

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 19, 2015

Patrick McCain Senior Regulatory Product Manager, Seedcare Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, NC 27419

Subject: Label Amendment – Added modes of action & formulation descriptor, made

revisions to CAS numbers, First Aid, Environmental Hazards, and Resistance

Management sections and some other minor edits.

Product Name: Vibrance Extreme EPA Registration Number: 100-1382 Application Date: June 17, 2015

Decision Number: 506989

Dear Ms. McCain:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the 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 the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list 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 the Agency 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.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Aswathy Balan by phone at 703-347-0510, or via email at balan.aswathy@epa.gov.

Sincerely,

Heather Garvie, Product Manager 24

Fungicide and Herbicide

Registration Division (7505P)

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Office of Pesticide Programs

# [MASTER]

# GROUP 3 4 7 FUNGICIDES

#### Vibrance® Extreme

# **Fungicide**

A seed treatment for protection against certain diseases of barley, oats, rye, triticale, and wheat.

Active Ingredient:

Sedaxane <sup>1</sup>	1.22%
Difenoconazole <sup>2</sup>	5.86%
Mefenoxam <sup>3</sup>	1.46%
Other Ingredients:	91.46%
Total:	100.00%

<sup>&</sup>lt;sup>1</sup>CAS No. 874967-67-6

Vibrance Extreme is a flowable concentrate for seed treatment containing 0.115 pounds of sedaxane, 0.552 pounds of difenoconazole, and 0.138 pounds of mefenoxam per gallon.

#### KEEP OUT OF REACH OF CHILDREN.

# **CAUTION**

See additional precautionary statements and directions for use inside booklet.

EPA Reg. No. 100-1382

EPA Est.

2.5 gallons 30 gallons 110 gallons \_\_\_\_ gallons **Net Contents** 

ACCEPTED

11/19/2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 100-1382

<sup>&</sup>lt;sup>2</sup>CAS No. 119446-68-3

<sup>&</sup>lt;sup>3</sup>CAS Nos. 70630-17-0 and 69516-34-3

	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	
	continuing rinsing.	
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
If swallowed	Call a poison control center or doctor immediately for treatment	
	advice.	
	<ul> <li>Have person sip a glass of water if able to swallow.</li> </ul>	
	Do not induce vomiting unless told to by a poison control center	
	or doctor.	
	<ul> <li>Do not give anything to an unconscious person.</li> </ul>	
If on skin or	Take off contaminated clothing.	
clothing	<ul> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>	
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
If inhaled	Move person to fresh air.	
	• If person is not breathing, call 911 or an ambulance, then give	
artificial respiration, preferably mouth-to-mouth if possible.		
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
Have the product	container or label with you when calling a poison control center or	
doctor, or going for treatment.		
HOT LINE NUMBER		
For 24-Hour Medical Emergency Assistance (Human or Animal) or		
Chem	Chemical Emergency Assistance (Spill, Leak, Fire, or Accident),	
Call		
1-800-888-8372		

# PRECAUTIONARY STATEMENTS

# **Hazards to Humans and Domestic Animals**

# **CAUTION**

Causes moderate eye irritation. Avoid contact with 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.

## Personal Protective Equipment (PPE)

# Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical resistant gloves: barrier laminate, butyl rubber ≥14 mils, nitrile rubber
   ≥14 mils, neoprene rubber ≥14 mils, polyvinyl chloride (PVC) ≥14 mils, or Viton®
   ≥14 mils
- Shoes plus socks

# **User Safety Requirements**

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

## **Engineering Controls**

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6)), the handler PPE requirements may be reduced or modified as specified in the WPS.

# 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**

This product is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwater or rinsate. Treated seed exposed on soil surface may be hazardous to birds. Cover or collect seeds spilled during loading.

# **Groundwater Advisory**

Mefenoxam is known to leach through soil into groundwater under certain conditions as a result of label use. Mefenoxam may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.

#### CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. 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 manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

# **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 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), notifications to workers, 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 48 hours. Exception: If the seed is treated with the product and the treated seed 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
- Chemical resistant gloves: barrier laminate, butyl rubber ≥14 mils, nitrile rubber ≥14 mils, neoprene rubber ≥14 mils, polyvinyl chloride (PVC) ≥14 mils, Viton ≥14 mils
- Shoes plus socks

FAILURE TO FOLLOW THE DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN CROP INJURY, POOR DISEASE CONTROL, AND/OR ILLEGAL RESIDUES.

#### PRODUCT INFORMATION

Vibrance Extreme is a systemic seed treatment that provides protection against certain seed-borne, soil-borne, and early season foliar diseases of wheat, barley, oats, rye and triticale. The active ingredients in Vibrance Extreme are sedaxane, difenoconazole and mefenoxam. Sedaxane enhances protection against *Ustilago* spp. and *Rhizoctonia* spp. in cereals. Difenoconazole provides protection against several seed, seedling and certain foliar diseases including bunts and smuts. Mefenoxam provides protection against damping-off caused by *Pythium* spp.

