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TYPE PRODUCT(S) : I, D, H, F, N, R, S

DATA ACCESSION NO(S). 264302, 264303

PRODUCT MANAGER NO. H. Jacoby (21)

PRODUCT NAME(S) Ronilan Fungicide 50 W

COMPANY NAME BASF Wyandotte Corporation

SUBMISSION PURPOSE Submission of further data in response to previous EEB reviews

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Submission of Data From BASF Wyandotte Corporation to Support Registration of Ronilan 50W Fungicide

FROM: Thomas M. Armitage Thomas M Armitage 11-20-86
Fisheries Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: Raymond W. Matheny Raymond W Matheny 11-21-86
Head - Section I
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: Michael W. Slimak, Chief 11/24/86
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

TO: H. Jacoby
PM (21)
Registration Division (TS-767-C)

Ecological Effects Branch (EEB) has reviewed the studies listed below to support registration of Ronilan 50W fungicide. In the most recent EEB review of this chemical for use on peanuts and phaseolus beans (Zucker, 1985) it was stated that the available acute toxicity data for warmwater and coldwater fish were inadequate to complete a hazard assessment. Studies were rejected due to insolubility of the test material. In response to this review the registrant (BASF Wyondotte) has submitted the following studies.

1) Report on testing for acute toxicity - Rainbow trout/BAS 352-F/Vinclozolin. EPA Acc. # 264302.

EEB Conclusions: The study documents a 96-hour LC_{50} equal to 2.84 ppm for rainbow trout exposed to technical vinclozolin (Ronilan). Due to the low water solubility of this chemical, large amounts of acetone and cremophor were used to dissolve the test material. Despite the use of these solvents, insolubility was a problem, and precipitation was observed in the test chambers. Measured concentrations of test material were, however, reported for all but the highest two test concentrations (after 96 hours). These measured concentrations may be used to derive the LC_{50}. However, the study does not fulfill the requirement for a coldwater fish LC_{50} determination because: the percent active ingredient in the test material was not reported, and the test water temperature (16°C $\pm$ 1°C) was higher than the required 12°C for a rainbow trout study.

The study must be repeated at a test water temperature of 12°C. If insolubility is a problem at this temperature, use of a flow-through test system is recommended. Measured concentrations of test material must be reported for exposure concentrations.

2) Report on testing of acute toxicity - bluegill sunfish/BAS 352 F-vinclozolin. EPA Accession # 264302.

EEB conclusions: This study documents a 96-hr. LC_{50} > 3.4 mg/l for bluegill sunfish exposed to technical vinclozolin. Due to low water solubility of this chemical, large amounts of acetone and cremophor were used to dissolve the test material. Despite the use of solvents, insolubility of the test compound was a problem. Measured concentrations of test material were, however, reported for all but the highest two dose concentrations. The observed LC_{50} was higher than the highest measured test concentration. The study does not fulfill the requirement for a warmwater fish LC_{50} determination because the percent of active ingredient in the test material was not reported.

The study may be upgraded to fulfill the requirement if the purity of the test material is reported.

3) Report on testing for acute toxicity - bluegill sunfish/BAS 352 04F/Ronilan.

EEB Conclusions: The study documents a 96-hr. LC_{50} > 68.1 < 100.1 ppm for bluegill sunfish (Lepomis gibbosus) exposed to Ronilan fungicide. The study does not, however, fulfill the Guidelines requirement for a 96-hour LC_{50} determination using formulated product. This is because the test water was aerated, and sedimentation was observed during the course of the study. Nominal test concentrations may not reflect the actual exposure concentrations of test material.

The study must be repeated if it is to fulfill the Guidelines requirement. Measured concentrations of test material must be reported, It is recommended that a flow-through system be used to maintain water quality during the study, and to assure that constant exposure to test material is achieved during the study.

4) Report on testing for acute toxicty - rainbow trout/BAS 352 04F/Ronilan.

