PROLINE™ 480 SC Fungicide

For control of specified diseases on various crops.

Active Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione .......................................................... 41.0%
Inert Ingredients: .......................................................................................... 59.0%

Contains 4 pounds Prothioconazole per gallon

EPA Reg. No. 264-825 EPA Est.

STOP - Read the label before use
KEEP OUT OF REACH OF CHILDREN

CAUTION

For MEDICAL AND TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED:
- Immediately call a poison control center or doctor for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

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.
- Call a poison control center or doctor for further treatment advice.

IF ON SKIN OR CLOTHING:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

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.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: No specific antidote. Treat symptomatically.

PRECAUTIONARY STATEMENTS

HAZARD (TO HUMANS AND DOMESTIC ANIMALS)

CAUTION

Harmful if swallowed or inhaled. Causes moderate eye irritation. Avoid contact with eyes and clothing. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.
Personal Protective Equipment
Applicators and other handlers must wear:
- Long-sleeved shirt and long pants
- Chemical resistant gloves made of any waterproof material
- Shoes plus socks

Follow 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.

Engineering Control Statements
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 immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Wash the outside of gloves before removing.

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 rinsewater.

This product is toxic to estuarine/marine invertebrates, and freshwater/estuarine/marine aquatic plants. 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 rinsewater.

Prothioconazole-desthio (a degrade of prothioconazole) is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

Drift and runoff are hazardous to aquatic organisms in water adjacent to treated areas. This product has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow watertables are more prone to produce runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

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) and restricted-entry interval and notification to workers (as applicable). 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.

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 made of any waterproof material.
- Shoes plus socks
STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If container is leaking, invert to prevent leakage. If the container is leaking or material is spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed for pesticides below. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer CropScience Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer CropScience Emergency Response Telephone No. is 1-800-334-7577.

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

Container Disposal: Non-refillable container. Do not reuse or refill this container. Triple rinse or pressure 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. 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.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Offer for recycling, if available. If not recycled, then puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

GENERAL INFORMATION

PROLINE™ 480 SC is a broad-spectrum systemic fungicide for the control of Ascomycetes, Basidiomycetes and Deuteromycetes diseases in a variety of crops including barley, canola, dry bean crop group (chickpeas, lentils), peanuts, rapeseed, Indian rapeseed, field mustard, crambe, soybean, sugar beets and wheat. Under conditions conducive to extended infection periods or high disease pressure, additional fungicide applications beyond the number allowed by this label may be needed. Under these conditions use another fungicide registered for the crop/disease. Equipment must be properly calibrated before use.

Resistance Management Statement

PROLINE 480 SC is a Group 3 fungicide which exhibits no known cross-resistance to other fungicide groups. However, fungal pathogens are known to develop resistance to products with the same mode of action when used repeatedly. Any fungal population may contain or develop individuals that are resistant to PROLINE 480 SC and other Group 3 fungicides. If Group 3 fungicides are used repeatedly in the same field or in successive years as the primary method of control for targeted diseases, the resistant isolates may eventually dominate the fungal population. Because resistance development cannot be predicted, the use of this product should conform to resistance management strategies established for the crop and use area. Such strategies may include rotation and/or tank mixing with products having different modes of action or limiting the total number of applications per season. Contact your local extension specialist, certified crop advisor, and/or manufacturer for fungicide resistance management and/or integrated disease management recommendations for specific crops and pathogen populations. Bayer CropScience encourages responsible resistance management to ensure effective long-term control of the fungal diseases on this label.

Spray Equipment/Volumes

PROLINE 480 SC may be applied by either ground or aerial application equipment. Apply in a minimum of 10 gallons of spray solution per acre by ground sprayer or in a minimum of 5 gallons of spray solution per acre by aircraft spray equipment. Check equipment calibration frequently. Complete coverage and uniform application are essential for the most effective results, especially when lower spray volumes are applied. If necessary, increase the spray volume per acre for complete crop coverage.

Mixing Procedures

Prepare no more spray mixture than is necessary for the immediate operation. Thoroughly clean spray equipment before using this product. Maintain maximum agitation throughout the spray operation. Do not let the spray mixture stand overnight in the spray tank. Flush the spray equipment thoroughly following each use and apply the rinsate to the previously treated area or dispose of the rinsate according to local regulations.

PROLINE 480 SC Alone: Add ½ of the required amount of water to the mix tank. With the agitator running, add the PROLINE 480 SC to the tank. Continue agitation while adding the remainder of the water. Begin application of the solution after the product has completely and uniformly dispersed into the mix water. Maintain agitation until all of the mixture has been applied.

PROLINE 480 SC + Tank-Mix Partners: Add ¼ of the required amount of water to the mix tank. Start the agitator running before adding any of the tank-mix partners. In general, tank-mix partners should be added in this order: products packaged in water-soluble packaging*, wettable powders, wettable granules (dry flowables), liquid flowables, liquids and emulsifiable concentrates. Always allow each tank-mix partner to become fully and uniformly dispersed before adding the next product. Provide sufficient agitation while adding the remainder of the water. Maintain agitation until all of the mixture has been applied.
*Note: When using PROLINE 480 SC in tank mixtures, all products in water-soluble packaging should be added to the tank before any other tank-mix partner, including PROLINE 480 SC. Allow the water-soluble packaging to completely disperse before adding any other tank-mix partner to the tank.

If using PROLINE 480 SC in a tank mixture, observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations; which appear on the tank-mix product label. No label dosage rate should be exceeded, and the most restrictive label precautions and limitations must be followed. This product must not be mixed with any product that prohibits such mixing. Tank mixtures or other applications of products are permitted only in those states in which the products are registered.

PROLINE 480 SC is compatible with most insecticides, fungicide, herbicide and foliar nutrient products. However, the physical compatibility of PROLINE 480 SC with tank-mix partners should be tested before use. To determine the physical compatibility of PROLINE 480 SC with other products, use a jar test, as described below.

Using a quart jar, add the proportionate amounts of the products to 1 qt. of water. Add wettable powders and water-dispersible granular products first, then liquids, and emulsifiable concentrates last. After thoroughly mixing, let stand for at least 5 minutes. If the combination remains mixed or can be remixed readily, it is physically compatible. Once compatibility has been proven, use the same procedure for adding required ingredients to the spray tank. For further information contact your local Bayer CropScience representative.

The crop safety of all potential tank mixes including additives and other pesticides on all crops has not been tested. Before applying any tank mixture not specifically recommended on this label, the safety to the target crop should be confirmed. To test for crop safety, apply PROLINE 480 SC to the target crop in a small area and in accordance with label instructions for the target crop.

Aerial Application: Avoid application under conditions when uniform coverage cannot be obtained or when excessive spray drift may occur. Do not apply directly to humans or animals.

Chemigation: Do not apply this product through any type of irrigation system.

Adjuvants: PROLINE 480 SC is recommended to be used with a registered non-ionic surfactant at the lowest recommended labeled rate for most crops. Refer to the individual crop recommendations for those specific uses where a surfactant is not recommended.

Recommendations to Avoid Spray Drift
Do not make applications when conditions favor drift beyond the target application area. When drift may be a problem, take measures to reduce drift, including:
1. Do not spray if wind speeds are or become excessive. Do not spray if wind speed is 15 mph or greater. If non-target crops are located downwind, use caution when spraying if wind is present. Do not spray if winds are gusty.
2. Use caution when conditions are favorable for drift (high temperatures, drought, low relative humidity).
3. Do not apply when temperature inversion exists. If inversion conditions are suspected, consult with local weather services before making an application.

ROTATIONAL RESTRICTIONS
Treated areas may be replanted with any crop specified on this label as soon as practical after last application. For crops not listed on this label, do not plant back within 30 days of last application.

USE DIRECTIONS FOR SPECIFIC CROPS
PROLINE 480 SC provides control or suppression of many important diseases of barley, canola, the dry bean crop group (including chickpeas, lentils), peanuts, rapeseed, Indian rapeseed, field mustard, crambe, soybean, sugar beets and wheat. When reference is made to disease suppression, suppression can mean either erratic control from good to fair or consistent control at a level below that obtained with the best commercial disease control products.
### Recommended Applications

<table>
<thead>
<tr>
<th>CROP</th>
<th>DISEASE CONTROLLED</th>
<th>RATE OF PROLINE 480 SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barley</td>
<td>Fusarium Head Blight <em>(Fusarium spp.)</em> <em>(Suppression Only)</em></td>
<td>4.3 to 5.7 fl oz. per acre</td>
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<tr>
<td></td>
<td>Leaf and Stem Diseases</td>
<td></td>
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<tr>
<td></td>
<td>Net Blotch <em>(Pyrenophora teres)</em></td>
<td>2.8 to 4.3 fl oz. per acre</td>
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<tr>
<td></td>
<td>Scald <em>(Rhychosporium secalis)</em></td>
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<tr>
<td></td>
<td>Spot Blotch <em>(Cochliobolus sativus)</em></td>
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</table>

**Application Directions**

**Fusarium Head Blight (Suppression Only):** Apply PROLINE 480 SC as a preventative foliar spray within the time period when 70 to 100% of the barley heads on the main stem are fully emerged (~ Feekes Growth Stages 10.3 to 10.5) when weather conditions are favorable for disease development and up to 3 to 5 days after full head emergence. Spray equipment must be set up to provide good coverage to barley heads. To achieve thorough barley head coverage using ground application equipment, it is recommended to use forward and backward mounted nozzles or nozzles that have a two-directional spray, such as Twinjet nozzles. Nozzles should be operated within the spray pressure recommendations suggested by the manufacturer.

