

Bear File

11
REVIEW NO.

113201
SHAUGHNESSEY NO.

EEB BRANCH REVIEW

DATE: IN 4-26-82 OUT 7/1/82

FILE OR REG. NO. 7969-LT
PETITION OR EXP. PERMIT NO. _____
DATE OF SUBMISSION 3-31-82
DATE RECEIVED BY HED 4-23-82
RD REQUESTED COMPLETION DATE 7-8-82
EEB ESTIMATED COMPLETION DATE _____
RD ACTION CODE/TYPE OF REVIEW 175/Old Chemical - New Nonfood/Nonfeed Use
TYPE PRODUCT(S): I, D, H, F, N, R, S Fungicide
DATA ACCESSION NO(S). _____
PRODUCT MANAGER NO. H. Jacoby (21)
PRODUCT NAME(S) Ronilan
COMPANY NAME BASF Wyandotte Corporation
SUBMISSION PURPOSE Proposed Registration of a Manufacturing Use Product for the
Preparation of use formulation of Ronilan Fungicide

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
<u>113201</u>	<u>Vinclozolin</u>	<u>93</u>
<u> </u>	<u>Inert</u>	<u>7</u>
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Ronilan Manufacturer's Concentrate

100 Pesticide Label Information

100.1 Pesticide Use

A solid technical product for formulating
Ronilan fungicides
- For Formulating Use Only -

101 Physical and Chemical Properties }
and } See previous reviews
102 Behavior in the Environment }
103 Toxicological Properties

The following data were referenced in support of this MUP. The status of each study is noted.

<u>Study</u>	<u>Species</u>	<u>Values (for technical)</u>	<u>Status</u>
Acute Oral	Rat	LD50 >10,000 mg/kg	_____
I.P.	Mouse	LD50 5,000 mg/kg	_____
Acute Oral	Guinea Pig	LD50 8,000 mg/kg	_____
Acute Oral	Bobwhite Quail	LD50 > 2510 mg/kg	Core
Dietary	Bobwhite Quail	LC50 > 5620 ppm	Core
Dietary	Mallard Duck	LC50 > 5620 ppm	Core
Acute	Bluegill Sunfish	LC50 = 47.3 ppm	Supplemental
Acute	Rainbow Trout	LC50 = 19.4 ppm	Supplemental
Acute	Daphnia	LC50 = 4.0 ppm	Core
<u>Study</u>	<u>Species</u>	<u>Values (for Metabolite B)</u>	<u>Status</u>
Acute	Bluegill Sunfish	135.4 ppm	Unvalidated
Acute	Rainbow Trout	80.6 ppm	"
Acute	Daphnia	79.7 ppm	"

The following acute study was not referenced in this submission, but it is in EEB files and was submitted by BASF under Accession No. 242222:

<u>Study</u>	<u>Species</u>	<u>Test Material</u>	<u>Values</u>	<u>Status</u>
Acute	Punkinseed Sunfish (<u>Lepomis gibbosus</u>)	Technical 96.5%	LC ₅₀ =49.8 ppm	Supplemental*

*This study was determined to be acceptable to support the strawberry use registration, and for other registrations that will result in a warmwater aquatic environmental concentration of less than 1/100,000th the warmwater fish 96-hr LC₅₀ (See EEB review dated 12/10/80 by J. Leitzske).

104 Hazard Assessment

No hazard assessment is necessary for manufacturing use product registration.

104.4 Adequacy of Toxicity Data

Manufacturing use products that legally maybe used to make outdoor end-use products, generally need to be supported, by six core acute toxicity studies on wildlife and aquatic organisms before approval for registration. The applicant has referenced core data for the following.

- Acute Oral LD₅₀ on Bobwhite Quail;
- Dietary LC₅₀'s on Bobwhite Quail and Mallard Duck;
- Aquatic Invertebrate LC₅₀ on Daphnia.

The following referenced data were determined to be supplemental:

- Fish LC₅₀'s on Bluegill Sunfish and Rainbow trout.

In both studies the solubility of the test substance was a problem. A white flocculent material was abserved on the surface of the test containers.

104.5 Additional Data Required

No additional data are required for this manufacturing use product. While no fish toxicity data are core, there is sufficient supplemental data to determine that vinclozolin is only slightly toxic to fish. We do not believe that any further acute testing on fish would change this determination. The solubility problem is not likely to be solved by additional static fish testing. Also, there is not sufficient concern for this MUP to require the more costly flow-through test.

It is important to note however, that these data may not be adequate to support an end-use product registration, especially if the registered use would result in an estimated envrionmental concentration of less than 1/100,000 of the fish 96-hr LC₅₀ value. In this case, flow-through testing of the technical grade active ingredient may be needed.

107 Conclusions

EEB has completed an incremental risk assessment (3(C)(7)Finding) of the proposed conditional registration of Ronilan Manufacturer's Concentrate for the preparation of use formulation of Ronilan Fungicide. Based on the available data EEB concludes that the proposed manufacturing use provides for no significant increase in exposure or risks to nontarget organisms.

107.3 Environmental Hazards Labeling

The Environmental Hazards Label should be changed to read as follows:

"Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance contact your Regional Office of the EPA."

107.4 Data Adequacy Conclusions

The referenced data are adequate and acceptable to support this MUP registration.

107.5 Data Requests

No additional data are required to support the registration of this MUP.

It is important to note, however, that the fish acute toxicity data may not be acceptable for use in support of an end-use product registration (see section 104.5 this review).

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