EEB Conclusions: In this toxicity study, measured concentrations of active ingredient were reported after 96 hours of exposure to Ronilan 50W. Although 100 percent mortality was observed at a measured concentration of 8.16 ppm active ingredient, not mortality was observed at a measured concentration of 13.6 ppm active ingredient. A possible explanation for this dose-response could be the effect of precipitate on exposed fish species. The study does document a 96-hr. LC_{50} > 13.6 ppm for rainbow trout exposed to vinilozin in a 96 hour study. This study does not, however, fulfill the Guidelines requirement for a coldwater fish LC_{50} determination. this is because it was conducted at a test temperature of 16°C rather than the required 12°C for rainbow trout studies.

In order to fulfill the Guideline requirement, the study must be repeated using a test water temperature of 12°C. If insolubility at this temperature is a problem, a flow-through system must be used, and analytically measured concentrations must be reported.

5) Acute contact LD_{50} study on honeybees prepared by Stauber (6-6-86).

After reviewing the submitted data, EEB concludes that the registrant has not fulfilled Guidelines requirements for acute toxicity studies using warm and cold water fish species and honey bees. Recommended procedures to fulfill these study requirements are described above.

EEB has reviewed the material submitted on the toxicity of Ronilan to honey bees. All data indicate that Ronilan is low toxicity to bees. However, none of the material submitted provides sufficient information to allow validation of the data. EEB still requires data from a honey bee acute contact study. Data from this study will be required prior to registration of the product for outdoor use. As noted in the attached DER, any number of the studies submitted might satisfy the data requirement with submission of additional information.

DATA EVALUATION RECORD

1. CHEMICAL: Vinclozolin
   3-(3,5-dichlorophenyl)-5-ethenyl-
   5-methyl-2,4-oxazolindinedione

2. TEST MATERIAL: Vinclozolin technical
   purity of test material not identified

   97% ai
   DQ 11-7-89
   req. letter from
   BASF.

3. STUDY TYPE: Freshwater fish acute toxicity
   Species tested: *Salmo gairdneri*

4. STUDY IDENTIFICATION: Gelbke, H.P. nd R. Munk. 1980. Report on Testing for Acute Toxicity - Rainbow trout/BAS 352 - F vinclozolin prepared and submitted by BASF Corporation Chemicals Division. EPA Accession # 264302.

5. REVIEW BY:

   Thomas M. Armitage
   Fisheries Biologist
   Ecological Effects Branch
   Hazard Evaluation Division

   Signature: Thomas M. Armitage
   Date: 11-20-86

6. APPROVED BY:

   Raymond W. Matheny
   Head - Section I
   Ecological Effects Branch
   Hazard Evaluation Division

   Signature: Raymond W. Matheny
   Date: 11/21/86

7. CONCLUSIONS: The study documents a 96-hr. LC_{50} equal to 2.84 ppm for rainbow trout exposed to technical vinclozolin. Due to the low water solubility of this chemical large amounts of acetone and cremphor were used to dissolve the test material. Despite the use of these solvents, insolubility was still a problem, and precipitation was observed in the test chambers. Measured concentrations of test material were, however, reported for all but the two highest test concentrations. The LC_{50} was calculated by EEB on the basis of measured test concentrations (after 96 hours). The study does not fulfill the requirement for a coldwater fish LC_{50} determination because the percent active ingredient in the test material was not reported. Also, the test temperature 16°C $\pm$ 1.5°C is higher than the required 12°C for a rainbow trout study.

8. RECOMMENDATIONS: The study must be repeated using a test water temperature of 12°C. If solubility is a problem at this temperature a flow-through system must be used, and analytically measured concentrations must be reported.

9. BACKGROUND: The study was submitted to support registration of vinclozolin because previously submitted studies had been rejected due to insolubility of test material. White flocculation of the active ingredient was observed in all dose levels greater than 18 mg/l.

10. DISCUSSION OF INDIVIDUAL TEST

N/A

11. MATERIALS AND METHODS

(definitive test)

A. Test animals -
Rainbow trout (*Salmo gairdneri*) supplied by Forellenhof Fredelslon, 3413 Moringen 1, FRG. Mean body weight was 0.7 g. Mean body length was 4.1 cm.