**Leaf and Stem Diseases:** Apply PROLINE 480 SC as a preventive foliar spray when the earliest disease symptoms appear on the leaves or stems. Barley fields should be observed closely for early disease symptoms, particularly when susceptible varieties are planted and/or under prolonged conditions favorable for disease development.

**General Comments:** Apply up to two (2) applications of PROLINE® 480SC per year. Repeat applications using a 14-day spray interval if conditions remain favorable for continued or increasing disease development. Applications may be made by ground or aerial spray equipment.

A maximum of 9.37 fl oz. of PROLINE 480 SC may be applied per acre per year. Do not apply two applications at 5.7 fl oz. per acre per year. PROLINE 480 SC may be applied up to the point where barley heads are in the full flower growth stage (Feekes 10.52).

Do not apply within 32 days of harvest.

### Recommended Applications

<table>
<thead>
<tr>
<th>CROP</th>
<th>DISEASE CONTROLLED</th>
<th>RATE OF PROLINE 480 SC</th>
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</thead>
<tbody>
<tr>
<td>Canola</td>
<td>Sclerotinia Stem Rot <em>(Sclerotinia sclerotiorum)</em></td>
<td>4.3 to 5.7 fl oz. per acre</td>
</tr>
</tbody>
</table>

**Application Directions**

Apply PROLINE 480 SC when the canola crop is in the 20 - 50% bloom stage. This will be approximately 4-8 days after the canola crop begins to flower. Best protection will be achieved when the fungicide is applied prior to petals beginning to fall, and will allow for the maximum number of petals to be protected. The 4.3 fl oz. per acre rate is the recommended rate for most canola crops, however, the higher rate is recommended for fields with a history of heavy disease pressure or for dense crop stands. Good spray coverage of the plants is essential.

**General Comments:** Apply up to two (2) applications of PROLINE 480 SC per year. Repeat applications as needed using a 14-day spray interval if conditions remain favorable for continued or increasing disease development. Applications may be made by ground or aerial spray equipment.

A maximum of 11.4 fl oz. of PROLINE 480 SC may be applied per year. PROLINE 480 SC may be applied until the 50% bloom stage. This will be when the canola crop is at its maximum yellow color, and prior to significant petal fall. Do not apply within 36 days of harvest.
### RECOMMENDED APPLICATIONS

<table>
<thead>
<tr>
<th>CROP</th>
<th>DISEASE CONTROLLED</th>
<th>RATE OF PROLINE 480 SC</th>
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</thead>
<tbody>
<tr>
<td>Chickpea</td>
<td>Ascochyta Blight (Ascochyta spp.)</td>
<td>4.3 to 5.7 fl oz. per acre</td>
</tr>
</tbody>
</table>

**Application Directions**

Apply PROLINE 480 SC at the first sign of disease. Use the higher use rate when conditions are favorable for severe disease pressure and/or when growing less disease resistant varieties.

**General Comments**: Apply up to three (3) applications of PROLINE 480 SC per year. Repeat applications as needed using a 10- to 14-day spray interval if conditions remain favorable for continued or increasing disease development. To optimize disease control, the lowest labeled rate of a spray surfactant should be tank-mixed with PROLINE 480 SC. Applications may be made by ground or aerial spray equipment.

A maximum of 17.1 fl oz. of PROLINE 480 SC may be applied per acre per year. Allow a minimum of 7 days from the last application until cutting or swathing the crop for harvest.

### RECOMMENDED APPLICATIONS

<table>
<thead>
<tr>
<th>CROP</th>
<th>DISEASE CONTROLLED</th>
<th>RATE OF PROLINE 480 SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dried Shelled Peas and Beans Subgroup (except soybeans)</td>
<td>White Mold (<em>Sclerotinia sclerotiorum</em>)</td>
<td>4.3 to 5.7 fl oz. per acre</td>
</tr>
<tr>
<td><em>Lupinus</em> spp. (Grain, Sweet, White and White Sweet lupins)</td>
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<tr>
<td><em>Phaseolus</em> spp. (Field, Kidney, Dry lima, Navy, Pinto and Tepary beans)</td>
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<tr>
<td><em>Vigna</em> spp. (Adzuki bean, Blackeyed pea, Catjang, Cowpea, Crowder pea, Moth bean, Mung bean, Rice bean, Southern pea and Urd bean)</td>
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<tr>
<td>Dry broad bean</td>
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<tr>
<td>Guar</td>
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<tr>
<td>Lablab bean</td>
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<tr>
<td><em>Pisum</em> spp. (Pea (including Field pea) and Pigeon pea)</td>
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</tbody>
</table>

**Application Directions**

Apply PROLINE 480 SC at the first sign of disease. Use the higher use rate when conditions are favorable for severe disease pressure and/or when growing less disease resistant varieties.

**General Comments**: Apply up to three (3) applications of PROLINE 480 SC per year. Repeat applications as needed using a 5- to 14-day spray interval if conditions remain favorable for continued or increasing disease development. To optimize disease control, the lowest labeled rate of a spray surfactant should be tank-mixed with PROLINE 480 SC. Applications may be made by ground or aerial spray equipment.

A maximum of 17.1 fl oz. of PROLINE 480 SC may be applied per acre per year. Allow a minimum of 7 days from the last application until cutting or swathing the crop for harvest.
### RECOMMENDED APPLICATIONS

<table>
<thead>
<tr>
<th>CROP</th>
<th>DISEASE CONTROLLED</th>
<th>RATE OF PROLINE 480 SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lentils</td>
<td>Ascochyta Blight (Ascochyta spp.)</td>
<td>4.3 to 5.7 fl oz. per acre</td>
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<tr>
<td></td>
<td>Application Directions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Apply PROLINE 480 SC at early flower or at the first sign of disease. Use the higher use rate when conditions are favorable for severe disease pressure and/or when growing less disease resistant varieties.</td>
<td></td>
</tr>
</tbody>
</table>

General Comments: Apply up to three (3) applications of PROLINE 480 SC per year. Repeat applications as needed using a 10- to 14-day spray interval if conditions remain favorable for continued or increasing disease development. To optimize disease control, the lowest labeled rate of a spray surfactant should be tank-mixed with PROLINE 480 SC. Applications may be made by ground or aerial spray equipment.

A maximum of 17.1 fl oz. of PROLINE 480 SC may be applied per acre per year. Allow a minimum of 7 days from the last application until cutting or swathing the crop for harvest.

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<thead>
<tr>
<th>CROP</th>
<th>DISEASE CONTROLLED</th>
<th>RATE OF PROLINE 480 SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapeseed</td>
<td>Sclerotinia Stem Rot (Sclerotinia sclerotiorum)</td>
<td>4.3 to 5.7 fl oz. per acre</td>
</tr>
<tr>
<td>Indian rapeseed</td>
<td>Application Directions</td>
<td></td>
</tr>
<tr>
<td>Field mustard</td>
<td>Apply PROLINE 480 SC when the crop is in the 20 - 50% bloom stage. Utilize the higher rate for fields with a history of heavy disease pressure or for dense crop stands. Good spray coverage of the plants is essential.</td>
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<tr>
<td>Crambe</td>
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</table>

General Comments: Apply up to two (2) applications of PROLINE 480 SC per year. Repeat applications as needed using a 14-day spray interval if conditions remain favorable for continued or increasing disease development. Applications may be made by ground or aerial spray equipment.

A maximum of 11.4 fl oz. of PROLINE 480 SC may be applied per year. PROLINE 480 SC may be applied until the 50% bloom stage. Do not apply within 36 days of harvest.
### RECOMMENDED APPLICATIONS

<table>
<thead>
<tr>
<th>CROP</th>
<th>DISEASE CONTROLLED</th>
<th>RATE OF PROLINE 480 SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanut</td>
<td>In-furrow and Banded Cylindrocladium Black Rot (<em>Cylindrocladium crotalariae</em>)</td>
<td>0.4 fl oz. per 1000 row feet (5.7 fl oz. per acre)</td>
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<tr>
<td></td>
<td>(Suppression Only)</td>
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<tr>
<td></td>
<td>Soil-Borne</td>
<td>5.7 fl oz. per acre</td>
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<tr>
<td></td>
<td>Sclerotium Rot (<em>Sclerotium rolfsii</em>)</td>
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<tr>
<td></td>
<td>White Mold, Southern Blight, Southern Stem Rot</td>
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<tr>
<td></td>
<td>Rhizoctonia Limb Rot, Peg Rot, Pod Rot (<em>Rhizoctonia solani</em>)</td>
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<tr>
<td></td>
<td>Cylindrocladium Black Rot (<em>Cylindrocladium crotalariae</em>) (Suppression Only)</td>
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<tr>
<td></td>
<td>Foliar</td>
<td>5.0 to 5.7 fl oz. per acre</td>
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<tr>
<td></td>
<td>Early Leaf Spot (<em>Cercospora arachidicola</em>)</td>
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<tr>
<td></td>
<td>Late Leaf Spot (<em>Cercosporidium personatum</em>)</td>
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<tr>
<td></td>
<td>Leaf Rust (<em>Puccinia arachidicola</em>)</td>
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<tr>
<td></td>
<td>Web Blotch (<em>Phoma arachidicola</em>)</td>
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<tr>
<td></td>
<td>Leaf Scorch and Pepper Spot (<em>Leptosphaeria cruciata</em>)</td>
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</tbody>
</table>

**Application Directions**

**In-furrow and Banded Spray Program:** Apply 5.7 fl oz. per acre (0.4 fl oz. per 1000 row feet if on 36 inch row spacing) in the furrow at planting. PROLINE 480 SC may also be applied in a 4- to 6-inch band over the row at or near emergence.

