

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 8, 2023

Patricia Flis
Product Registration Manager
Agricultural Solutions
BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709-3528

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

Amendment and BASF's Response to Storage Stability and Corrosion Characteristics) Terms of Registration –Revision to the Basic Confidential Statement of Formula (CSF), and Revision to the Labeling to Remove Expiration date, and Update the Mode of

Action Information Box, and Respirator Description)

Product Name: Velondis Extra

EPA Registration Number: 71840-24 EPA Receipt Date: 01/05/2018

Action Case Number: 00074893

Dear Ms. Flis:

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 05/22/2023

Any CSFs other than that listed above are superseded/no longer valid.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

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

Page 2 of 2 EPA Reg. No. 71840-24 Action Case No. 00074893

12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements 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 EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to 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.

Additionally, in a memorandum dated October 8, 2019 (see one of the enclosures), the EPA rated submitted Storage Stability and Corrosion Characteristics (MRID No. 50812801) as acceptable. Thus, you have fulfilled term #2 of the December 20, 2017, Velondis Extra Registration Notice.

If you have any questions, please contact me by phone at (202) 566-1516 or via email at cerrelli.susanne@epa.gov.

Sincerely,

Susanne Cerrelli Digitally signed by Susanne Cerrelli Date: 2023.06.08 09:59:59 -04'00'

Susanne Cerrelli, Risk Manager Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511M) Office of Pesticide Programs

Enclosures

- 1. Assessment of Term of Registration-Storage Stability and Corrosion Characteristics Studies for Velondis Extra dated 10-8-2019
- 2. EPA Accepted Velondis Extra label



ACCEPTED

Jun 08, 2023

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 71840-24

Velondis™ Extra

{Optional Descriptor: Biofungicide}

For commercial and on-farm use

Seed treatment for disease suppression in corn

Active Ingredients:

Bacillus subtilis strain BU1814*	0.213%
Bacillus amyloliquefaciens strain MBI 600**	3.915%
Other Ingredients:	95.872%
Total:	00.000%

^{*} **Velondis™ Extra biofungicide** contains a minimum of 1.76 x 10⁸ colony forming units per mL

EPA Reg. No. 71840-24

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

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 inside 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 Contents:

Batch Code: Located on physical container

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

^{**} **Velondis Extra** contains a minimum of 1.76 x 10¹⁰ colony forming units per mL

FIRST AID

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 at 1-800-832-HELP (4357).

Precautionary Statements

Personal Protective Equipment (PPE)

The PPE requirements below apply to both Worker Protection Standard (WPS) uses (in general, agricultural-plant uses are covered by the Worker Protection Standard (40 CFR Part 170)) and Non-WPS uses.

Applicators and other handlers must wear:

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

Mixer/loaders and applicators must wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; OR a NIOSH-approved powered air-purifying respirator with an HE filter. Repeated exposures 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.

ENGINEERING CONTROLS

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.607(d) and (e)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- 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

{Environmental hazards statements for container sizes less than 5 gallons.}

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 washwater or rinsate.

{Environmental hazards statements for containers greater than or equal to 5 gallons.}

DO NOT discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. **DO NOT** discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

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.

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
- Shoes plus socks

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses that are NOT within the scope of the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Keep unprotected persons out of treatment area until seeds have dried or been packaged.

STORAGE AND DISPOSAL

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

Pesticide Storage

Ensure container closures are tight. Store in a cool, dry place.