System: Static exposure to reconstituted soft water. Fifty liters of test water in glass aquaria (60 cm x 35 cm x 40 cm). Test temperature 16°C ± 1.5°C, 96-hrs. duration.

B. Dose - Static bioassay using measured concentrations. Acetone (230 mg/l) and cremphor RH 40 (230 mg/l) were used as solvents.

C. Design - 10 fish per level. Measured concentrations after 96-hours (<0.05, < 0.05, 0.07, 0.14, 0.34, 1.04, 2.40, 5.20, 3.20 ppm).

D. Statistics - EEB statistical analysis using probit, moving average, and binomial probability methods to calculate the LC_{50} was conducted.

12. REPORTED RESULTS: Rainbow trout 96-hr. LC_{50} > 21.50 < 31.60 ppm nominal test concentration.

13. STUDY AUTHOR'S CONCLUSIONS: 96 hr. LC_{50} > 21.50 < 31.60 ppm.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY:

A. Test procedures: The test procedures deviated from accepted protocol because large amounts of solvent, noted above, were required to get the test material into solution. The percent active ingredient in the test material was not identified, and the test chambers were aerated. Aeration is not expected to affect study results because measured concentrations of toxicant were reported. The study was also conducted at a test temperature of 16°C. The acceptable test temperature for rainbow trout is 12°C.

B. Statistical Analysis: Statistical analysis using the moving average method of calculating the LC_{50} indicates that the LC_{50} is approximately 2.84 ppm. This value is based upon analytically measured concentration after 96 hours. Probit and binomial methods cannot be used because 80% mortality was observed at the second highest concentration tested, and 0% mortality was observed at the highest concentration tested. It must be assumed therefore that the highest measured concentration was reported or measured incorrectly. The moving average method accounts for this problem when the LC_{50} is calculated.

C. Discussion/Results: On the basis of the statistical analysis conducted by EEB using reported mortalities and the concentration of toxicant measured after 96 hours, the document LC_{50} is 2.84 mg/l. This study cannot however, be used to fulfill guidelines requirements because it was conducted at an unacceptably high test temperature (16°C).

D. Adequacy of Study

1. Classification: Supplemental

2. Rationale: The percent active ingredient in the test material was not reported, and the study was conducted at an unacceptably high test water temperature.

3. Repair: The study must be repeated using the recommended water temperature of 12°C. If insolubility is a problem at this temperature, a flow-through system must be used, and analytically measured concentrations msut be reported.

15. COMPLETION OF ONE LINER FOR STUDY:

one liner form completed 11-13-86

16. CBI APPENDIX

N/A

Armitage vinclozin rainbow trout 11-12-86

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
5.2	10	0	0	9.765625E-02
3.2	10	8	80	5.46875
2.4	10	1	10	1.074219
1.04	10	0	0	9.765625E-02
.34	10	0	0	9.765625E-02
.14	10	0	0	9.765625E-02
.07	10	0	0	9.765625E-02
.05	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 2.4 AND +INFINITY CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 0

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	.3707726	2.841154	2.575047	3.228113

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	4.120229	3.921029	0

A PROBABILITY OF 0 MEANS THAT IT IS LESS THAN 0.001.

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 1.659563
95 PERCENT CONFIDENCE LIMITS =-1.709075 AND 5.0282

LC50 = 8.1963
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = 1.4072
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

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DATA EVALUATION RECORD

1. CHEMICAL: Vinclozolin
3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2, 4-oxazolindinedione

2. TEST MATERIAL: Vinclozolin technical
purity of test material not identified 97% ai DR 11-7-89
re: May 4, 1988 Letter

3. STUDY TYPE: Freshwater fish acute toxicity
Species tested: Lepomis gibbosus

4. STUDY IDENTIFICATION: Gelbke, H.P. and R. Munk 1980. Report on testing for acute toxicity - Bluegill sunfish/BAS 352 F-vinclozolin. Prepared and submitted by BASF Corporation Chemicals Division EPA Acc. # 264302.