**Foliar Disease Spray Program:** Apply the specified rate in a preventive spray schedule. Apply up to four (4) sprays using a 14-day interval. Use the higher use rate when conditions are favorable for severe disease pressure and/or when growing less disease resistant varieties.

**Soil-Borne Disease Spray Program:** For optimum control of the specified soil-borne diseases, four consecutive applications of PROLINE 480 SC must be made at 14-day intervals. In a typical 7 spray application program beginning 30-40 days after planting or as recommended by the local Extension Service, PROLINE 480 SC should be applied for sprays 3, 4, 5 and 6. Applications of fungicides with a different mode of action should be made prior to and following applications of PROLINE 480 SC to discourage development of resistant strains of fungi. Use PROLINE 480 SC in conjunction with cultural practices that are known to reduce the severity of soil-borne diseases, such as proper crop rotation practices.

For control of soil-borne diseases when using a Leaf Spot Advisory Program schedule, apply PROLINE® 480 SC in the first advisory spray in July and continue PROLINE® 480 SC applications at 14-day intervals.

PROLINE 480 SC must be carried by rainfall or irrigation into the root and pod zone for control of root and pod rots caused by *Sclerotium rolfsii* and *Rhizoctonia solani*. Drought conditions will decrease the effectiveness of PROLINE 480 SC against the root and pod rots.

**General Comments:** Apply up to four (4) applications of PROLINE 480 SC per year, including the in-furrow and banded applications. When planting varieties with good to excellent levels of resistance to foliar diseases, the application interval may be extended up to 21 days in the absence of soil borne diseases. A maximum of 22.8 fl oz. of PROLINE 480 SC may be applied per year. PROLINE 480 SC may be applied up to 14 days before harvest. Do not use hay or threshings or allow livestock to graze in treated areas. Applications may be made by ground or aerial spray equipment.
<table>
<thead>
<tr>
<th>CROP</th>
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<th>RATE OF PROLINE 480 SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soybean</td>
<td>Asian Soybean Rust</td>
<td>2.5 – 3.0 fl oz per acre</td>
</tr>
<tr>
<td></td>
<td>(Phakopsora pachyrhizi)</td>
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<tr>
<td></td>
<td>Powdery Mildew</td>
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<tr>
<td></td>
<td>(Microsphaera diffusa)</td>
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</tbody>
</table>

**Application Directions:** Apply PROLINE 480 SC as a broadcast foliar spray as a preventative spray or at first visible symptoms of disease. Repeat applications on a 10- to 21-day spray interval if environmental conditions are favorable for continued disease development. Use of the higher rate and shorter spray intervals are recommended when disease pressure is severe. Use of spray adjuvants may enhance performance of PROLINE 480 SC, especially when disease is already present at time of application. If utilized, apply the lowest labeled rate of a registered nonionic surfactant or spreader sticker. PROLINE 480 SC should be applied in a minimum of 15 gallons of spray solution by ground sprayer or in a minimum of 5 gallons per acre by aircraft spray equipment.

**General Comments:** Applications may not be made within 21 days of harvest. Do not apply more than 3 applications per season. Do not apply more than 9 fl oz./a per use season.

<table>
<thead>
<tr>
<th>CROP</th>
<th>DISEASE CONTROLLED</th>
<th>RATE OF PROLINE 480 SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugar beets</td>
<td>Foliar Diseases</td>
<td>4.3 to 5.7 fl oz per acre</td>
</tr>
<tr>
<td></td>
<td>Cercoспорa Leaf Spot</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Cercoспорa beticola)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Powdery Mildew</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Ersisplе polygoni)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Soil-borne diseases</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rhizoctonia Stem Canker,</td>
<td>5.7 fl oz. per acre</td>
</tr>
<tr>
<td></td>
<td>Crown rot</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Rhizoctonia solani)</td>
<td></td>
</tr>
</tbody>
</table>

**Application Directions:**

- **Foliar disease control:** Apply PROLINE 480 SC at the first sign of disease. Use the higher use rate and shorter intervals when conditions are favorable for severe disease pressure and/or when growing less disease resistant varieties.

- **Soil-borne disease control:** Apply PROLINE 480 SC in a seven-inch band at the 4-leaf to row closure growth stage.

**General Comments:** Apply up to 3 applications of PROLINE 480 SC per year. Repeat applications as needed using a 14- to 21-day spray interval depending on disease pressure. Use a 14-day spray interval under normal to heavy disease pressure and a 21-day spray interval under light disease pressure.

To optimize disease control, the lowest labeled rate of a spray surfactant may be tank-mixed with PROLINE 480 SC. Applications may be made by ground or aerial spray equipment.

A maximum of 17.1 fl oz of PROLINE 480 SC may be applied per acre per crop year. Allow a minimum of 7 days from the last application before harvesting.

**General Comments:**

- **Alternate every application of PROLINE 480 SC with a non-Group 3 fungicide.**
<table>
<thead>
<tr>
<th>CROP</th>
<th>DISEASE CONTROLLED</th>
<th>RATE OF PROLINE 480 SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wheat (spring, durum and winter)</td>
<td><strong>Fusarium Head Blight</strong> (<em>Fusarium spp.</em>) (Suppression Only)</td>
<td>4.3 to 5.7 fl oz. per acre</td>
</tr>
<tr>
<td></td>
<td><strong>Leaf and Stem Diseases</strong></td>
<td>4.3 to 5.0 fl oz. per acre</td>
</tr>
<tr>
<td></td>
<td><strong>Leaf Rust</strong> (<em>Puccinia recondita f.sp. tritici</em>)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Septoria Leaf and Glume Blotch</strong> (<em>Septoria tritici, S. nodorum</em>)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Stem Rust</strong> (<em>Puccinia graminis</em>)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Tan Spot</strong> (<em>Pyrenophora tritici-repentis</em>)</td>
<td></td>
</tr>
</tbody>
</table>

**Application Directions**

**Fusarium Head Blight (Suppression Only):** Apply PROLINE 480 SC within the time period from when at least 75% of the wheat heads on the main stem are fully emerged (~ Feekes Growth Stages 10.4) to when 50% of the heads on the mainstem are in flower (~ Feekes Growth Stage 10.52). Optimal timing of application may be at or around 15% flower (~ Feekes 10.51). Spray equipment must be set up to provide good coverage to wheat heads. To achieve thorough wheat head coverage using ground application equipment, it is recommended to use forward and backward mounted nozzles or nozzles that have a two-directional spray, such as Twinjet nozzles. Nozzles should be operated within the spray pressure recommendations suggested by the manufacturer.

**Leaf and Stem Diseases:** Apply PROLINE 480 SC as a preventive foliar spray when the earliest disease symptoms appear on the leaves or stems. Wheat fields should be observed closely for early disease symptoms, particularly when susceptible varieties are planted and/or under prolonged conditions favorable for disease development.

**General Comments:** Apply up to two (2) applications of PROLINE 480 SC per year. Repeat applications using a 14-day spray interval if conditions remain favorable for continued or increasing disease development. Applications may be made by ground or aerial spray equipment.

A maximum of 9.37 fl oz. of PROLINE 480 SC may be applied per acre per year. Do not apply two applications at 5.7 fl oz per acre per year. PROLINE 480 SC may be applied up to the point where wheat heads are in the full flower growth stage (Feekes 10.52). Do not apply within 30 days of harvest.
IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

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NET CONTENTS:

Proline is a trademark of Bayer.

PRODUCED FOR

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

07/22/08
August 7, 2009

VIA UPS

Ms. Debra Krueger
State Registration Manager
Bayer CropScience, LP
P.O. Box 12014
Research Triangle Park, North Carolina 27709

Dear Ms. Krueger:

Re: Registration of Proline 480 SC Fungicide (EPA Reg. No. 264-825) Containing the New Active Ingredient Prothioconazole. Chemical Code: 113961

The New York State Department of Environmental Conservation (Department) has completed its technical review of the Bayer CropScience, LP application to register Proline 480 SC Fungicide which contains the active ingredient prothioconazole. This active ingredient had not been registered previously in New York State and, as such, required a full technical review as a new active ingredient (NAI) product application. This application was received on August 5, 2008 and determined to be complete for technical review on January 6, 2009. The initial registration decision date was set for June 5, 2009. However, the Department required more time to fully evaluate impacts to human health. The Department has completed its review without a request for further information and appreciates Bayer’s agreement to waive the decision date. The Department will register Proline 480 SC Fungicide for general use in New York State.

