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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: BASF Protocol for Study of Exposure to Workers
Applying Ronilan WP (50 % Vinclozolin - HED # 0-
1037).

TO: Jim Stone, PM 21
Registration Division (H7505C)

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INTRODUCTION

BASF has submitted a mixer/loader/applicator exposure study protocol for Ronilan WP (50% vinclozolin). The following is NDEB's review and recommendations pertaining to the intended study.

CONCLUSION

NDEB has reviewed the subject protocol and found it to be unacceptable. The following concerns should be addressed.

1) Additional sites and replicates for ground boom and aerial applications are necessary.

2) The clothing scenario monitored must be representative of the clothing recommended on the pesticide label (see Attachment #2).

3) Air sampling media should be tested for efficiency and checked for break through. Air sampling should not be discontinued during the monitoring period.

4) Biological monitoring is not valid if conducted on a worker wearing a whole body dosimeter.

5) Alternative methods to monitoring hand and facial exposures should be investigated.

6) Exposure calculations should be clearly presented with the results expressed in units of mg/hr and mg/lb ai handled.

7) The registrant may wish to use some of the replicates to examine the effects of closed loading systems and closed cab tractors.

8) All QA/QC data described in Subdivision U of the Pesticide Assessment Guidelines must be collected.

Additional details are provided under Detailed Considerations, # II - NDEB Comments/Recommendations.

DETAILED CONSIDERATIONS

I) Protocol Summary

Mixer/loader and applicator activities will be monitored for three different types of application equipment. The number of sites, number of replicates and application rate are presented in table 1 (see attachment #1).

In these studies, the mixer/loaders will wear long sleeved shirts, long pants, socks, work boots, goggles, nitrile gloves and chemical resistant aprons. Applicators will wear long sleeved shirts, long pants, socks and shoes. It is also stated on page 8 of the subject protocol that applicators will wear nitrile gloves.

Application will be monitored for a minimum of 1.5 hours of spraying time per replicate. Mixing and loading will be monitored for one full cycle per replicate.

Air sampling will be conducted via the use of MSA model - S (or equivalent) samplers adjusted to a flow rate of 1.5 l/minute. A single stage filter consisting of glass fiber media will be used for sample collection. Air sampling will be discontinued if there is a work stoppage exceeding 30 minutes..

Dermal exposure will be monitored using modified Durham - Wolfe type patches and whole body dosimeters (long underwear).

Patches will be placed on the outside of the workers coveralls at the following positions.

Left Shoulder	Right Shoulder
Upper Back	Chest
Left Thigh	Right Thigh
Left Shin	Right Shin
Left Forearm	Right Forearm

Whole body dosimeters (long underwear) will also be worn under work clothing.

Hand exposure will be measured via hand washes in two, 300 ml portions of a 0.1% Surten (detergent) solution. The nitrile gloves worn during the mixing/loading and application will also be analyzed.

Exposure to the face and neck will be measured by swabbing the exposed areas with a 12 layer gauze square (similar to that used for the patches) wet with the 0.1% Surten solution. Two swabs per replicate will be used and combined for analysis.

Urine samples will also be collected from all workers prior to exposure, during exposure, and for 48 hours after the exposure period.

Field fortified samples (prepared from each sampling media) will be set up each day and exposed to the environment for the duration of one monitoring period. Control samples (blanks) will also be set up and treated similarly. A control person will also be set up during one monitoring period. This person will wear the same type of clothing and monitoring devices as the other study participants but, will remain in an area that is free from exposure (probably near the other control samples).

All samples will be packed in ice and shipped (overnight) to Pan-Agricultural Laboratories where they will be stored in a freezer (-20° C) until analysis.

The final report will include the following information.

- 1) Hourly weather data: temperature, humidity, % cloud cover, wind direction and velocity.
- 2) A description and map of the test sites.
- 3) A description of the application equipment and calibration processes.
- 4) Application information (e.g. lbs ai handled).
- 5) A description of the test material.

- 6) Historical data on the test site.
- 7) Unusual events or disruptions to the sampling period.
- 8) Worker data: name, sex, age, weight, height, general health, years in occupation.
- 9) Photographs of workers wearing dosimeters etc..
- 10) Any additional information as needed.

