

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

JUN 2 1 2000

Dr. Thomas R. Nelsen
BASF Corporation
Agricultural Products
P.O. Box 13528
Research Triangle Park

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Research Triangle Park, NC 27709-3528

Dear Dr. Nelsen:

Subject: Ronilan EG

EPA Reg. No. 7969-85

Your Submission of November 12, 1999

The supplemental labels for canola and snap beans, included with the amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), are conditionally accepted provided that you will submit the data indicated below and make the indicated labeling revisions for each supplemental label:

The following data must be submitted for vinclozolin:

- 1. A developmental Neurotoxicity study with an expanded protocol (due 3 years from the date of this amendment).
 - 2. A vinification study which will be due in 3 years.
- 3. In accordance with section 408(b)(2)(E)(ii) of the Federal Food, Drug, and Cosmetic Act (FFDCA), because anticipated or actual residue levels are being relied on for all commodities, the Agency is requiring, pursuant to subsection (f)(1), that you provide, five years after the date on which the tolerances are established, modified or left in effect, and thereafter as the Admnistrator deems appropriate, data demonstrating that such resisdue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e) (1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

These amendments adding the canola and snapbean use expire on September 30, 2003. The labeling for each supplemental label must bear an expiration date of September 30, 2003 to coincide with the expiration date of the time-limited tolerances.

The following labeling changes must be made for the specific crops as follows.

For canola:

Under PPE for early entry in the Agricultural Use Requirements box, change "waterproof gloves" to "chemical-resistant gloves made of any waterproof material".

Assure that the Agricultural Use Requirements are enclosed in a box.

Also in the Agricultural Use Requirements box, change the REI to 9 days and add the following advisory statement "Advisory to Certified Crop Advisors: Users should inform Certified Crop Advisors [as defined by the Worker Protection Standard (WPS)] that people engaged in scouting activities should wear coveralls, shoes and socks, and chemical-resistant gloves made of any waterproof material when entering treated areas during the first 48 hours following application (72 hours in areas where average rainfall is less than 25 inches per year)."

Under Special Directions for Aerial Application, in the first sentence, change "cautions" to "precautions".

Under Time and Rate of Application, the sentence "A maximum of 10.6 ounces to 1.0 lb. Of Ronilan per acre per application may be used" is awkward and confusing and must be revised. The use of the word "maximum" for a rate range is inappropriate. Delete "maximum" or revise to indicate that it refers only to the higher rate. It is preferable that the rates be expressed in the same units: i.e, 2/3 to 1.0 pound/acre. Since only one application may be made, the term "per application" should be deleted since it implies more than one application.

For snap beans:

Add the statement "Apply only to beans which will be mechanically harvested."

Under PPE in the Precautionary Statements and in the Agricultural Use Requirements box, change "waterproof gloves" to "chemical-resistant gloves made of any waterproof material".

Also in the Agricultural Use Requirements box, change the REI to 10 days as on the previously accepted labeling for snap beans.

Submit one (1) copy of the final printed labeling before you release the supplemental labels for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Stamped copies of the supplemental labels are enclosed for your records.

Sincerely yours,

Mary J. Waller
Mary L. Waller

Product Manager (21)

Fungicide Branch

Registration Division (7505C)

Enclosures

ACCEPTED with COMMENTS In EPA Letter Dated:

Fungicide, and Redenticide Act as amended, for the pesticide registered under EPA Reg. No.

For use on snap beans. For ground and air application. Prohibited from residential use.

EPA Reg. No. 7969-85 EPA Est. No. 39578-WG-01

All applicable directions, restrictions, precautions and Conditions of Sale and Warranty on the EPAregistered label are to be followed. This labeling must be in the possession of the user at the time of herbicide application.

Ronilan® EG

Precautionary Statements Hazards to Humans and **Domestic Animals**

Harmful if swallowed, inhaled, or absorbed through skin. Causes eve irritation. Do not get on skin, in eyes, or on clothing. Avoid breathing vapor or spray mist. Prolonged exposure or frequently repeated skin contact may cause allergic reactions in some individuals.

Statement of Practical Treatment

If on skin: Wash with plenty of soap and water. Get medical attention

If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-tomouth. Get medical attention. If in eyes: Flush with plenty of water. Call a physician if irritation persists.