Proline 480 SC Fungicide (EPA Reg. No. 264-825) is labeled for the control of Ascomycetes, Basidiomycetes, and Deuteromycetes disease in barley, canola, chickpea, dried shelled peas and beans subgroup (except soybeans), lentils, rapeseed, Indian rapeseed, field mustard, crambe, peanut, soybean, sugar beets, and wheat. The formulated product contains 41% by weight (4 lb. prothioconazole per gallon of product). The maximum application rate for crops grown in New York State is 17.1 fl. oz. product/acre/yr, or 0.54 lb. ai/acre/yr on chickpeas, lentils, dried shelled peas and beans subgroup. The formulated product may be applied to peanut crops at a higher maximum annual rate of 22.8 fl. oz. which was not considered for this review.

Prothioconazole is a triazole-related broad spectrum fungicide. It is described as a member of the triazolinithione class of fungicides. Its mode of action is to disrupt biosynthesis of ergosterol, a precursor to vitamin D₂ and an important component of fungal cell walls.
Complete technical reviews for impacts to human health, nontarget organisms, environmental fate and labeling review are provided as follows:

**HUMAN HEALTH ASSESSMENT:**

The New York State Department of Health (NYSDOH) reviewed the application and supporting data submitted by Bayer CropScience to register the pesticide product Proline 480 SC Fungicide (EPA Reg. No. 264-825) in New York State. This pesticide product contains the new active ingredient prothioconazole [2-[(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione] and is labeled for the control of fungal diseases in a variety of field crops, including peas, shelled beans, soybeans and wheat.

Neither prothioconazole nor Proline 480 SC Fungicide was very acutely toxic by the oral, dermal and inhalation routes of exposure in laboratory animal studies. The active ingredient and the formulated product were also not irritating to skin or eyes (tested on rabbits) and were not skin sensitizers (tested on guinea pigs). Acute toxicity tests were also conducted on prothioconazole-dethio, the primary metabolite/derivative of prothioconazole. Prothioconazole-dethio was not very acutely toxic by the oral, dermal and inhalation routes of exposure. This compound was a slight eye irritant, but not a skin irritant or skin sensitizer.

Acute, subchronic, and developmental neurotoxicity studies were conducted on either prothioconazole or prothioconazole-dethio. In the acute oral neurotoxicity study on prothioconazole, reduced motor and locomotor activity were reported at 750 and 2,000 milligrams per kilogram body weight (mg/kg) in male and female rats, respectively. The no-observed-effect levels (NOELs) in this study were 200 and 750 mg/kg for males and females, respectively. No neurotoxicity was reported in the subchronic neurotoxicity study with prothioconazole at doses up to 1,000 milligrams per kilogram body weight per day (mg/kg/day). In the developmental neurotoxicity study with prothioconazole-dethio, developmental toxicity consisted of malocclusion and deviated snout at 15.1 mg/kg/day; the NOEL was 3.6 mg/kg/day. Apparent neurotoxic effects to offspring in this study, characterized by an increased incidence in lesions of the peripheral nerves and changes in brain morphometrics (increased corpus callosum measurements and increased frontal cortex measurements) were observed at the highest dose tested, 43.3 mg/kg/day. Initially, the neurotoxicity of prothioconazole-dethio could not be fully determined from this study as the parameters noted above were not measured in the low- and mid-dose test animals. Recently, additional data on this study was submitted to the United States Environmental Protection Agency (USEPA), and this agency determined that the effects previously noted in the study were not treatment related.

Prothioconazole also caused some toxicity in chronic animal feeding studies. In a one-year dog feeding study, prothioconazole caused decreased T3 and T4 thyroid hormone levels, increased urine volume, and increased inflammation/pigmentation in the kidneys of males, as well as decreased T4, increased spleen weight and pigmentation, and increased incidence of crystals in the kidneys of females at 40 mg/kg/day; the NOEL was 5 mg/kg/day. A chronic feeding study in mice reported tubular degeneration/regeneration of the kidney in males, and increased relative liver weight in both sexes at 70 mg/kg/day prothioconazole; the NOEL was 10 mg/kg/day. In a chronic feeding study in rats, prothioconazole caused decreased body weight and body weight gain, alterations in hematology and clinical chemistry indicating liver and kidney damage, increased liver and kidney weights, and histopathological alterations in the liver, kidney and urinary bladder of both sexes at 750 mg/kg/day; the NOEL was 50 mg/kg/day.
Chronic animal feeding studies were also conducted on prothioconazole-desthio. In a dog feeding study, no effects were reported at doses up to 69.9 and 77.1 mg/kg/day for males and females, respectively. In a mouse feeding study, increased liver weight, histopathology of hepatocytes and clinical chemistry changes in both sexes, decreased body weight gain in males, and increased kidney weight and eosinophilic droplets in the cortical tubules of the kidneys in females were reported at doses of 51.7 and 80 mg/kg/day prothioconazole-desthio for males and females, respectively. The NOELs were 12.8 and 20.3 mg/kg/day, respectively. In a rat feeding study, the LOEL was determined to be 8 and 11.2 mg/kg/day prothioconazole-desthio for males and females, respectively, based on increased hepatocellular vacuolation and fatty changes in the liver of both sexes. The NOELs were 1.1 and 1.6 mg/kg/day, respectively. The USEPA Office of Pesticide Programs calculated a chronic oral reference dose (CRfD) of 0.001 mg/kg/day for prothioconazole based on a NOEL of 1.1 mg/kg/day in the rat feeding study using prothioconazole-desthio (liver histopathology in males and females) and an uncertainty factor of 1,000 (to account for intra- and inter-species variation and database uncertainty from the developmental neurotoxicity study). This CRfD has not yet been adopted by USEPA's Integrated Risk Information System (IRIS).

Prothioconazole caused some toxicity in developmental and reproductive studies. In the rat, maternal effects were observed at 500 mg/kg/day prothioconazole and included increased urination, increased water consumption, and decreased body weight gain; the NOEL was 80 mg/kg/day. Developmental effects in the rat included delayed ossification and skeletal changes at 500 mg/kg/day; the NOEL was 80 mg/kg/day. In the rabbit, the maternal LOEL was 350 mg/kg/day based on decreased food consumption and body weight; the NOEL was 80 mg/kg/day. Developmental effects in the rabbit included increased resorptions, increased abortions, and decreased fetal body weight at 350 mg/kg/day prothioconazole; the NOEL was 80 mg/kg/day. In a multigeneration reproduction study in rats, prothioconazole was associated with a decreased number of estrous cycles in both generations, as well as decreased body weight and decreased spleen weight in the offspring at a dose of 750 mg/kg/day; the NOEL was 100 mg/kg/day. Parental toxicity consisted of decreased body weight and body weight gain, increased food consumption, increased liver and kidney weight, decreased thymus, testicular, prostate and epididymis weight, and histopathological findings in the liver and kidney at a dose of 750 mg/kg/day, with a NOEL of 100 mg/kg/day.

Prothioconazole-desthio was also tested in developmental and reproductive toxicity studies. In the rat, maternal effects were observed at 100 mg/kg/day prothioconazole-desthio and included decreased body weight gain, increased liver weight and liver histopathology; the NOEL was 30 mg/kg/day. Developmental effects in the rat study included increased supernumerary ribs, and incomplete or delayed ossification at prothioconazole-desthio doses of 10 mg/kg/day, with a NOEL of 3 mg/kg/day. In the rabbit, maternal effects included decreased food consumption, decreased body weight gain at a dose of 50 mg/kg/day; the NOEL was 10 mg/kg/day. Developmental effects were observed at 10 mg/kg/day and included multiple malformations, increased resorptions, and decreased fetuses per dam; the NOEL was 2 mg/kg/day. In a multigeneration reproduction study in rats, the LOEL was reported at prothioconazole-desthio doses of 43 and 50 mg/kg/day to males and females, respectively, and the NOEL was 10.4 and 12 mg/kg/day, respectively. The NOEL and LOEL were the same for parental, reproductive, and offspring effects. The LOEL was based on birthing difficulty, decreased viability, and decreased pup body weight (reproductive effects); increased incidence of cleft palate, and dilated renal pelvis, ureters, and bladder (offspring effects); as well as increased liver weight, increased liver histopathology, and decreased food consumption during lactation in
the females (parental effects). In a dermal developmental toxicity study, no maternal effects were observed up to the highest dose tested (1,000 mg/kg/day). However, developmental effects (increased incidence of supernumerary ribs) were observed at 100 mg/kg/day; the NOEL was 30 mg/kg/day. The USEPA calculated an acute oral reference dose (aRfD) of 0.002 mg/kg/day for prothioconazole for females between the ages of 13 and 49, based on the NOEL of 2 mg/kg/day in the developmental toxicity study in rabbits using prothioconazole-desthio (multiple malformations, increased resorptions and decreased fetuses per dam) and an uncertainty factor of 1,000. This RfD also has not yet been adopted by the USEPA's IRIS.