Pesticide Disposal

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

(continued)

STORAGE AND DISPOSAL (continued)

Container Handling

{For containers with capacities less than or equal to 5 gallons}

Nonrefillable container. DO NOT reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Add water - at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of 1/4 of the container volume, and recap. Shake for 30 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water. Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council at 1-877-952-2272 or www.acrecycle.org. Alternatively, puncture and dispose of in a sanitary landfill or by incineration. DO NOT burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

(For containers with capacities greater than 5 gallons)

Nonrefillable container. DO NOT reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Add water - at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of 1/4 of the container volume. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 60 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water. Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council at 1-877-952-2272 or www.acrecycle.org. Alternatively, puncture and dispose of in a sanitary landfill or by incineration. DO NOT burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

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

VelondisTM Extra biofungicide is a product that includes:

 Biofungicide active ingredient, Bacillus subtilis strain BU1814, that inhibits seedling and root pathogens, such as Fusarium spp., Rhizoctonia solani, and Bipolaris sorokiniana

Bacillus subtilis strain BU1814 rapidly colonizes germinating seeds and the developing root system. The same bacteria quickly produce a beneficial biofilm and antimicrobial components promoting Induced Systemic Resistance (ISR) within the plant. This results in suppression of disease organisms that attack such root systems (e.g., Fusarium spp., Rhizoctonia solani, and Bipolaris sorokiniana).

 Biofungicide active ingredient, Bacillus amyloliquefaciens strain MBI 600, that inhibits seedling and root pathogens, such as Fusarium spp., Rhizoctonia spp., and Pythium ultimum

Bacillus amyloliquefaciens strain MBI 600 initially colonizes germinating seeds. The same bacteria then colonize the developing root systems of plants and suppress disease organisms that attack such root systems (e.g., Fusarium spp., Rhizoctonia spp., and, under some conditions, Pythium ultimum).

When combined as **Velondis Extra**, the differential modes of action of the two biological actives can contribute to complementary activity with certain chemical seed treatments, resulting in increased and more uniform field performance. Both biofungicide active components grow along the developing root system, and can extend the window of disease protection longer into the growing season. The plants produce a more vigorous root system, which often results in more uniform stands, overall improved plant growth and greater yield potential.

Label statement required by the State of Oregon

Information regarding the contents and levels of metals in this product is available on the Internet at http://www.aapfco.org/metals.html

Application Instructions

Velondis Extra biofungicide can be used in commercial seed treatment facilities and on-farm. **DO NOT** use for applications at hopper box and planter box. For use with commercial treatment application equipment only.

Mixing Instructions: Apply **Velondis Extra** as a water-based slurry alone or with other seed treatment products (fungicides, insecticides, nematicides, fertilizers, and rhizobial inoculants). **DO NOT** mix **Velondis Extra** with any copper-based products.

Prior to mixing, determine physical compatibility by mixing proportional quantities of the products in water. **DO NOT** mix **Velondis Extra** with any other seed treatment product that bears a label prohibition against such mixing. When tank mixing **Velondis Extra** with any other seed treatment product, observe the most restrictive of the labeling limitations and precautions of all products used in mixtures.

ATTENTION: Use only cool, chlorine-free water in the tank mix. If one or more treatments are not physically compatible (harmful), mix those products in, and apply them from, a separate mix tank.

To mix, first add the other seed treatment product(s) to the mix tank with approximately 1/2 of the required water. Slowly add **Velondis Extra** to the slurry until a uniform suspension is obtained. Add the remainder of the water while maintaining constant agitation. **DO NOT** store mixed slurries for longer than 24 hours.

Some ingredients in **Velondis Extra** may not completely solubilize; therefore, it is important to maintain a uniform suspension by continuously agitating the solution throughout the application process. **DO NOT** exceed label application dosage rates.

Because smaller seed has a greater surface area to volume ratio than larger seed, the average size of the seed being treated influences the application rate. For each crop listed in the **Crop Specific Directions** table, apply **Velondis Extra** at rates from the higher end of the specified application rate range when treating smaller seed. Additionally, use the higher end of the specified application range when treated seed is to be planted in fields that historically experience severe disease pressure.

Crop Specific Directions

Crop	Target Diseases	Velondis [™] Extra biofungicide Use Rate per Application
Corn, all types	Fusarium spp.	0.10-1.00 fl oz per 100 lbs of seed 3.0-30 mL per 100 kg of seed
	Rhizoctonia solani	
	Bipolaris sorokiniana	
	Pythium ultimum	

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.

Velondis is a trademark of BASF.

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Supersedes: NVA 2016-04-545-0095

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