Personal Protective Equipment: Applicators and other handlers must wear:

- Coveralls over long-sleeved shirt and long pants
- Waterproof gloves
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant headgear for overhead exposure
- Chemical-resistant apron when cleaning equipment, mixing, or loading

- For exposures in enclosed areas, a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC 23-C), or a canister approved for pesticides (MSHA/NIOSH approval prefix
- For exposures outdoors, dust/mist filtering respirator (MSHA/NIOSH) approval number prefix TC-21C)

Engineering Controls Statement 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.
- 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. Do not apply directly to water, 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 washwaters.

Directions For Use

It is a violation of federal law to use this product in a manner consistent 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 agricultura pesticides, It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions partaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 3

the Worker Protection Standard.

No workers may enter treated areas during the first 4 hours after application.

Under the Worker Protection Standard early entry exception for irrigation workers, workers performing tasks related to operating, moving, or repairing irrigation



5/8

Agricultural Use Requirements (continued)

equipment may reenter treated areas, after the first 4 hours following application, for up to 4 hours per each 24-hour period during and until the end of the REI. These early-entry irrigation workers must wear coveralls over long-sleeved shirt and long pants, waterproof gloves, chemical-resistant footwear plus socks, protective eyewear, and chemical-resistant headwear for overhead exposure.

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 over long-sleeved shirt and long pants ; •

Waterproof gloves

Chemical-resistant footwear plus socks

Protective eyewear

 Chemical-resistant headwear for overhead exposure

Storage and Disposal

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

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Time and Rate of Application for Control of White Mold and Gray Mold in Snap Beans by Ground and Air Application

Ronilan EG may be applied up to two times per growing season. The first application is recommended during early bloom (approximately 10%). Depending on conditions which favor disease development, a second application of Ronilan EG may be required at full bloom or 7-21 days after the first application. A maximum of 1 pound of Ronilan EG per acre per application may be used.

Method of Application

Thorough spray coverage is essential. Therefore, use adequate spray volumes and proper spray equipment. Note that plants grown in narrow rows form a dense canopy early. This may promote disease development and decrease spray penetration. Particular attention to spray coverage is required in this situation.

When applying Ronilan EG with ground equipment, use a minimum of 40 gallons of water per acre. When applying Ronilan EG with air equipment, use a minimum of 5 gallons of water per acre.

Restrictions and Limitations Snap Beans

Do not apply **Ronilan EG** within 10 days of harvest.

Do not make more than 2 applications of **Ronilan EG** per season. Do not apply more than 2 pounds of **Ronilan EG** per season. Do not apply **Ronilan EG** during rain. Apply when conditions will permit spray to dry on the plant. Do not feed green or dry forage (bean hay from treated fields) to livestock or permit livestock to graze in treated fields.

Do not feed succulent green bean seed from treated fields to poultry or livestock.

Conditions of Sale and Warranty The Directions For Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as: weather conditions, presence of other materials, or use of the product in a manner inconsistent with its labeling, all of which are beyond the control of BASF CORPORATION ("BASF"), or the Seller. All such risks shall be assumed by the Buyer. BASF warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions For Use, subject to the inherent risks referred to above. BASE MAKES NO OTHER EXPRESSED OR IMPLIED WAR-RANTY OF FITNESS OR MER-CHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRAN-TY. IN NO CASE SHALL BASE OR THE SELLER BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, BASE and the Seller offer this product, and the Buyer and User accept it, subject to the foregoing Conditions of Sale and Warranty, which may be varied only by agreement in writing signed by a duly authorized representative of BASF.

Made in Germany.

Ronilan is a registered trademark of BASF AG.

© 1998 BASF Corporation

NVA 97-4-34-0174





BASF Corporation P.O. Box 13528 Research Triangle Park, NC 27709



RONILAN EG

fungicide

For use on canola

EPA Registration No. 7969-85 EPA Establishment No. 39578-WG-01

ACCEPTED with COMMENTS In EPA Letter Dated:

6/21/00

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

7969-85

Precautionary Statements

Hazards to Humans and Domestic Animals Caution. Harmful if swallowed, inhaled, or absorbed through skin. Causes irritation. Do not get on skin, in eyes, or on clothing. Avoid breathing vapor or spray mist. Prolonged exposure or frequently repeated skin contact may cause allergic reactions in some individuals.

Statement of Practical Treatment

If on skin: Wash with plenty of soap and water. Get medical attention.