Carcinogenicity studies were conducted for both prothioconazole and the metabolite prothioconazole-desthio. Neither compound displayed evidence of carcinogenicity and the USEPA classified prothioconazole as “not likely to be carcinogenic to humans.” Prothioconazole and prothioconazole-desthio were negative in a number of genotoxicity studies with the exception of one structural chromosomal aberration study with prothioconazole. This study concluded that prothioconazole may be considered clastogenic, but the observed effects may be from secondary cytotoxicity rather than direct structural DNA damage.

The USEPA established tolerances for combined prothioconazole and prothioconazole-desthio residues in a number of food commodities. The chronic population adjusted dose (cPAD) for prothioconazole for the general public was originally determined to be 0.001 mg/kg/day and had the same basis as the cRfD. The acute population adjusted dose (aPAD) of prothioconazole for females aged 13-49 years was determined to be 0.002 mg/kg/day and had the same basis as the aRfD. Recently, the USEPA determined that the 10-fold database uncertainty factor can be removed, and the aPAD and cPAD values should be increased by 10-fold accordingly (Fed. Reg. 74:14,744-14,749. April 1, 2009). Based on these new values, the USEPA estimated that the chronic dietary exposure to prothioconazole residues in food and upper bound drinking water would be 22% of the cPAD in infants less than 1 year old (the population group with the highest exposure). The USEPA also estimated that the acute dietary exposure to prothioconazole residues in food and upper bound drinking water would be 8% of the aPAD for this specific subpopulation. These exposure analyses are based on the assumptions that 100% of the crops are treated and that these treated crops contain average residue concentrations. Actual residues and resulting exposure levels are expected to be less than this assessment predicts.

The USEPA conducted a risk assessment for dermal and inhalation exposure of workers to prothioconazole from field crop use of the Proline 480SC product. For determining margins of exposure (MOEs), the USEPA compared estimated dermal exposures to the NOEL of 30 mg/kg/day from a dermal developmental toxicity study in the rat with prothioconazole-desthio and estimated inhalation exposures to the NOEL of 2 mg/kg/day from an oral developmental toxicity study in rabbits with prothioconazole-desthio. The short- and intermediate-term total MOEs for the combined dermal and inhalation routes to mixer/loaders were estimated to range from 870 (closed system for aerial application to wheat) to 3,100 (open pouring for groundboom applications to barley, oil-seed crops and peas/beans). These exposure scenarios assumed that mixer/loaders wore the personal protective equipment (PPE) required on the label (long-sleeved shirt and long pants, chemical-resistant gloves, and shoes plus socks). For applicators, the estimated short- and intermediate-term combined dermal and inhalation total MOEs were estimated to be between 1,400 and 5,000, depending on the application method and crop. Post-application MOEs ranged from 380 (for full scouting and irrigation of field crops) to 5,700. For the above risk assessments, the USEPA considered MOEs of 1,000-fold or greater for both
handler risk and post-application risk to provide adequate worker protection. This was derived from the uncertainty factors for interspecies extrapolation (10x), intraspecies variation (10x), and database uncertainty (10x). The MOEs for mixing/loading in a closed system for aerial applications to wheat, and full scouting and irrigation of labeled field crops were below the target MOE of 1,000-fold or greater. However, USEPA noted that this is due to the use of endpoints from prothioconazole-desthio studies and a proposed reentry interval (REI) of 24 hours. If studies with prothioconazole were used (which would be appropriate given that handlers would primarily be exposed to prothioconazole, not the degradate/metabolite, prothioconazole-desthio), the MOEs would be greater than 1,000. In addition, the REI on the newest accepted label for Proline 480SC is 48 hours. This REI was stated by USEPA as being protective of workers during post-application activities.

There are no chemical specific federal or New York State drinking water/groundwater standards for prothioconazole or its degradates. Based on their chemical structures, these chemicals fall under the 50 microgram per liter (μg/L) New York State drinking water standard for “unspecified organic contaminants” (10 NYCRR Part 5, Public Water Systems). The New York State drinking water standard for the sum of “unspecified organic contaminants” and “principal organic contaminants” is 100 μg/L.

The available information indicates that prothioconazole, prothioconazole-desthio, and the formulated product Proline 480 SC Fungicide were not very acutely toxic, irritating to the eyes or skin, nor sensitizers. Data from chronic and developmental/reproductive animal studies indicate that both prothioconazole and prothioconazole-desthio have the potential to cause toxicity, with prothioconazole-desthio being more toxic than prothioconazole in some cases. However, neither prothioconazole nor prothioconazole-desthio (unlike many other fungicides in the triazole chemical class) demonstrated carcinogenic potential in laboratory animals.

The estimated risks to workers from use of Proline on the labeled field crops, taking into account USEPA’s removal of the additional 10-fold database uncertainty factor, the longer REIs on the final label and that prothioconazole-desthio toxicity endpoints were used in the assessment, are within the range that is generally considered to be acceptable. Dietary exposure to residues from prothioconazole and prothioconazole-desthio in food commodities and drinking water are also at levels that do not exceed the aPAD and cPAD.

Given the above, we do not object to the registration of Proline 480 SC Fungicide in New York State based on direct health concerns.

ECOLOGICAL ASSESSMENT:

The following assessment was prepared by our Bureau of Habitat (BOH) staff to determine impact to nontarget organisms when Proline 480 SC Fungicide is applied to listed crops in New York State. The product application rate is modeled using PONDTOX and MAMTOX, for impact to New York State specific terrestrial and aquatic species and evaluated for impact to ecologically sensitive areas of New York State.

The maximum single and maximum seasonal application rates are 0.18 and 0.54 lbs AI/acre, respectively. Using a mean field dissipation life of $T_{1/2} = 137$ days for the metabolite prothioconazole-desthio, the total accumulation of prothioconazole resulting from multiple applications can be estimated using the HALFLIFEVB program. Based on the very slow
degradation of the metabolite, the application of three single applications of 0.18 lbs AI/acre with time intervals of 5, 10, and 14 days are equivalent to single applications of 0.53; 0.52; and 0.51 lbs AI/acre respectively.

The toxicity profile for prothioconazole indicates that it breaks down very rapidly. Two degradates are considered to be major degradates, because they occur in concentrations >10% of the applied parent compound. These are prothioconazole-desthio and prothioconazole-S-methyl. Prothioconazole-desthio appears to be more toxic to nontarget organisms than the parent. The limited toxicity data available for prothioconazole-S-methyl suggests that it is about as toxic as the parent. Toxicity data for prothioconazole-S-methyl was only available for aquatic species.

The USEPA classified prothioconazole and its degradates/metabolites as practically nontoxic to avian and mammalian species and moderately toxic to aquatic species. Prothioconazole-desthio was classified as highly toxic to aquatic plants and to marine/estuarine invertebrates. Prothioconazole and its degradates/metabolites were not mutagenic, however, they were found to be developmentally toxic (teratogenic). Rabbits were the most sensitive species tested, with developmental lowest observed adverse effect levels (LOAELs) for offspring of 10 mg/kg, and maternal and offspring developmental no observed adverse effect levels (NOAELs) of 10 and 2 mg/kg body weight (bw), respectively. Given the body weight and food consumption data provided, the mg/kg doses can be converted to 445 and 90 parts per million of food, respectively.

Assessment of the potential for exposure to prothioconazole is greatly complicated by the complex degradation and fate of the compound. In soil, the primary degradation process is aerobic metabolism. Prothioconazole degraded rapidly, on the order of two or three days, to prothioconazole-desthio, prothioconazole-S-methyl (to a much lesser extent), and other minor degradates. As degradation proceeded, the fraction of applied material that was unextractable, that is, bound to soil organic carbon, increased by 35 to 50%.

In soil, the concentration of prothioconazole-desthio reached a maximum value ranging between 23.4 to 27% of the applied parent compound, and declined with a calculated half-life ranging from 84.5 to 315.1 days. The concentration of prothioconazole-S-methyl reached a maximum value ranging between 1.7 to 4.57% of the applied parent compound, and declined with a calculated half-life ranging from 21 to 147.5 days.

The fate of prothioconazole in water was similar. Prothioconazole rapidly degrades, primarily via aerobic metabolism, to prothioconazole-desthio and prothioconazole-S-methyl. The half-life of the parent in water ranged from 0.6 to 4.5 days. The concentration of prothioconazole-desthio ranged from 17 to 33% of the applied parent compound, and the concentration of prothioconazole-S-methyl was much lower, on the order of less than 1%. Prothioconazole-desthio persisted in sediment with a half-life ranging from 90 to 203.9 days. Neither prothioconazole nor prothioconazole-S-methyl were frequently detected in aerobic sediment above the level of quantification (LOQ). In anaerobic sediment, prothioconazole-S-methyl was the primary degradate, with concentrations as high as 78% of the parent prothioconazole.