5. REVIEW BY:

Thomas M. Armitage
Fisheries Biologist
Ecological Effects Branch
Hazard Evaluation Division

Signature: Thomas M. Armitage
Date: 11-20-86

6. APPROVED BY:

Raymond W. Matheny
Head - Section I
Ecological Effects Branch
Hazard Evaluation Division

Signature: Raymond W. Matheny
Date: 11/21/86

7. CONCLUSIONS: The study documents a 96-hour LC_{50} > 3.4 mg/l for bluegill sunfish exposed to technical vinclozolin. Due to the low water solubility of this chemical, large amounts of acetone and cremophor were used to dissolve the test material. Despite the use of these solvents, insolubility was still a problem, and precipitation was observed in the test chambers. Measured concentrations of test material were however reported for all but the highest two test concentration. The LC_{50} was higher than the highest measured test concentration. The study does not fulfill the requirement for a warmwater fish LC_{50} determination because the percent active ingredient in the test material was not reported.

Study fulfills requirement because % ai was reported in subsequent correspondence. DR 11-7-89

8. RECOMMENDATIONS: The study may be upgraded to fulfill the requirement if the purity of test material is reported.

9. BACKGROUND: The study was submitted to support registration of vinclozolin because previously submitted studies had been rejected. Those studies were rejected because of solubility problems. White flocculation of the active ingredient on the surface of the water was observed in all concentrations with bluegill sunfish, and in doses of > 18 mg/l in the trout study.

10. DISCUSSION OF INDIVIDUAL TEST

N/A

11. MATERIALS AND METHODS

(definitive test)

A. Test animals - Blue gill (*Lepomis gibbosus* supplied by F.A. Eggert, 67 Ludwigshafer Mean body weight was 2.4g mean body length was 5.8 cm.

System Static exposure to reconstituted soft water 100 liter of water in glass aquaria (80 cm x 35 cm x 45 cm). Test temperature - 77°C ± 1°C, 96-hrs. duration.

B. Dose - Static bioassay using measured concentrations. Acetone (1000 mg/l) and cremphor RH 40 (2000 mg/l) were used as solvents.

C. Design - 10 fish per level. Measured concentrations after 96-hrs. (<0.05, <0.05, 0.08, 0.18, 0.88, 1.7 2.4, 4.4, 3.4 ppm).

D. Statistics: LC_{50} was calculated using Probit analysis (Finney, 1971).

12. REPORTED RESULTS: Bluegill sunfish 96-hr. LC_{50} = 50 mg/l based upon nominal concentration. No effect level = 0.464 mg/l based upon nominal concentrations.

13. STUDY AUTHOR'S CONCLUSIONS: Bluegill 96-hr. LC_{50} mg/l based upon nominal concentratons.

14. REVIEWERS DISCUSSION AND INTERPRETATION OF STUDY

A. Test procedures : The test procedures deviated from accepted protocol because large amounts of solvent, noted above, were required to get the test material into solution. The percent active ingredient in the test material was not identified, and the test chambers were aerated. Aeration is not expected to affect the results of this study because test concentrations were measured. 97% DR 11-7-89

B. Statistical Analysis: EEB statistical analysis was not conducted because only 30 percent mortality was observed at the highest measured test concentration.

C. Discussion/Results: On the basis of 30% mortality observed at the greatest measured test concentration (3.4 mg/l after 96 hrs.), it must be concluded that the 96-hr. LC_{50} for bluegill sunfish exposed to technical vinclozin is > 3.4 mg/l.