II) NDEB Comments/Recommendations

NDEB has reviewed the subject protocol and found it to be unacceptable. Several points should be addressed in a revised protocol. NDEB's concerns are as follows.

1) An additional site with 5 applicator replicates for ground boom application and an additional site with 1 pilot replicate for aerial application are needed to satisfy the recommendations of Subdivision U of the Pesticide Assessment Guidelines. If mechanical flaggers are not used, 15 replicates of monitoring flagger exposure during aerial application will also be required.

2) The clothing scenario monitored in the study must be representative of the clothing recommended on the product label. The proposed label for Ronilan WP (provided with the protocol, see attachment #2), does not mention any use of protective clothing in the directions for application. The protocol states that mixer/loaders will wear chemical resistant aprons, nitrile gloves and goggles in addition to long sleeved shirts, long pants and work boots. It is also stated that the applicator will wear a long sleeved shirt, long pants, and nitrile gloves (p. 8, protocol). The product label must be modified to require the use of this protective clothing. If it is not, the patches must be placed where they will not be over protected and the use of whole body dosimeters and biological monitoring will be invalid. NDEB does not believe that the use of nitrile gloves by the applicators will be practical and therefore, it may be desirable to omit this clothing item from the list for applicators. Finally, the protocol makes a reference to workers wearing coveralls (p. 8). This clothing item is not mentioned in the original list and, therefore, has created some confusion.

3) The trapping efficiency of the air sampling media must be evaluated and, an additional filter should be used to check for break through. Also, sampling should not be discontinued if there is a work stoppage exceeding 30 minutes unless the worker leaves the monitoring site. Air sampling should be continued if there is a work stoppage for routine maintenance.

4) Biological monitoring is not valid if workers are wearing whole body dosimeters.

5) With respect to monitoring hand exposure by hand rinses, the Agency is concerned about the inadequacy of associated field recovery techniques that initiate with spiking the rinsate. Such methodology fails to account for the ability of the dosimeter to trap or retain residues under a variety of environmental and/or physiological conditions. In addition, there is a failure to account for extraction efficiency of the solvent for removing residues from the hand. These deficiencies in generating adequate field recovery data may produce an underestimation of actual hand exposure. The use of light weight cotton glove dosimeters, which may be directly spiked for field recovery determination, minimizes these problems when used for exposure monitoring. The Agency recommends that the registrant address these concerns when selecting and developing hand exposure monitoring methodology.

The results of the extraction of the nitrile gloves will not be used by NDEB in the exposure estimates. This data will only be used to provide qualitative information concerning the value of the protective glove.

6) The concerns expressed in #5 (above) also apply to the use of facial swabs. The use of hat patches and/or other techniques to monitor facial exposure may be desirable.

7) NDEB recommends that in the final report, the exposure results be presented in units of mg/hr and mg/lb ai handled. All calculations, from recovery correction of raw data through estimation of exposure, should be presented in a clear and concise manner.

8) The results of a preliminary exposure assessment indicate that some of the uses described in this study may have inadequate Margins of Safety (MOS). Therefore, the registrant may wish to use some of the replicates to examine the effect of engineering controls such as closed loading systems and closed cab tractors.

9) All QA/QC recommendations in Subdivision U of the Pesticide Assessment Guidelines must be followed.

Attachment (2)

cc: Circulation
Correspondence File
Vinclozolin File
SACB

TABLE 1 : Ronilan M/L/A Exposure Study

Equipment/ Crop type	Number of Sites	Location of Site (State)	Number of Replicates per Site	Total Number of Replicates	Pesticide/ Application Rate
Airblast/ Trees	2 1	CA NY	5 Applicator 5 Mixer/Loader (NY Only)	15 Applicator 5 Mixer/Loader	Ronilan 50 WP 1 lb ai/Acre 1 Application
Groundboom/ Field Crops	2	CA	5 Applicator 5 Mixer/Loader	10 Applicator 10 Mixer/Loader	Ronilan 50 WP 1 lb ai/Acre 1 Application
Aerial	2	CA	3 Mixer/Loader	6 Mixer/Loader	Ronilan 50 WP 1 lb ai/Acre

BASF

Ronilan® WP

Fungicide

A wettable powder containing:

Active Ingredient

3-(3, 5-Dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolinedione

50%

Inert Ingredients

50%

EPA Reg. No. 7969-53

KEEP OUT OF REACH OF CHILDREN.