The concentration of unextractable residues, in both soil and sediment, reached concentrations as high as 35 to 50% of the applied parent compound. It is unknown if this bound, unextractable fraction is parent prothioconazole, or the -desthio or -S-methyl degradate,
or some other unidentified fraction of the parent molecule. In the Environmental Fate and Effects Division (EFED) review, USEPA was unsure whether the unextractable fraction was truly not bioavailable or if the extraction process had simply not been harsh enough, and that under some future soil conditions, undegraded prothioconazole or prothioconazole-dethio might become "unbound," and would be biologically available. However, the USEPA also points out that in radio labeled studies, the decrease in prothioconazole concentrations was not proportional to the increase in non-extractable residues, and the major transformation products (-dethio and -S-methyl) were detected in quantities >10% by 1 to 3 days post treatment in all applications, which indicates that at least part of the parent compound was transformed and did not simply move to the non-extractable phase.

RISK ASSESSMENT MODELING

Due to the complicated degradation of prothioconazole, it was difficult to devise scenarios that could be used with the NYS Pesticide Screening System risk assessment models. The following scenarios were utilized to evaluate the toxicity of prothioconazole and its degradates:

A. The first modeling scenario run was to disregard the rapid degradation of prothioconazole parent and to run the suite of models using the parent molecule applied at the maximum seasonal application rate of 0.53 lbs AI/acre, using only toxicity data for the parent molecule.

B. The second modeling scenario was to estimate the risks to birds and mammals from prothioconazole-dethio by using dethio toxicity values in the models. To obtain residue values for prothioconazole in forage plants, the USEPA EFED Risk Assessment was consulted. Several studies of the foliar dissipation of prothioconazole were completed by the registrant and reviewed by the USEPA. These studies were not part of the material that was provided to New York, however, the USEPA EFED Risk Assessment reviewed and summarized those data. From those data, the percentage of parent molecule that transformed into the prothioconazole-dethio degrade was found to range from 9.5 to 72.7%, with a mean of 46%. To estimate the risks of prothioconazole-dethio to birds and mammals that would feed upon treated vegetation, the typical and upper limit residues derived from the Hoerger and Kenaga nomograph were multiplied by 46% (mean transformation rate) and 73% (maximum transformation rate). The AVTOX and MAMTOX models were then used to compare these residues to prothioconazole-dethio acute and chronic toxicity feeding thresholds.

C. To estimate aquatic risks from prothioconazole-dethio, an estimate had to be made of the prothioconazole-dethio available for runoff in soil. The field dissipation studies showed that the concentration of prothioconazole-dethio produced ranged from 23.4 to 27% of the applied parent compound. To estimate the risks of prothioconazole-dethio to aquatic life from runoff, the maximum seasonal application rate of 0.53 pounds per acre was multiplied by 27% to estimate an equivalent application rate of prothioconazole-dethio. The PONDTOX model selects runoff rates to evaluate based on the $K_{ow}$ of the product being evaluated. The $K_{ow}$ of prothioconazole-dethio was unreported, so the PONDTOX model used the log $K_{ow}$ for the parent molecule at pH 7, which was 3.82.
Note: No modeling was conducted for prothioconazole-S-methyl. No avian or mammalian toxicity data were provided for this degradate; only limited aquatic toxicity data. The aquatic toxicity data show that the toxicity of prothioconazole-S-methyl was very similar to prothioconazole parent. Prothioconazole-S-methyl was detected most abundantly in anaerobic sediment. For risk assessment purposes, the parent prothioconazole molecule will be considered as a surrogate for the toxicity of the -S-methyl degradate.

RESULTS OF RISK ASSESSMENT MODELING

A. Prothioconazole Parent

The AVTOX model showed that no avian toxicity thresholds were exceeded.

The MAMTOX model showed that with the Hoerger and Kenaga upper limit residue values, chronic no effect levels were exceeded on short grass, long grass, leafy crops, and forage. Reproductive no effect levels were exceeded on short grass, long grass, and leafy crops. None of the lowest observed effect levels were exceeded. The size of the exceedances ranged from Risk Quotients (RQ) of 1.1 to 4.5. When the residue levels were reduced to the Hoerger and Kenaga typical residue values, the chronic no effect levels were exceeded on short and long grass (RQs of 2.4 and 1.8) and reproductive no effect level was exceeded on short grass only, with a RQ of 1.3.

The PONDTOX model showed that when applied at the maximum seasonal application rate of 0.53 lbs Al/acre, and using a maximum runoff rate of 3%, the no effect concentrations for macrophytes (Lemna) were exceeded in the 1 foot, 3 foot, and 6 foot deep ponds. The no effect concentrations for freshwater diatoms (Navicula) were exceeded in the 1 foot and 3 foot deep ponds. No LC₅₀ concentrations were exceeded.

B. Prothioconazole-dethio

The AVTOX model showed that no avian toxicity thresholds were exceeded.

Four iterations of the MAMTOX model were run for prothioconazole-dethio:

- Assuming a production rate for prothioconazole-dethio from the prothioconazole parent of 46% (mean from foliar dissipation study) and
  - Hoerger and Kenaga upper limit residues resulting from the maximum seasonal application rate of 0.53 lbs Al/acre;
  - Hoerger and Kenaga typical residues resulting from the maximum seasonal application rate of 0.53 lbs Al/acre;

- Assuming a production rate for prothioconazole-dethio from the prothioconazole parent of 73% (maximum from foliar dissipation study) and
  - Hoerger and Kenaga upper limit residues resulting from the maximum seasonal application rate of 0.53 lbs Al/acre;
  - Hoerger and Kenaga typical residues resulting from the maximum seasonal application rate of 0.53 lbs Al/acre.
The results of the mammalian prothioconazole-desthio modeling can be summarized as follows:

- No lowest observed effect concentration threshold was exceeded under any modeling scenario.

- The reproductive no effect concentration was not exceeded under any modeling scenario, however, when the production rate of prothioconazole-desthio was assumed to be 73% and Hoerger and Kenaga upper limit residues were used, the Risk Quotient for short grass was RQ=1; that is, the concentration of prothioconazole-desthio on short grass equaled the reproductive no effect concentration.

- Similarly, when the production rate of prothioconazole-desthio was assumed to be 46% and the Hoerger and Kenaga typical residue values were used, the chronic feeding Risk Quotient for short grass was RQ=1; that is, the concentration of prothioconazole-desthio on short grass equaled the chronic feeding no effect concentration.

- When the production rate of prothioconazole was assumed to be 73% and the Hoerger and Kenaga typical residue values were used, the chronic feeding no effect concentration Risk Quotients for short grass and long grass were marginally exceeded; RQs = 1.6 and 1.2, respectively.

- As would be expected, greatest exceedances resulted when the production rate of prothioconazole was assumed to be 73% and the Hoerger and Kenaga Upper Limit residue values were used. The chronic feeding no effect concentration Risk Quotient for short grass, long grass, and leafy vegetables were exceeded with RQs of 3.1; 1.4; and 1.6, respectively.

The results of the aquatic toxicity modeling using the PONDTOX model and scenario C for prothioconazole-desthio described above, show no acute or chronic toxicity thresholds to be exceeded.

DISCUSSION AND MITIGATION

The results of risk assessment modeling suggest that prothioconazole has the potential to pose chronic risks to mammals that feed upon treated vegetation, and risks to aquatic plants. Also, the potential risks to sediment-dwelling organisms, has not been adequately studied. Another concern is the potential persistence of prothioconazole and prothioconazole-desthio as untransformed material in soil or sediment that was characterized as unextracted material.

A. Chronic mammalian toxicity.

When applied at the maximum seasonal application rate, prothioconazole exceeded the chronic and reproductive toxicity mammalian toxicity thresholds for some types of plant forage. However, when the maximum single application rate is used, the exceedances are largely diminished. Prothioconazole, prothioconazole-desthio, and prothioconazole-S-methyl are rapidly metabolized in plants, with an overall foliar dissipation half-life of
6.44 days. Given that over two full half-lives will pass between repeat applications, very little of the prothioconazole or major degradates will persist in or on plants between applications. Thus, the use of the maximum seasonal application rate is inappropriate and the resulting risk predictions are probably over-estimated. The fairly rapid foliar dissipation rate suggests that chronic toxicity is not likely to be a significant concern, as the material will degrade from treated foliage before a mammal could consume a potentially toxic dose. Furthermore, primarily no effect concentrations were exceeded, not lowest effect concentrations. Lowest effect concentrations were exceeded only when the maximum seasonal application rate was combined with Hoerger and Kenaga Upper Limit residue predictions.

Similarly, low exceedances of some chronic no effect thresholds occurred with the prothioconazole-desthiomethyl degrade only with the highest transformation ratio of parent prothioconazole to prothioconazole-desthiomethyl and Hoerger and Kenaga upper limit residue values. When the rapid metabolism of all prothioconazole-derived residues in plants is taken into account, it appears unlikely that either the no effect or lowest effect thresholds would be exceeded for any substantial length of time.

It appears that while the concentrations of prothioconazole and its major degradates might briefly exceed chronic no effect thresholds, those short exceedances are not likely to result in chronic toxicity to exposed, nontarget mammals.