D. Adequacy of Study:

1. Classification: supplemental

2. Rationale: The registrant has had difficulty getting the test material into solutions. Large amounts of solvent were used in this study and a precipitate was still observed. The highest measured test concentration contained 3.4 ppm of test material. Only 30% mortality was observed at this dose level. Therefore, the study may be used to document a 96-hr. LC_{50} > 3.4 mg/l if the registrant can provide an indication of the purity of test material. If the registrant wishes to document a higher LC_{50}, a flow-through system should be used. 97% ai DR 11-7-89

3. Repair: The registrant must provide an indication of the amount of active ingredient in the test material. 97% DR. 11-7-89 re: letter from BASF dated 5-4-88

15. COMPLETION OF ONE LINER FOR STUDY:

one liner form completed 11-10-86

16. CBI APPENDIX

N/A

DATA EVALUATION RECORD

1. CHEMICAL: Vinclozolin
   3-(3,5-dichlorophenyl)-5-
   ethenyl-5-methyl-2,4-oxazolidinedione

2. TEST MATERIAL: Formulated Ronilan 50W
   Fungicide
   50% vinclozolin

3. STUDY TYPE: Freshwater fish acute toxicity species tested:
   Lepomis gibbosus

4. STUDY IDENTIFICATION: Gelbke, H.P. and R. Monk. 1980.
   Report on Testing for Acute toxicity
   Bluegill sunfish/BAS 352 04F/Ronilan.
   Prepared and submitted by BASF Corporation
   Chemical Division. EPA Acc# 264302.

5. REVIEW BY:

   Thomas M. Armitage
   Fisheries Biologist
   Ecological Effects Branch
   Hazard Evaluation Division

   Signature: Thomas M. Armitage
   Date: 11-20-86

6. APPROVED BY:

   Raymond W. Matheny
   Head - Section I
   Ecological Effects Branch
   Hazard Evaluation Division

   Signature: Raymond W. Matheny
   Date: 11/21/86

7. CONCLUSIONS: The study documents a 96-hr. LC_{50} > 68.1 < 100.1 ppm for ~~bluegill sunfish~~ pumpkinseed (Lepomis gibbosus) exposed to ronilan fungicide. The study does not, however, fulfill the Guidelines requirement for a 96-hr. LC_{50} determinator using formulated product. This is because the test water was aerated, and sedimentation areas observed during the course of the study. Nominal test concentration may not reflect the actual exposure concentrations of test material.

8. RECOMMENDATIONS. The study must be repeated using measured test concentrations. It is recommended that a flow through system be used to maintain water quality during the study and to assure constant exposure to test material at each dose level throughout the study.

9. BACKGROUND: The study was submitted to support registration of vinclozolin because studies with the technical material were rejected due to insolubility of test material.

10. DISCUSSION OF INDIVIDUAL TEST
N/A

11. MATERIALS AND METHODS
(definitive test)

A. Test animals-
Bluegill sunfish (*Lepomis gibbosus*)

Supplied by FA Zoohaus Schanzenloecher, 6700 uduigshafen/Rheim, FRG. Mean bodyweight was 3.4g. Mean body length was 6.1 cm.

System: Static exposure to reconstituted soft water. One hundred liters of test water in glass aquaria (80 cm x 35 cm x 45 cm), 10 fish per aquarium. Test temperature 22°C $\pm$ 1°C., 96-hr. study.

B. Dose - Static bioassay with nominal concentrations. No solvents used.

C. Design - 10 fish per level. Nominal concentrations of 10, 14.7, 21.5, 31.6, 46.4, 68.1, 100.0, 147.0, 215.0, and 316.0 ppm) plus solvent control.

D. Statistics - Probit analysis was used to calculate the 96-hr. LC_{50} (Finney, D.J. 1971).

12. REPORTED RESULTS: 96-hr. LC_{50} > 68.1 ppm (5% significance level). < 100.0 ppm (1% significance level).

13. STUDY AUTHORS CONCLUSIONS: 96-hr. LC_{50} > 68.1 < 100 ppm.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY

A. Test procedures: The test procedures deviated from accepted protocol because the test chambers were aerated. A precipitate was also observed in the test chambers. Other procedures appeared to be conducted in accordance with accepted protocol.

B. Statistical analysis: EEB agrees with the authors reported result. However, measured concentrations were not reported. Because the test chambers were aerated, and because precipitation of one test material was observed, nominal concentrations may not be used to calculate the LC_{50}.

