

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATE: August 24, 1981

SUBJECT: EPA Registration Number: 7969:53
Ronilan - PP 9F 2205

FROM: Deloris F. Graham *RFG 8/31/81*
FHB/TSS *E 8/31/81*

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TO: Henry Jacoby
Product Manager (21)

Applicant: BASF Wyandotte Corporation
100 Cherry Hill Road
P.O. Box 181
Parsippany, NJ 07054

Active Ingredient:
Vinclozolin.....50%
Inert Ingredient.....50%

Background: Submitted two Dermal Sensitization studies. These studies were conducted by BASF. Data was not accessioned. Method of support not indicated.

Recommendation:

(1) FHB/TSS finds the Dermal Sensitization Study using the intradermal injections unacceptable to support conditional registration of this product until an explanation of what happened to 3 of the 12 animals used is given. As stated in the data, only 9 of the 12 animals survived.

(2) FHB/TSS finds the Dermal Sensitization Study using open epicutaneous method acceptable to support conditional registration of this product.

(3) Based on the intradermal injection sensitization test, vinclozolin (active ingredient) is a potential sensitizer. However, the Open Epicutaneous Test showed that vinclozolin at diluted-use strengths does not cause sensitization.

Review:

(1) Dermal Sensitization Study: BASF; Report #79/89; September 7, 1979.
using active ingredient only

Procedure: Six intradermal injections are made in groups of two. Front row - 2 injections each of 0.1 ml of Freund Complete adjuvant/aquatest (1:1) without test compound. Middle row - 2 injections of 0.1 ml of test allergen in

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suitable solvent without Freund adjuvant. Back row - 2 injections each of 0.1 ml of test allergen in Freund adjuvant 24 hours after the intradermal application. The skin findings are scored at each application site.

One week after the intracutaneous induction in exactly the same area, 24 hours before, the local application of a 10% formulation of sodium laurylsulphate in white vaseline is massaged into this area with a glass rod without a dressing applied.

For the actual induction, the test allergen is applied to the skin with a 2x4 cm filter paper. Solid compounds are applied as a paste in white vaseline. In case of liquid, filter paper is impregnated with undiluted compound or appropriate formulation. The dressing is removed after 48 hours and the dermal irritation effects are read. The challenge is carried out about 10-14 days after percutaneous induction.

Evaluations are made 24, 48, and 72 hours after the beginning of the contact period. About a week later, a second challenge was carried out with another solvent.

Results: After the intracutaneous induction, some distinct erythema and some necrosis and edema with suppurating ulceration were noted.

The first challenge was carried out with a compound formulation in white vaseline. Seven of 12 test animals were found to have skin changes, the intensity and course of which indicated previous sensitization. Vaseline on its own caused slight skin changes not only in the test group, but also in controls.

In the second challenge, skin changes were detectable in four of nine surviving test animals, which unequivocally indicated sensitization. No skin effects were detected in the control group.

On the basis of the test results, vinclozolin has sensitization effect on skin of a guinea pig.

Study Classification: Core Supplementary Data. Individual report on animals used during the study including the animals that died during the study.

Toxicity Category: Potential sensitizer

(2) Dermal Sensitization Study: BASF; WNT No. 79/661; April 29, 1981.

Procedure: Eight animals per group for each of the following concentrations: 2, 6, 20 and 60% formulation. Each animal received a 0.1 ml/8 cm² dose of each concentration per respective group. Eighteen (the usual 20 applications were not carried out since there were 2 holidays during phase of induction) days, 1 application per day for a total of 18 applications.

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Observations made 24, 48, and 72 hours after applications (on Saturday, Sunday, and holidays no readings were made). A concentration was considered to be sensitizing if at least one guinea pig of the concentration group concerned showed positive skin reactions using a nonirritating concentration while the control animals showed negative reactions.

Results: No sensitizing effect was found in this study carried out with percutaneous application. Thus, a sensitizing potential that might be of importance under the conditions of practice is not assumed to exist for the concentrations used in practice (up to 1%).

Study Classification: Core Minimum Data.

Toxicity Category: Nonsensitizing



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RonilanTM

Fungicide 50 W

For the Control of Botrytis Fruit Rot
on Strawberries

A wettable powder containing:

ACTIVE INGREDIENT

3-(3,5-Dichlorophenyl)-5-Ethenyl-5-Methyl-2,4-
Oxazolidinedione 50%
INERT INGREDIENTS..... 50%

EPA Reg. No. 7969-53

WARNING KEEP OUT OF REACH OF CHILDREN.
CAUSES EYE AND SKIN IRRITATION.