If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical

If in eyes: Flush with plenty of water. Call a physician if irritation persists.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Coveralls over long-sleeved shirt and long pants
- Chemical resistant gloves made of any waterproof material
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant headgear overhead exposure
- Chemical-resistant apron when cleaning equipment, mixing, or loading
- For exposures in enclosed areas, a respirator with either an organic vaporremoving cartridge with a prefilter approved
- for pesticides (MSHA/NIOSH approval number prefix TC 23-C), or a canister

approved for pesticides (MSHA/NIOSH approval prefix TC-14G)

For exposures outdoors, dust/mist filtering respirator (MSHA/NIOSH) approval number prefix TC-21C)

Wash thoroughly with soap and water after handling. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not re-use them. Follow the manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Controls Statement

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 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. Do not apply directly to water, 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 washwaters.

Directions For Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling. This product is not permitted for residential use. 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.

All applicable directions, restrictions, precautions and Conditions of Sale and Warranty are to be followed. This labeling must be in the user's possession during application.

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 agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 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 over long-sleeved shirt and long pants
- Waterproof gloves
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant headwear for overhead exposure

Storage and Disposal

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

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

Container Disposal: This package contains water-soluble bags inside a foil liner (outer bag). The water-soluble bags dissolve in water and the contents will disperse. If all the water-soluble bags are not used, carefully reseal the foil bag. Each foil bag contains five water-soluble bags. Do not remove the water-soluble bags from the overwrap bags except for immediate use. If exposed to moisture, the water-soluble bags may break. The outer box and inner overwrap packaging of the water-soluble bags should be incinerated or disposed of in a sanitary landfill, or if allowed by state and local authorities; by burning. If burned, stay out of smoke. Do not re-use the empty packaging.

Time and Rate of Application for Control of White Mold, Sclerotinia Stem Rot (Sclerotinia sclerotiorum) by Ground and Air Application

Ronilan EG may be applied up to one time growing season. Application recommended at 20-50% flower. This will normally be about 4-8 days after the beginning of flowering. A maximum of 10.6 ounces to 1.0 pound of Ronilan EG per acre per application may be used. Thorough spray coverage is essential. Therefore, use adequate spray volumes and proper spray equipment. Note that plants grown in narrow rows form a dense canopy early. This may promote disease development and decrease spray penetration. Particular attention to spray coverage is required in this situation.

8/8

When applying Ronilan EG with ground equipment, use a minimum of 20 gallons of water per acre.

Air Application

Water Volume: Use 5-20 gallons of water

per acre.

Spray Pressure: Use a maximum of 40 psi.

Application Equipment:

- Nozzles: Use nozzles that develop a sheet of spray through a sheet or straight stream discharge, such as CP, Lund, and flat fans with angles of 25°-65°. Narrow fan angles provide better droplet size control than wider angle versions. Nozzles should be positioned no more than 15 feet above the crop and pointed toward the rear of the aircraft. The downward angle of the nozzles should not be greater than 20°.
- Screens: If used, do not use screens greater than 50 mesh size as nozzle plugging is possible.

Special Directions for Aerial Application

The applicator must follow the most restrictive use cautions to avoid drift hazards, including those found in this labeling as well as applicable state and local regulations and ordinances. Do not apply by aircraft when wind is blowing more than 10 mph.

on fixed wing aircraft: The nozzles should be positioned so that the spray being emitted is rearward, slightly downward, and so that the stream or sheet is parallel to the surrounding airstream around the nozzle. The nozzle outlet should also be positioned below any turbulence layer such as those created by the wing and boom. A good rule of thumb is for the nozzle outlet to be at least 2" below the boom when booms are mounted in a drop boom configuration.

 On helicopters: The nozzles should be positioned so that the stream or sheet is parallel to the surrounding airstream around the nozzle.

Conditions of Sale and Warranty

The Directions For Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness or other unintended consequences may because of such factors as weather conditions, presence of other materials, or use of the product in a manner inconsistent with its labeling, all of which are beyond the control of BASF CORPORATION ("BASF") or the Seller. All such risks shall be assumed by the Buyer. BASF warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions For Use, subject to the inherent risks, referred to above. BASE MAKES NO **EXPRESS IMPLIED** OTHER **OR FITNESS** WARRANTY OF MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. IN NO CASE SHALL BASE OR THE SELLER LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT **DAMAGES** RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. BASF and the Seller offer this product, and the Buyer and User accept it, subject to the foregoing Conditions of Sale and Warranty which may be varied only by agreement in writing signed by a duly authorized representative of BASF.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

WARNING: This product contains a chemical known to the State of California to cause cancer.