C. Adequacy of Study:

1. Classification - supplemental

2. Rationale - Test chambers were aerated and precipitation of test material was observed.

3. Repair - Study must be repeated reporting measured exposure concentration. In order to avoid solubility problem and to maintain water quality, use of a flow through system is recommended.

15. COMPLETION OF ONE LINER FOR STUDY

one liner form completed 11-13-86

16. CBI APPENDIX

N/A

DATA EVALUATION RECORD

1. CHEMICAL: Vinclozolin
3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2, 4-oxazolidinedione

2. TEST MATERIAL: Formulate Ronilan 50W
Fungicide
50% vinclozolin

3. STUDY TYPE: Freshwater Fish Acute Toxicity
species tested: *Salmo gairdneri*

4. STUDY IDENTIFICATION: Gelbke, H.P. and R. Munk. 1980. Report on Testing for Acute Toxicity Rainbow Trout/BAS 352 04F/Ronilan. Prepared and submitted by BASF Corporation Chemicals Division EPA Acc. # 264302

5. REVIEW BY:

Thomas M. Armitage
Fisheries Biologist
Ecological Effects Branch
Hazard Evaluation Division

Signature: Thomas M. Armitage
Date: 11-20-86

6. APPROVED BY:

Raymond W. Matheny
Head - Section I
Ecological Effects Branch
Hazard Evaluation Division

Signature: Raymond W. Matheny
Date: 11/21/86

7. CONCLUSIONS: Measured concentrations of active ingredient were reported of the 96 hours of exposure to Ronilan 50W. Although 100% mortality was observed at a measured concentration of 8.16 ppm active ingredient, no mortality was observed at a measured concentration of 13.6 ppm active ingredient. Clearly, mortality was caused by factors other than the concentration of active ingredient in the water. A possible explanation for this dose response could be the effect of precipitate upon exposed fish species. The study does document a 96-hr. LC_{50} > 13.6 ppm vinclozin for rainbow trout in a 96-hr. study. The study does not, however fulfill the guidelines requirement for a coldwater fish acute LC_{50} determination. This is because it was conducted of a test temperature of 16°C rather than the required 12°C.

8. RECOMMENDATONS: The study must be repeated using a test water temperature of 12°C. If insolubility at this temperature is a problem, a flow through system must be used, and analytically measured concentrations must be reported.

9. BACKGROUND: The study was submitted to support registration of vinclozolin because previously submitted studies had been rejected due to insolubility of the test material.

10. DISCUSSION OF INDIVIDUAL TEST
N/A

11. MATERIALS AND METHODS
(definitive test)

A. Test animals - were rainbow trout obtained from Forellenhof Fredelsloh, 3413 Moringen, 1, FRG. Mean body weight was 4.0g. Mean body length was 7.1 cm.

System: Static exposure to reconstituted soft water. One hundred liters of test water in glass aquaria (80 x 35 x 45 cm). Test temperature, 16°C ± 1.5°C., 96-hrs. test duration

B. Dose - Static bioassay using measured concentrations of active ingredient.

C. Design - 10 fish per level. Measured concentrations after 96-hr. (8. 18, 8.65, 13.6, 8.88, 5.61, 3.18, 1.40, 0.72, 0.25 ppm) fresh water control.

D. Statistics - EEB statistical analysis was not conducted because no mortality was observed at the highest measured concentration of active ingredient.

12. REPORTED RESULTS: The author's reported LC_{50} for rainbow trout receiving 96-hours of exposure to Ronilan was > 68.1 < 100.0 ppm. ← wrong ref !!

13. STUDY AUTHORS CONCLUSIONS:

Reported above.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY

A. Test Procedures: With the following exception, the study was conducted according to accepted protocol. The test water temperature was 16°C ± 1°C. Rainbow trout must be tested at a water temperature of 12°C.

B. Statistical Analysis: No statistical analysis was required because no mortality was observed at the highest measured dose concentration.