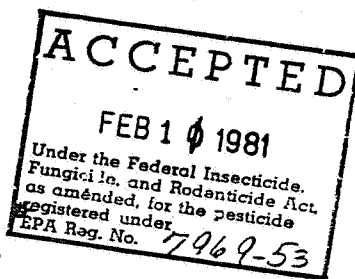
Do not get on skin, in eyes or on clothing.

FIRST AID If contacted, flush eyes immediately with water for at least 15 minutes. Remove contaminated clothing and wash exposed skin thoroughly with soap and water. Consult physician if irritation persists.

Net Contents 3 Lbs.

(2 x 1½ LB. BAGS. Do not remove bags from carton except for immediate use.)

BASF Wyandotte Corporation Parsippany, New Jersey 07054



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION

Ronilan[®] is a contact fungicide for the control of botrytis fruit rot (gray mold). If other diseases are a problem, an additional fungicide will be needed.

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STRAWBERRIES

Time and Rate of Application: Spray coverage of the developing fruit is essential. For full season control of botrytis disease the following spray program is recommended. The first application should be made not later than 10% primary bloom at rates indicated below (see table). The interval between subsequent applications will vary according to weather conditions and resultant disease pressure. A rate of 1½ pounds product per acre is generally recommended. A 1 pound product per acre rate of Ronilan should be used only when low disease pressure can be predicted. A 2 pound product per acre rate should be used when the foliage is dense and/or disease pressure is high. If a heavy rainfall occurs any time during this spray program or if a wet period (light rain, fog or dew) lasting more than 24 hours occurs, immediate retreatment is necessary at a rate of 1½-2 pounds product per acre as soon as conditions allow the spray to dry on the plants.

APPLICATION RATES FOR STRAWBERRIES*			
Moisture Conditions	Spray** Interval (Days)	Rate lbs. Product/A	
		1st Year Plants Or Sparse Foliage	Dense Foliage
Frequent natural moisture (intermittent rain, fog, dew) or when using sprinkler irrigation (high disease pressure)	7-9	1½	1½-2
Limited natural moisture or infrequent sprinkler irrigation (low disease pressure)	10-14	1	1½-2

*For all states except Florida

**Use spray interval throughout the bearing cycle.

Method of Application: Application of Ronilan should be made in not less than 100 gallons of spray solution per acre to obtain thorough coverage of the developing fruit. An operating pressure of 60-150 psi is recommended to obtain adequate penetration of the spray through the canopy. Cone-type nozzles are recommended. Spray booms with at least 3 nozzles per row (1 over row; 2 side drops) are recommended.

NOTICE TO USER

Do not apply Ronilan during rain. Wait until conditions are such that the spray will dry on the plants.

Do not apply more than a total of 35 pounds of Ronilan per acre in one season.

Ronilan does not control rhizopus rot of strawberries in the field or in storage. There may be a competitive relationship between botrytis and rhizopus incidence such that control of botrytis may result in an increase of rhizopus rot in stored fruit. Rhizopus rot becomes a problem as a result of certain climatic conditions (such as, prolonged warm, humid periods) and cultural practices (such as, high nitrogen fertilization which may lead to the production of softer fruit). If conditions are conducive for rhizopus development, including those described above, do not use Ronilan.

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Leafy vegetables may be planted 6 months after treatment that does not exceed 12 pounds active ingredient per acre (24 pounds product per acre).

Cucurbits may be planted 2 months after treatment that does not exceed 9 pounds active ingredient per acre (18 pounds product per acre).

Corn may be planted 2 months after treatment that does not exceed 9 pounds active ingredient per acre (18 pounds product per acre), provided only the corn grain is used for food and/or feed purposes.

Other grain crops may be planted 9 months after treatment that does not exceed 8 pounds active ingredient per acre (16 pounds product per acre).

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STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

Pesticide, spray mixture, or rinsate that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticides or buried in a safe place away from water supplies.

Dispose container in an incinerator or landfill approved for pesticide containers, or bury in a safe place.

Consult federal, state, or local disposal authorities for approved alternative procedures such as limited open burning.

ENVIRONMENTAL HAZARDS

Do not apply directly to lakes, ponds, or streams.

Do not contaminate water by cleaning of equipment or disposal of wastes.

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 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 WYANDOTTE CORPORATION ("BWC") or the Seller. All such risks shall be assumed by the Buyer.

"BWC" 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.

BWC MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. In no case shall "BWC" or the Seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. "BWC" 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 "BWC".

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EPA ESTABLISHMENT NO. 279-NJ-1

Made in West Germany.

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Ronilan™ Fungicide trademark of BASF AG CC 1-186