Maximum usage when applying both metalaxyl- and mefenoxam-containing products to the same crop within the same season: Do not apply more than the maximum seasonal total for the active ingredient as stated on the label of the product containing the lowest seasonal total on that crop.

#### RESISTANCE MANAGEMENT

# GROUP 3 4 7 FUNGICIDES

Vibrance Extreme contains difenoconazole, a Group 3 fungicide; mefenoxam, a Group 4 fungicide; and sedaxane, a Group 7 fungicide. Difenoconazole belongs to the triazole class of chemistry and is a demethylation inhibitor of sterol biosynthesis (DMI) which disrupts membrane synthesis of the fungal cell. Mefenoxam belongs to the phenylamide class of chemistry which interferes with fungal RNA synthesis. Sedaxane is a succinate dehydrogenase inhibitor (SDHI) and belongs to the carboxamide class of chemistry which disrupts cellular respiration and energy generation.

Fungal populations may contain individuals naturally resistant to Group 3, 4, or 7 fungicides and if used repeatedly in the same fields, then resistant members may eventually dominate the population. Because resistance development cannot be predicted, the use of this product should conform to sound resistance management strategies such as alternation with fungicides with a different mode of action and/or tank mixes established for the crop and use area.

Use should be based on an IPM program that includes field sanitation, scouting, historical information related to pesticide use, and crop rotation. The IPM program should also consider cultural, biological, and other chemical control practices.

Syngenta encourages responsible product stewardship to ensure effective long term control of the fungal diseases on this label.

## For additional information on Fungicide Resistance Management:

- Contact Syngenta representatives at 1-800-334-9481
- Contact your local extension specialist or certified crop advisor
- Visit the Fungicide Resistance Action Committee (FRAC) on the web at: http://www.frac.info

#### MIXING INSTRUCTIONS

Apply Vibrance Extreme as a water-based slurry utilizing standard slurry treatment equipment which provides uniform seed coverage. Uneven or incomplete seed coverage may not give the desired level of disease control. Thoroughly mix the specified amount of Vibrance Extreme into the required amount of water for the slurry and dilution rate to be used. Follow the manufacturer instructions for the seed treatment equipment being used. Maintain constant agitation of the slurry during the treatment. If application is stopped maintain agitation of slurry until all of the slurry has been used. Vibrance Extreme contains an EPA-approved/colorant that imparts an unnatural color to the seed as required by the Federal Seed Act. Allow seed to dry before bagging.

#### **TANK MIXES**

Tank mix when a problem is expected with the diseases that are not controlled by Vibrance Extreme. Confirm physical compatibility, seed safety, seed safety in stored seed, and biological efficacy before tank mixing with other seed treatment products.

Follow the label directions for the most restrictive of label precautions and limitations. This product cannot be mixed with any product containing a label prohibiting such mixing.

For protection from various insects on registered crops, Vibrance Extreme seed treatment may be mixed with Cruiser® 5FS seed treatment Insecticide in commercial seed treatment facilities with closed transfer including closed mixing, loading, calibrating, and closed treatment equipment only. This tank-mix option is only valid for those crops common to the registered labels of Vibrance Extreme seed treatment and Cruiser 5FS seed treatment insecticide. Follow all appropriate directions, precautions, as specified on the respective product labels.

#### SEED BAG LABEL REQUIREMENT

The Federal Seed Act requires that bags containing treated seeds shall be labeled with the following statements:

- This seed has been treated with sedaxane, difenoconazole, and mefenoxam, fungicides.
- Do not use for feed, food, or oil purposes.
- User is responsible for ensuring that the seed bag meets all requirements under the Federal Seed Act.

In addition, the U.S. Environmental Protection Agency requires the following statements on bags containing seed treated with Vibrance Extreme fungicide:

- Store away from food and feedstuffs.
- Do not allow children, pets, or livestock to have access to treated seeds.
- Wear long-sleeved shirt, long pants, and waterproof gloves when handling treated seed.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Dispose of all excess treated seed. Left over treated seed may be doublesown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwater.
- Dispose of seed packaging in accordance with local requirements.
- In the event of crop failure or harvest of a crop grown from seed treated with Vibrance Extreme, the following crops may be replanted immediately: canola, soybean, and cereal grains (barley, oat, rye, triticale, and wheat). For any other crops the minimum plantback interval is 30 days from the date seeds treated with Vibrance Extreme were planted.
- Excess treated seed may be used for ethanol production only if (1) byproducts are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used for agronomic practice.
- The maximum number of applications per season is 2.

# **CROP USE DIRECTIONS**

# **Restrictions:**

The maximum number of applications per season is 2.