C. Discussion/Results: On the basis of reported mortality and reported concentrations of active ingredient after 96 hours, the LC_{50} for rainbow trout exposed to vinclozin would appear to be greater than 13.6 ppm. This dose level was the highest concentration measured.

D. Adequacy of Study:

1. Classification: supplemental ✓

2. Rationale: The study was conducted of an unacceptably high test temperature.

3. Repair: The study must be repeated using the recommended water temperature of 12°C. If insolubility is a problem at this temperature, a flow-through system must be used, analytically measured concentrations must be reported.

15. COMPLETION OF ONE LINER FOR STUDY

One liner form completed 11-13-86.

16. CBI APPENDIX

N/A

DATA EVALUATION RECORD

1. Chemical: Ronilan (vinclozolin)

2. Test Material: Various formulated products

3. Study Type: Honey bee Toxicity

   Species Tested: Apis mellifera

4. Study ID: Stauber. 1986. Ronilan: Acute contact LD50 study on honey bees. Series of studies prepared by various laboratories in West Germany. Submitted by BASF Corp., Chemicals Division, Parsippany, NJ. EPA Acc. # 264303.

5. Reviewed By:

   Allen W. Vaughan
   Entomologist
   EEB/HED

   Signature: Allen W. Vaughan
   Date: 11/12/86

6. Approved By:

   Norman J. Cook
   Supervisory Biologist
   EEB/HED

   Signature: Norman J. Cook
   Date: 11.18.86

7. Conclusions:

   This submission comprises a number of summary data sheets and brief reports covering more than a dozen different research efforts. All the data indicate that Ronilan had no adverse effects on honey bees. However, in all cases the information provided is insufficient to allow evaluation of the data.

   With the submission of a complete report, any number of the studies cited would probably fulfill the data requirement for a honey bee acute contact LD50 study. As submitted, however, none of the information is sufficient to satisfy the requirement.

8. Recommendations:

   As noted above, none of the submitted material is sufficient to satisfy any of the data requirements for honey bee testing. Specifically, the following comments apply:

INVALID

Enclosure A - This is a discussion of the standard methods used for honey bee testing in West Germany. It would provide useful information on methodology, except for the fact that only pages 3, 5, and 7 were submitted.

Enclosure B - This is a series of data summary tables covering a number of different studies. Information on methods and materials is completely lacking, as is any type of raw data.

Enclosure C - This is a brief report of a "tent study" conducted to assess impact on honey bee colonies. Information provided is insufficient to allow evaluation of the study. Especially important would be information on methods, as this type of study is not routinely conducted in the U.S. As with the material under Enclosure B, complete reports are essential to allow validation of the studies.

Enclosure D - This includes brief reports on two field tests. Again, information provided (especially on methods) is not sufficient to allow evaluation of the studies. Complete reports are needed.

As submitted, none of the studies would rate better than "supplemental". Some of the studies might be reparable to "core" status with the submission of additional information.

9. Background: This material was submitted in support of registration.

10. Discussion of Individual Test: N/A

11. Materials and Methods

Methods included exposure via respiration, contact, and oral routes, as well as various types of field tests. Detailed discussion in this area will not be applicable until completed reports are submitted.

12. Reported Results: In all the submitted reports and data tables, Ronilan showed little or no toxicity to honey bees.

13. Study Author's Conclusions/Q.A. Measures:

Up to concentration rates of 6% or 2 kg Ronilan per hectare, no adverse effects as contact poison could be observed, for mortality in the test groups did not exceed that of the control group at a significant rate.

Q.A. measures were not reported.

14. Reviewer's Discussion and Interpretation of the Study

A. Test Procedures: Information provided was insufficient to allow evaluation in this area.

B. Statistical Analysis: Discussion not applicable at this point.

C. Discussion/Results: See #8, above (Recommendations)

D. Adequacy of Study:

1. Classification: Invalid as submitted.

2. Rationale: Insufficient information.

3. Reparability: Some of these studies might be reparable to "Core" with submission of additional information.

15. Completion of One-Liner: N/A

16. CBI Appendix: N/A