B. Aquatic risks.

Runoff from fields treated with prothioconazole exceeded no effect concentrations for macrophytes and freshwater diatoms. However, prothioconazole is rapidly degraded on soil and in water. Actual risks to aquatic plants are likely to occur only if a significant runoff event occurs within a day or two of the application. The highest concentration of prothioconazole-desthiomethyl observed in the three field dissipation studies was 27%. Using an application rate of 27% of the maximum seasonal application rate for prothioconazole as an equivalent application rate for prothioconazole-desthio, no aquatic risk thresholds for prothioconazole-desthiomethyl were exceeded, including the highly sensitive acute and chronic thresholds for mysid shrimp.

An important deficiency, however, is the potential for sediment toxicity from concentrations of prothioconazole, prothioconazole-desthiomethyl, and prothioconazole-S-methyl that will persist, particularly in anaerobic sediments. A crayfish study found a no effect concentration of 26 mg/L for prothioconazole-desthiomethyl, but this study was considered to be not acceptable because of excessive control mortality (20%). It does suggest, however, that a major freshwater benthic invertebrate is not sensitive to prothioconazole-desthiomethyl. A chronic 28-day chironomid sediment toxicity test was also conducted, that was classified only as supplemental, because not all exposure levels were analytically verified. As a condition of registration, this study must be repeated. The summary of the study, described in the EFED risk assessment, does not state if the test material was the parent compound or a degradeate. However, the assumption can be made that prothioconazole would break down in the test sediments in the same manner that it would in the field, so the results of the sediment toxicity test probably integrated both parent prothioconazole and the relevant degradates. The supplemental test found that the
no effect concentrations lie between 99 and 1010 ppb, and these concentrations are below the concentrations that are likely to be found in sediment.

C. Concerns about persistence.

A major concern about prothioconazole, identified by the USEPA, is that an unusually large fraction of applied material appears as soil-bound, unextractable material. This unextractable fraction may consist of undegraded prothioconazole, prothioconazole-desthioc, prothioconazole-S-methyl, or other degradates. Even though this material could not be extracted with standard methods (i.e., extraction with acetonitrile/water), there is concern that with some change in environmental conditions, this unextracted material of unknown composition could become bioavailable.

This unextractable material in soil is not likely to be a problem unless it can be taken up by plants, or released from the soil by runoff. The registrant conducted a study of the accumulation of prothioconazole by rotational crops. In this study, bare ground was treated twice with prothioconazole at a rate of 0.36 lbs Al/acre for a total treatment of 0.72 lbs Al/acre, with a 14-day interval between applications. Mustard, turnips, and wheat were planted at plantback intervals of 1, 4, 8, and 12 months. The crops were sampled when they reached maturity. When crops that were planted at the one month plantback interval were analyzed, it was found that all prothioconazole-derived residues were below the limits of quantification (LOQ; <0.02 ppm for wheat grain and <0.05 ppm for all other commodities). This result suggests that either prothioconazole-derivatives that persisted in treated soil were not able to be accumulated by plants, or that some fraction was accumulated but was then metabolized in the plants in the same manner that prothioconazole is metabolized in plants when applied during a foliar treatment. A laboratory crop rotational study, in which vegetation was sampled more frequently, showed that in fact, prothioconazole-derivatives were taken up in small quantities by plants and then rapidly metabolized.

These studies suggest that while prothioconazole may persist in bare soil, both agricultural and wild native plants are likely to detoxify treated soil by extracting and metabolizing accumulated prothioconazole-derived substances.

The BOH has no objection to registration of Proline 480 SC Fungicide as labeled, as prothioconazole appears unlikely to present any significant risk to ecological resources. It is persistent in soil, but those residues are not likely to be taken up and accumulated in plants that could be fed upon by herbivorous mammals, because prothioconazole is rapidly metabolized by plants.

ENVIRONMENTAL FATE ASSESSMENT:

The following assessment was prepared by our staff geologist to determine impact to groundwater when Proline 480 SC Fungicide is applied to labeled crops in New York State. The product application rate is modeled using LEACHM, after geology common to New York State and evaluated for impact to sensitive aquifers found primarily in sandy areas of New York State.
PARENT COMPOUND

Solubility: Prothioconazole has a solubility of 5 ppm at pH 4 and 300 ppm at pH 8.

Hydrolysis: (MRID 46246505 acceptable) Prothioconazole was stable in pH 4 (>10 years), 7 (>1 year), and 9 (>1 year) aqueous buffer solutions.

Aqueous Photolysis: (MRID 46246507 supplemental) Prothioconazole had an environmental phototransformation half-life of 9.7 days with major transformation products JAU6476-desthiol at 54.8% and JAU6476-thiazocine at 14.1% on the phenyl label, and JAU6476-desthiol at 55.7% and 1,2,4-triazole at 11.9% in the triazole label.

Soil Photolysis: (MRID 46246510 acceptable) Prothioconazole data indicated the same half-life for the irradiated samples as the dark samples, therefore, phototransformation on soil does not appear to be a route of degradation. Major transformation product JAU6476-desthiol was found in the irradiated sample at 38%.

Aerobic Soil Metabolism:

<table>
<thead>
<tr>
<th>Soil</th>
<th>pH</th>
<th>% OC</th>
<th>Observed T ½</th>
<th>Transformation products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silt ¹</td>
<td>7.1</td>
<td>2.14</td>
<td>0-1 days</td>
<td>JAU6476-desthiol 49.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>JAU6476-S-methyl 12.8%</td>
</tr>
<tr>
<td>Loamy sand ¹</td>
<td>6.8</td>
<td>0.79</td>
<td>0-3 days</td>
<td>JAU6476-desthiol 41.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>JAU6476-S-methyl 14.6%</td>
</tr>
<tr>
<td>Sandy loam ²</td>
<td>7.2</td>
<td>2.0</td>
<td>0-1 days</td>
<td>JAU6476-desthiol 42.3%</td>
</tr>
<tr>
<td>Silty clay loam ²</td>
<td>5.9</td>
<td>1.66</td>
<td>0-1 days</td>
<td>JAU6476-desthiol 20.9%</td>
</tr>
</tbody>
</table>

¹MRID 46246511 acceptable; ²MRID 46246512 acceptable.

Aerobic Aquatic Soil Metabolism:

<table>
<thead>
<tr>
<th>Soil</th>
<th>pH</th>
<th>% OC</th>
<th>Observed T ½ water/soil/system</th>
<th>Transformation products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water/loam ¹</td>
<td>6.6</td>
<td>4.8</td>
<td>14.9 days water 48.5 days system</td>
<td>JAU6476-desthiol 32.3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>JAU6476-desthiol 21.9%</td>
</tr>
<tr>
<td>Water/loamy sand ¹</td>
<td>8.5</td>
<td>1.37</td>
<td>17.8 days water 33.6 days system</td>
<td>1,2,4-triazole 37.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>JAU6476-S-methyl 26.9%</td>
</tr>
<tr>
<td>Water/sandy clay loam ²</td>
<td>1-3 days water 91-120 days system</td>
<td>JAU6476-desthiol 32.9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>JAU6476-S-methyl 77.0%</td>
</tr>
</tbody>
</table>

¹MRID 46246515 supplemental; ²MRID 46246515 acceptable.

Aged Leaching: (MRID 46246539 supplemental) Sorption coefficients could not be determined due to instability of the compound in the systems.

MRID 46246504 acceptable, but Kocs could not be calculated due to low column resolution. However, USEPA went on to say that prothioconazole showed very little potential for leaching as very low total radioactive residues were detected in the leachate and very little unchanged parent compound was translocated below the aged soil layer. The studies also indicate that the
parent has lower mobility than the degradates JAU6476-desthio, and JAU6476-S-methyl, and batch studies for these two transformation products indicate that they have low mobility.

**Terrestrial Field Dissipation:** MRID 46246517 supplemental. Field dissipation studies performed on a sandy loam-loam (pH 7.9, %OC 0.27) indicated an observed half-life of 7 days. Major transformation product JAU6476-desthio was found at 21.5%. Observed major transformation half-lives were JAU6476-desthio 63 days and JAU6476-S-methyl at 14 to 29 days.

MRID 46246518 supplemental. Field dissipation studies performed on a loamy sand-sandy loam (pH 6.2, %OC 1.1) indicated an observed half-life of <2 days. Major transformation product JAU6476-desthio was found at 23.4%. Observed major transformation half-lives were JAU6476-desthio 28-61 days and JAU6476-S-methyl at 21 days.

MRID 46246519 supplemental. Field dissipation studies performed on a loamy sand soil from North Rose, NY (pH 6.4, %OC 3.38) indicated an observed half-life of <3 days. Major transformation product JAU6476-desthio was found at 24.3%. Observed major transformation half-lives were JAU6476-desthio 301 to 422 days and JAU6476-S-methyl at 28 to 301 days.

**Aquatic Field Dissipation:** (MRID 46246522 supplemental) Prothioconazole dissipated in paddy water with a calculated half-life of 1.7 days. The half-life in the sediment/soil was calculated to be 203.9 days.

(MRID 46246523 supplemental) Prothioconazole dissipated in paddy water with a calculated half-life of 4.8 days. The half-life in the sediment/soil could not be determined due to too few detections.

(MRID 46246524 supplemental) Prothioconazole dissipated in paddy water with a calculated half-life of 0.6 days. The half-life in the sediment/soil could not be determined due to too few detections.