CAUTION

Causes eye irritation. Do not get on skin, in eyes or on clothing.

Statement of practical treatment

If contacted, flush eyes immediately with water for 15 minutes. Get medical attention. In case of contact with skin or clothing, remove contaminated clothing, wash skin thoroughly with soap and water. This product is a potential skin sensitizer. If irritation persists get medical attention.

Environmental hazards

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

Net contents 3 lbs.

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

BASF Corporation Chemicals Division
100 Cherry Hill Road Parsippany, New Jersey 07054

Specimen Label

Re-entry and workers' protection statements

Do not apply this product in such a manner as to directly or through drift expose workers or other persons, except those knowingly involved in the application. The area being treated must be vacated by unprotected persons.

Do not enter treated areas without protective clothing until sprays have dried.

Because certain states may require more restrictive re-entry intervals for various crops treated with this product, consult your State Department of Agriculture for further information.

Written or oral warnings must be given to workers who are expected to be in a treated area or in an area about to be treated with this product. Oral warnings must inform workers of areas or fields that may not be entered without specific protective clothing until sprays have dried, and appropriate actions to take in case of accidental exposure. When oral warnings are given, warnings shall be given in a language customarily understood by workers. Oral warnings must be given if there is reason to believe that written warnings cannot be understood by workers. Written warnings must include the following information:

WARNING: Read label
Ronilan on (date of application).

Do not enter without appropriate protective clothing until sprays have dried. If contacted, flush eyes immediately with water for 15 minutes. Get medical attention.

In case of contact with skin or clothing, remove contaminated clothing, wash skin thoroughly with soap and water. Call physician if irritation occurs. Wash contaminated clothing before reuse."

Directions for use

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

Storage and disposal

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

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

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.

In case of emergency

In case of large-scale spillage regarding this product, call:

CHEMTREC 800-424-9300

BASF Corporation . . 201-316-3000

In case of medical emergency regarding this product, call:

1. Your local doctor for immediate treatment.

2. Your local poison control center (hospital).

3. BASF Corporation 201-316-3000

All applicable directions, restrictions, precautions and Conditions of sale and warranty are to be followed. This labeling must be in the possession of the user at the time of application.

General information

Ronilan is a contact fungicide for the control of *Botrytis* fruit rot (gray mold) of strawberries, *Sclerotinia* "drop" (watery soft rot) of head lettuce, and brown rot blossom and twig blight, and fruit brown rot on stonefruit (see page 5 for list of stonefruit). Thorough coverage of plant parts to be protected is essential for effective disease control. If other diseases are a problem, an additional fungicide will be needed.

The repeated exclusive use of Ronilan, as is the case with the exclusive use of other fungicides, may result in the buildup of resistant strains of *Botrytis* and loss of disease control. A spray program alternating other fungicides with Ronilan may delay the buildup of resistant strains. If treatment becomes ineffective due to the presence of a Ronilan resistant strain of *Botrytis*, then prompt use of other fungicides is necessary to maintain disease control.

Strawberries

Time and rate of application for states other than California and Florida

Thorough spray coverage of the blossoms and developing fruit is essential. For full season control of *Botrytis* disease, the following spray program is recommended. The first application should be made no later than 10% primary bloom at rates indicated (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 one pound product per acre rate of Ronilan should be used only when low disease pressure can be predicted. A two pounds 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 re-treatment is necessary at a rate of 1½ to 2 pounds product per acre as soon as conditions will allow the spray to dry on the plants.

Time and rate of application for California

Thorough spray coverage of blossoms and developing fruit is essential for good disease control. For full season control of *Botrytis* disease, fungicides may need to be applied at 7 to 14 day intervals throughout the production cycle. When using Ronilan, the first application should be made no later than 10% primary bloom. If conditions favorable for high disease pressure persist after the first application, a second application should be made 7 to 9 days after the first.

