During other times, call the poison control center at 1-800-222-1222.</b></p>	

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants.
- Shoes and socks.
- Waterproof gloves
- Protective Eyewear
- A minimum of a NIOSH-approved particulate filtering face piece respirator with any N, R or P filter (TC-84A); OR a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter (TC-84A); OR a NIOSH-approved powered air purifying respirator with HE filters (TC-21C).

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

#### USER SAFETY RECOMMENDATIONS

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

#### ENVIRONMENTAL HAZARDS

For terrestrial uses: 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 wash waters or rinsate.

#### PHYSICAL OR CHEMICAL HAZARDS

- May Form Combustible (Explosive) Dust - Air Mixtures: Keep away from all ignition sources including heat, sparks and flame. Take precautionary measures against static discharge. Prevent dust accumulations to minimize explosion hazard.
- Do not store in direct sunlight.

#### 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 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.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

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;
- Waterproof gloves; and
- Shoes and socks.

### PRODUCT INFORMATION

PHC-620 contains both a Seed Lubricant (a proven Talc/Graphite Replacement) and a biochemical molecule that stimulates the plant's natural growth and defense systems, enhancing overall plant health. Healthier plants exhibit increased plant stamina and vigor, leading to one or more of the following benefits: improved stand and root establishment, suppressed nematode egg production, increased marketable yield, and enhanced quality. PHC-620 works best when used in conjunction with good crop management practices.

### SITES

Use PHC-620 as a Seed Hopper/Seed Tank treatment for field production of corn and soybean.

### USE PRECAUTIONS

#### PACKAGING

Carefully reseal opened packages immediately after use to minimize exposure to air and moisture.

#### MIXING

PHC-620 may be used in conjunction with other commercial seed treatments and/or with other dry hopper box treatments. Apply PHC-620 only to dry seed. Do not mix PHC-620 with water or any other seed lubricant product. Check with your local Plant Health care, Inc. representative for specific compatibility information for PHC-620 and other labeled products.

#### STORAGE OF TREATED SEED

Seed treated with PHC-620 should be covered and stored in a cool, dry location. When stored properly, seed can be stored up to 3 months. Do not store excess treated seed beyond planting time.

### APPLICATION INSTRUCTIONS

Apply PHC-620 as a dry pre-plant seed treatment. Apply product to dry seed using standard seed treatment equipment or apply directly to the hopper box. When applying directly to the hopper box, fill half the hopper box with seed and sprinkle the appropriate half-rate of PHC-620 over seed. See the appropriate application rates under CROPS and APPLICATION RATES. Finish filling the hopper box with seed and sprinkle the remaining PHC-620 over the new seed. It is important that PHC-620 mixed thoroughly on to the seed.

### CROPS AND APPLICATION RATES

#### Field Crops

Crop	Rate per Unit* of Seed *(80,000 corn seeds or 140,000 soybean seeds)
<b>CORN</b> (Grain, Sweet, Silage, Seed, or Pop) <b>SOYBEAN</b>	One Level Scoop (supplied in container) or 0.38 oz or 10.8 grams

Note: When filling large central fill seed hoppers, add PHC-620 to seed as it is filling the hopper to assure even distribution

DO NOT USE MORE THAN 1 LEVEL SCOOP PER SEED UNIT AS THIS MAY RESULT IN REDUCED PERFORMANCE IN THE EQUIPMENT.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

**PESTICIDE STORAGE**

Keep product away from exposure to air, sunlight, moisture, or heat.

Do not store in temperatures over 110°F for more than 7 days.

Use product within 3 weeks of opening and the same day as mixing.

**PESTICIDE DISPOSAL**

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

**CONTAINER HANDLING**

Non-refillable container. Do not reuse or refill this container. Completely empty container into application equipment. Then offer for recycling if available or dispose of empty container in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND DISCLAIMER****CONDITIONS OF SALE AND EXCLUSIVE 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 of the product, or other unintended consequences may result because of such factors as horticultural practices, use with other products (unless otherwise expressly provided in the Directions for Use of this product), presence of other materials, the manner of use or application, and various environmental conditions, including but not limited to weather conditions and moisture conditions. To the extent consistent with applicable law, all of the aforementioned risks are beyond the control of Plant Health Care, Inc. and the Buyer shall assume all such risks.

**EXCLUSIVE WARRANTIES**

Plant Health Care, Inc. warrants that, at the time of first sale of this product, it conforms to the chemical description on this label and, under normal conditions, 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, if this product does not perform as warranted above, customer's sole remedy for breach of that warranty shall be replacement of the product or refund of the purchase price paid, at the option of Plant Health Care, Inc. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE FOREGOING WARRANTIES AND REMEDIES ARE EXCLUSIVE AND ARE IN LIEU OF ALL OTHER WARRANTIES, TERMS, OR CONDITIONS EXPRESSED OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES, TERMS, OR CONDITIONS OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND SATISFACTORY QUALITY.

**LIMITATION OF LIABILITY**

To the extent consistent with applicable law, Plant Health Care, Inc. excludes for itself and its suppliers any liability, whether based in contract or tort (including negligence), for incidental, consequential, indirect, special, or punitive damages of any kind, or for loss of revenue or profits, loss of business, or crop injury arising out of or in connection with the sale, use, injury, performance, or failure of this product, even if Plant Health Care, Inc. or its authorized reseller has been advised of the possibility of such damages, and limits its liability to replacement of the product or a refund of the purchase price paid, at the option of Plant Health Care, Inc. This disclaimer of liability for damages will not be affected if any remedy provided by this label fails of its essential purpose.

**ASSUMPTION OF RISK**

To the extent consistent with applicable law, Buyer and User of this product assume the risk of any use contrary to the Directions for Use and/or all of the risks inherent in the use of the product as set forth above. Plant Health Care, Inc. offers this product, and the Buyer and User accept it, subject to the foregoing Conditions of Sale and Exclusive Warranty, which may be varied only by agreement in writing signed by a duly authorized representative of Plant Health Care, Inc.

**PROMPT NOTICE OF CLAIM**

Plant Health Care, Inc. must have prompt notice as soon as Buyer or User has reason to believe they may have a claim (not to exceed twenty-one days from the date of application) so that an inspection of the affected property and growing crops may be made. To the extent consistent with applicable law, unless Buyer and User promptly notify Plant Health Care, Inc. of any claims, they shall be barred from obtaining any remedy.

**TANK MIXES**

To the extent consistent with applicable law, tank mixing or use of this product with any other product, which is not specifically and expressly authorized by this label, shall be the exclusive risk of User, Applicator, and/or Application Advisor. Read and follow the entire label of each product to be used in a mix with this product.

**LIMITED USE LICENSE AND PATENTS**

The contents of this package and/or the use of the contents are covered by U.S. Patent Nos. 5,849,868, 5,859,324, 5,776,889, 5,977,060, and 6,277,814 as well as pending patent applications. The purchase of this package grants the Buyer a license, under these patents and patent applications, to use its contents only for treating plants, plant seeds, and other plant parts as described by this label.

PHC-620™ is a trademark of Plant Health Care, Inc. Always read and follow label instructions before buying or using this product.

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