**TRANSFORMATION PRODUCTS:**

**Solubility JAU6476-desthio:** The solubility of JAU6476-desthio is 22 ppm.

**Hydrolysis JAU6476-desthio:** (MRID 46246506 supplemental) JAU6476-desthio was stable at pH 5, 7, and 9.

**Aerobic Metabolism JAU6476-desthio:** (MRID 46246513 supplemental). No major transformation products found.

<table>
<thead>
<tr>
<th>Soil</th>
<th>pH</th>
<th>% OC</th>
<th>T ½ JAU6476-desthio</th>
<th>T ½ JAU6476-desthio bound residues</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>linear/nonlinear/empirical</td>
<td>linear/nonlinear/empirical</td>
</tr>
<tr>
<td>Silt loam</td>
<td>7.3</td>
<td>1.55</td>
<td>55.5/29.4/3-7 days</td>
<td>165.0/144.4/ &lt;120 days</td>
</tr>
<tr>
<td>Silt loam</td>
<td>7.9</td>
<td>0.98</td>
<td>45.3/29.0/14-30 days</td>
<td>113.6 days</td>
</tr>
<tr>
<td>Sandy loam</td>
<td>7.2</td>
<td>1.02</td>
<td>22.6/6.8/3-7 days</td>
<td>106.6/91-120 days</td>
</tr>
<tr>
<td>Silty clay</td>
<td>6.3</td>
<td>1.46</td>
<td>30.3/18.6/7-14 days</td>
<td>128.4/115.5/9-120 days</td>
</tr>
</tbody>
</table>
Adsorption/Desorption Transformation Product JAU6476-desthio: (MRID 46246450 acceptable)

<table>
<thead>
<tr>
<th>Soil type</th>
<th>pH</th>
<th>%OC</th>
<th>Adsorption $K_{oc}$</th>
<th>Desorption $K_{oc}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandy loam</td>
<td>7.2</td>
<td>2.02</td>
<td>617</td>
<td>621</td>
</tr>
<tr>
<td>Silt</td>
<td>7.1</td>
<td>2.14</td>
<td>625</td>
<td>689</td>
</tr>
<tr>
<td>Silty clay loam</td>
<td>5.9</td>
<td>1.66</td>
<td>536</td>
<td>561</td>
</tr>
<tr>
<td>Loamy sand</td>
<td>6.8</td>
<td>0.79</td>
<td>523</td>
<td>873</td>
</tr>
</tbody>
</table>

Solubility JAU6476-S-methyl: The solubility of JAU6476-desthio is 1.45 ppm.

Aerobic Metabolism JAU6476-S-methyl: (MRID 46246514 supplemental)

<table>
<thead>
<tr>
<th>Soil type</th>
<th>pH</th>
<th>%OC</th>
<th>$T \frac{1}{2}$ JAU6476-S-methyl linear/nonlinear/empirical</th>
<th>$T \frac{1}{2}$ JAU6476-S-methyl and bound residues linear/nonlinear/empirical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silt loam</td>
<td>7.3</td>
<td>1.55</td>
<td>25.1/5.6/1-3 days</td>
<td>86.6/74.5/7-14 days</td>
</tr>
<tr>
<td>Silt loam</td>
<td>7.9</td>
<td>0.98</td>
<td>47.5/26.1/14 days</td>
<td>173.3/154/&gt;125 days</td>
</tr>
<tr>
<td>Sandy loam</td>
<td>7.2</td>
<td>1.02</td>
<td>28.4/7.5/3 days</td>
<td>123.8/92.4/14 days</td>
</tr>
<tr>
<td>Silty clay*</td>
<td>6.3</td>
<td>1.46</td>
<td>55.0/44.4/14-30 days</td>
<td>128.4/111.8/125 days</td>
</tr>
</tbody>
</table>

*Major transformation products found only in silty clay were M2 at 10.0% and M6 at 24.7%.

Adsorption/Desorption Transformation Product JAU6476-S-methyl: (MRID 462464501 acceptable)

<table>
<thead>
<tr>
<th>Soil type</th>
<th>pH</th>
<th>%OC</th>
<th>Adsorption $K_{oc}$</th>
<th>Desorption $K_{oc}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandy loam</td>
<td>7.2</td>
<td>2.02</td>
<td>2772</td>
<td>3124</td>
</tr>
<tr>
<td>Silt</td>
<td>7.1</td>
<td>2.14</td>
<td>2995</td>
<td>3358</td>
</tr>
<tr>
<td>Silty clay loam</td>
<td>5.9</td>
<td>1.66</td>
<td>2484</td>
<td>2926</td>
</tr>
<tr>
<td>Loamy sand</td>
<td>6.8</td>
<td>0.79</td>
<td>1973</td>
<td>2532</td>
</tr>
</tbody>
</table>

Computer Modeling: Staff were unable to run the parent because it degraded so rapidly into two major degradates. Therefore, staff ran LEACHM on JAU6476-desthio using Riverhead soil, an application rate of 0.26 lb ai/a/crop (49.4% of 0.53 lb), a $K_{oc}$ of 876 and an aerobic half-life of 120 days. Modeling projected steady peaks of up to 0.002 ppb. Running the degradable JAU6476-S-methyl with a $K_{oc}$ of 2532, a half-life of 125 days and an application rate of 0.077 lb ai/a/yr (14.6% of 0.53 lb), the model projected no leaching.

Label statements: “Prothioconazole-desthio (a degradate of prothioconazole) is known to leach through soil into groundwater under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.”
“Drift and runoff are hazardous to aquatic organisms in water adjacent to treated areas. This product has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.”

**Environmental Fate Summary:** According to the USEPA, the major uncertainties in characterizing the environmental fate of prothioconazole involve non-rigorous soil extraction procedures, lack of complete information on the fate of the 1,2,4-triazole degragate, and the ability to calculate parent adsorption coefficients and bioaccumulation factors. Because of the considerable uncertainty surrounding soil extraction procedures, the unextracted material in the aerobic soil, aerobic aquatic, and anaerobic aquatic metabolism studies was added to the parent in calculation of half-lives used in the USEPA environmental fate modeling and fate characterization. For this review for groundwater, staff used the bound residue data because, over time, there is the potential for those bound residues to leach into groundwater. In instances where compounds degrade rapidly to another toxic compound, the degragate, in this case prothioconazole-desphio, may in fact be the active ingredient. Additionally, prothioconazole degrades via metabolism to prothioconazole-S-methyl, which also has similar toxicity. Conclusions about the mobility of the prothioconazole combined residues of concern are drawn only from degradates.

USEPA indicated that these prothioconazole combined residues of concern are persistent and likely to dissipate off site mainly via runoff of sediment-bound and dissolved residues from treated fields and possibly via leaching through soil. They further stated that prothioconazole and prothioconazole-desphio reach anaerobic soil depths, however, degradation to prothioconazole-S-methyl will likely increase, and there will still be a chance of groundwater contamination.

USEPA felt that given its mobility and persistence in soil and detections at 15 to 30 cm and 30 to 45 cm in terrestrial field dissipation studies, prothioconazole-desphio may leach into groundwater, particularly in coarse, sandy soil types with less organic carbon content. However, modeling by the Department indicates no leaching by JAUS6476-S-methyl (prothioconazole-S-methyl), and leaching at the low part per trillion levels for JAUS6476-desphio (prothioconazole-desphio).

**PESTICIDE PRODUCT REGISTRATION SECTION SUMMARY:**

The Department is prepared to register Proline 480 SC Fungicide (EPA Reg. No. 264-825) after having evaluated impacts to human health, environmental fate, and nontarget organisms. We evaluated prothioconazole as well as the two major degradates, prothioconazole-desphio and prothioconazole-S-methyl due to the rapid degradation of prothioconazole under environmental conditions. Although these degradates are more persistent, the impact to nontarget organisms and groundwater is below our established threshold of concern. The product labeling precautions adequately protect human health. Therefore, the Department will register Proline 480 SC Fungicide as labeled.
Enclosed for your record, are copies of the stamped accepted labeling and the Certificate of Registration for Proline 480 SC Fungicide (EPA Reg. No. 264-825). Please note that a proposal by Bayer Crop Science or any other registrant, to register a product that contains prothioconazole, and whose labeled uses are likely to increase the potential for significant impact to humans, nontarget organisms, or the environment, would constitute a major change in labeled use (MCL) pattern. Such an application must be accompanied by a new application fee and meet the requirements listed in Appendix 1.B. of "New York State Pesticide Product Registration Procedures" (April 2009). Such information as well as forms can be accessed at our website as listed in our letterhead.

Please be aware that any unregistered product may not be sold, offered for sale, distributed, or used in New York State.

Please contact Paula McBath, of our Pesticide Product Registration Section, at (518) 402-8768, if you should have any questions.

Sincerely,

Maureen P. Serafini
Director
Bureau of Pesticides Management

Enclosure

cc: w/enc. – A. Grey/E. Horn/D. Luttinger - NYS Dept. of Health
R. Zimmerman/R. Mungari - NYS Dept. of Ag. & Markets
W. Smith - Cornell University, PSUR