To reduce the hazard of resistance developing, further use of Ronilan should be reserved for periods of high disease pressure and/or highest economic return. A rate of 1½ pounds product per acre is generally recommended. A 2 pounds product per acre rate should be used when foliage is dense and disease pressure is high. Make no more than a total of four applications of Ronilan per season.

Time and rate of application for Florida

Thorough spray coverage of the developing fruit is essential. For full season control of *Botrytis* disease, fungicides should be applied at 7 day intervals throughout the production cycle. If a frost protection irrigation is planned, an application of Ronilan must be made immediately before and after the irrigation. If a heavy rainfall occurs anytime during the spray program or if a wet period (light rain, fog, or dew) lasting more than 24 hours occurs, immediate re-treatment is necessary as soon as conditions will allow the spray to dry on the plants.

Method of application

Ground equipment: 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.

Application Rates for Strawberries in States other than California and Florida			
Moisture Conditions	Spray* Interval (Days)	Rate (Pounds Product/A)	
		1st Year Plants or Sparse Foliage	Dense Foliage
Frequent natural moisture (intermittent rain, fog, dew) or when using sprinkler irrigation (<i>high disease pressure</i>)	7-9	1½	1½-2
Limited natural moisture or infrequent sprinkler irrigation (<i>low disease pressure</i>)	10-14	1	1½-2

*Use spray interval throughout the bearing cycle.

Application Rates for Strawberries in California			
Moisture Conditions	Spray* Interval (Days)	Rate (Pounds Product/A)	
		1st Year Plants or Sparse Foliage	Dense Foliage
Frequent natural moisture (intermittent rain, fog, dew) or when using sprinkler irrigation (<i>high disease pressure</i>)	7-9	1½	2

*Make no more than four (4) applications per season.

Application Rates for Strawberries in Florida		
Moisture Conditions	Spray Interval (Days)	Rate (Pounds Product/A)
Frequent natural moisture (intermittent rain, fog, dew) or when using sprinkler irrigation (<i>high disease pressure</i>)	7	2

Air equipment: Application of Ronilan should be made in not less than 20 gallons of spray solution per acre. Thorough spray coverage of the developing fruit is essential.

Restrictions and limitations for strawberries

Do not apply more than a total of 12 pounds of product per acre in one season, except in California where the total is restricted to 8 pounds in no more than four applications.

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.

Do not use Ronilan as a plant dip, as injury will occur. Do not apply this product through any type of irrigation system.

Rotational crop restrictions for states other than California
Lettuce (head types only) may be planted after strawberries.

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

Cucurbits may be planted 2 months after treatment that does not exceed 6 pounds active ingredient per acre (12 pounds product per acre).

Corn may be planted 2 months after treatment that does not exceed 6 pounds active ingredient per acre (12 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 6 pounds active ingredient per acre (12 pounds product per acre).

Any rotational crops may be planted 20 days after treatment that does not exceed 3 pounds active ingredient per acre (6 pounds product per acre).

Rotational crop restrictions for California

Lettuce (head types only) may be planted after strawberries.

Leafy vegetables may be planted 6 months after treatment that does not exceed 4 pounds active ingredient per acre (8 pounds product per acre).

Cucurbits may be planted 2 months after treatment that does not exceed 4 pounds active ingredient per acre (8 pounds product per acre).

Corn may be planted 2 months after treatment that does not exceed 4 pounds active ingredient per acre (8 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 4 pounds active ingredient per acre (8 pounds product per acre).

Any rotational crops may be planted 20 days after treatment that does not exceed 3 pounds active ingredient per acre (6 pounds product per acre).

Application Rates for Lettuce (Head Types Only)			
Application	Timing	Rate (Pounds Product/Acre)	
		*Low Disease Pressure	*High Disease Pressure
First	Direct Seeded Lettuce—Application should be made immediately (within 2 days) after thinning.	1	1½-2
	Transplanted Lettuce—Application should be made 7-10 days after transplanting.		
Second	Application should be made 14 days after first spray if cool, wet conditions (which favor disease) occur for periods lasting 48 hours or more.		
Third	Direct Seeded Lettuce Only—Application should be made 14 days after second spray if conditions favoring disease occur.		

*Based on previous history of disease infestation in the field or adjacent fields.