Crop	Diseases Protection Against the Following	Rate (fl oz/100 lb seed)
Barley	General Seed Rots <sup>1</sup> : Seedling Blight, Root Rot, Damping-off caused by seed- and soil-borne Fusarium spp. or Rhicoztonia spp. Seedling Blight, Root Rot, Damping-off caused by soil-borne Pythium spp. Seed-borne Septoria <sup>2</sup> Covered Smut False Loose Smut True Loose Smut	2.8-5.6

Crop	Diseases Suppressed <sup>3</sup>	Rate (fl oz/100 lb seed)
Barley	Common Root Rot (Cochliobolus spp.)	2.8-5.6
	Fusarium Crown and Foot Rot	
	Take-All	

Crop	Diseases Protection Against the Following	Rate (fl oz/100 lb seed)
Oats	General Seed Rots <sup>1</sup> Seedling Blight, Root Rot, and Damping-Off caused by seed- and soil-borne <i>Fusarium</i> spp. or <i>Rhizoctonia</i> spp. Seedling Blight, Root Rot, and Damping-Off caused by soil-borne <i>Pythium</i> spp. Covered Smut Loose Smut	2.8-5.6

Crop	Diseases Suppressed <sup>3</sup>	Rate (fl oz/100 lb seed)
Oats	Common Root Rot (Cochliobolus spp.)	2.8-5.6

Crop	Diseases Controlled	Rate (fl oz/100 lb seed)
Rye	General Seed Rots <sup>1</sup> Seedling Blight, Root Rot, and Damping-Off caused by seed- and soil-borne Fusarium spp. or Rhizoctonia spp. Seedling Blight, Root Rot, and Damping-Off caused by soil-borne Pythium spp. Seed-borne Septoria <sup>2</sup>	2.8-5.6
	Common Bunt <sup>4</sup> Dwarf Bunt <sup>4</sup>	

Crop	Diseases Suppressed <sup>3</sup>	Rate (fl oz/100 lb seed)
Rye	Common Root Rot (Cochliobolus spp.)	2.8-5.6
	Fusarium Crown and Foot Rot	
	Take-All	

Crop	Diseases Protection Against the	Rate (fl oz/100 lb seed)
	Following	
Winter Wheat and Triticale	General Seed Rots <sup>1</sup> Seedling Blight, Root Rot, and Damping-Off caused by seed- and soil-borne Fusarium spp. or Rhizoctonia spp. Seedling Blight, Root Rot, and Damping-Off caused by soil-borne Pythium spp. Seed-borne Septoria <sup>2</sup> Septoria Leaf Blotch <sup>2,5</sup> Common Bunt <sup>4</sup> Dwarf Bunt <sup>4</sup> Karnal Bunt Flag Smut Fusarium Seed Scab Loose Smut Pythium Damping Off	2.8-5.6

Crop	Diseases Supressed <sup>3</sup>	Rate (fl oz/100 lb seed)
Winter Wheat	Common Root Rot (Cochliobolus spp.) Fusarium Crown and Foot or Root Rot	2.8-5.6
	Take-All	

Crop	Diseases Protection Against the Following Diseases Supressed <sup>3</sup>	Rate (fl oz/100 lb seed)
Spring Wheat	General Seed Rots <sup>1</sup> Seedling Blight, Root Rot, and Damping-Off caused by seed- and soil-borne Fusarium spp. or Rhizoctonia spp. Seed-borne Septoria <sup>2</sup> Seedling Blight, Root Rot, and Damping-Off caused by soil-borne Pythium spp. Common Bunt <sup>4</sup> Fusarium Seed Scab Karnal Bunt Loose Smut Pythium Damping Off	2.8-5.6

Crop	Diseases Supressed <sup>3</sup>	Rate (fl oz/100 lb seed)
Spring Wheat	Common Root Rot (Cochliobolus spp.) Fusarium Crown and Foot and Root Rot Take-All	2.8-5.6

<sup>&</sup>lt;sup>1</sup>Active on pathogens that cause general seed rots. This includes those caused by saprophytic organisms such as *Fusarium*, *Pythium*, *Rhizoctonia*, *Penicillium* and *Aspergillus*.

#### STORAGE AND DISPOSAL

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

#### **Pesticide Storage**

Store in original containers only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, mop and remove to chemical waste storage area until proper disposal can be made if product cannot be used according to the label.

#### **Pesticide Disposal**

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative of the nearest EPA Regional Office for guidance.

# **Container Handling [less than or equal to 5 gallons]**

Non-refillable 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

<sup>&</sup>lt;sup>2</sup>Use 5.6 fl oz/100 lb for protection against this disease.

<sup>&</sup>lt;sup>3</sup>Suppression means consistent protection at a level which is not optimal but is still of commercial benefit.

<sup>&</sup>lt;sup>4</sup>Provides protection against both seed- and soil-borne bunts (common, dwarf).

<sup>&</sup>lt;sup>5</sup>Early season foliar disease protection for first 4 weeks after planting. For full season protection, apply a foliar fungicide according to label directions.

begins to drip. Fill the container ¼ full with water and recap. Shake for 10 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. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

## Container Handling [greater than 5 gallons – mini bulk]

Non-refillable 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. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 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. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

# Container Handling [greater than 5 gallons - bulk]

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the person refilling. To clean container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup and disposal of wastes. In the event of a major spill, fire, or other emergency, call 1-800-888-8372, day or night.

CONTAINER IS NOT SAFE FOR FOOD, FEED OR DRINKING WATER.

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Manufactured for: Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, North Carolina 27419-8300

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