Lettuce (head types only)

Time and rate of application

For control of *Sclerotinia* "drop," up to three applications may be made under certain conditions in one season as specified in the rate table. Thorough spray coverage of plant parts to be protected is essential for effective disease control. Do not disturb soil after application.

Method of application

Application of Ronilan should be made in not less than 100 gallons of spray solution per acre (broadcast basis) to obtain thorough coverage of the lower leaves, plant stem and bed surface. An operating pressure of 50-100 psi is recommended. Use cone or flat fan nozzles. Flood type nozzles should not be used. To apply Ronilan to one-row beds, spray booms should have at least 2 nozzles per row. For two-row beds use three nozzles or more per bed.

Restrictions and limitations for lettuce

Do not apply Ronilan within 28 days of harvest.

Do not use on leaf type lettuce.

Do not use Ronilan as a plant dip, as injury may occur.

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

Stonefruit

General Information

Ronilan is effective for the control of brown rot blossom and twig blight, and fruit brown rot of stonefruit including apricots, cherries, nectarines, peaches, plums, and prunes. Ronilan is a contact fungicide, therefore, thorough coverage of plant parts to be protected is essential for effective disease control.

Time and rate of application

Depending on conditions which favor disease development, one to three applications should be made during bloom for control of brown rot blossom and twig blight. One or two preharvest applications should be made for control of fruit brown rot (see table).

A rate of 1½ pounds product per acre is generally recommended. A one pound product per acre rate of Ronilan should be used only when low disease pressure can be predicted. Under high disease pressure or in conditions very favorable for disease development, use the higher treatment rates specified, multiple applications, and shorter application intervals. For large mature trees, use the higher treatment rates specified.

Consistency of disease control with low recommended rates can be enhanced by 8-16 oz./100 gal. of a non-ionic surfactant in tank mix with Ronilan.

Method of application

Rates of Ronilan per 100 gallons are based on an application of 400 gallons per acre of dilute spray. Refer to the **Application Rates and Timing for Control of Brown Rot** if other than 400 gallons per acre is applied.

Apply Ronilan as a spray with ground equipment, using sufficient water to obtain **thorough coverage** (50-400 gallons per acre).

Mixing instructions: Thoroughly mix the required amount of Ronilan in a small volume of water. Partially fill the spray tank with clean water and begin agitation. Add the Ronilan mix to the tank and fill tank to the total volume required. Maintain agitation to keep the material in suspension and apply with properly calibrated spray equipment.

Ronilan is physically compatible with most pesticides used in a tank mix on stonefruit. To assure compatibility of Ronilan with other products, add correct proportions in a small container with water. Mix

Stonefruit Application Rates and Timing for Control of Brown Rot (<i>Monilinia</i> spp.)			
Crop	Pounds of Product* per		Timing
	100 Gallons	Acres	
Apricots Cherries Nectarines Peaches Plums Prunes	0.25 to 0.5 Rate is based on 400 GPA	1.0 to 2.0	Brown Rot Blossom & Twig Blight Apply at early bloom Apricots—Red Bud Peaches & Nectarines—Pink Bud Cherries—Early Popcorn Plums and Prunes—Green Tip Apply again at full bloom if conditions persist which favor disease development. Apply again at petal fall if conditions persist which favor disease development. Do not apply more than 3 bloom treatments. Fruit Brown Rot Apply when conditions favor disease development within 3 weeks of harvest. One additional application should be made 7 to 14 days later if these conditions persist. Do not apply more than 2 pre-harvest treatments. Do not apply within 3 days of harvest.
	Do not exceed 2 lbs. product per acre per application.		

*See Time and rate of application.

thoroughly and let the mixture stand for five minutes. The mixture is compatible if the combination remains mixed, or can be readily remixed.

Restrictions and limitations for stonefruit

Do not apply Ronilan within 3 days of harvest.

Do not apply more than 2 pounds of Ronilan per acre per application. Do not apply more than 10 pounds of Ronilan per acre per season (maximum of 6 pounds at bloom and 4 pounds preharvest).

Do not apply Ronilan during rain. Apply when conditions will permit spray to dry on the plants.

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

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 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. **BASF MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. IN NO CASE SHALL BASF OR THE SELLER BE 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.

EPA Establishment No. 39578-TX-1

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