

238691

RECORD NO.

081901

SHAUGHNESSEY NO

51

REVIEW NO.

EEB REVIEW

DATE: IN 2-1-89 OUT 3-30-89

FILE OR REG. NO. 50547-7

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 12-27-88

DATE RECEIVED BY HED 2-1-89

RD REQUESTED COMPLETION DATE 3-8-89

EEB ESTIMATED COMPLETION DATE 3-8-89

RD ACTION CODE/TYPE OF REVIEW 350

TYPE PRODUCT(S) Fungicide

DATA ACCESSION NO(S) _____

PRODUCT MANAGER, NO. D. Williams

PRODUCT NAME(S) Chlorothalonil

COMPANY NAME Fermenta Plant Protection Co.

SUBMISSION PURPOSE Registrant Response to "Draft"

Chlorothalonil Registration Standard

SHAUGHNESSEY NO.

CHEMICAL

% A.I.

_____	_____	_____
_____	_____	_____
_____	_____	_____

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MEMORANDUM

March 31, 1989

SUBJECT: Registrant Response to Draft Registration
Standard for Chlorothalonil

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division H7507C

TO: Donna Williams
Reregistration Branch
Special Review and Reregistration Division H7508C

A registrant of Chlorothalonil, Fermenta Plant Company, has responded to the Draft Registration Standard. Part of their comments pertain to EEB's science chapter. Our response is provided below.

Page 71, Paragraph 1:

The registrant notes that the field study identified by MRID Nos. 00137146 and 00127862 was not mentioned in the draft standard.

EEB Response:

The study was discussed in the EEB topical summaries and was probably the one referred to as Shults, RIOCHL06. It is not known why the MRID Nos. identified by the registrant were not available to EEB. The EEB is ordering copies of those MRID numbers to verify that they are in fact the same study. If they are the same, the MRID nos. provided by the registrant should be included in the draft data table where EEB included RIOCHL06 after 72-7.

This minor difference in reference numbers does not change the conclusions of the draft chapter. The study was performed to address hazards to field crops such as soybeans and EEB concluded no hazard to aquatic organisms from these uses. But to clarify EEB's position, while the study was determined to be acceptable in

CONCURRENCES

SYMBOL	H7507C	H7507C	H7507C					
SURNAME	Rieda	Cook	Alum					
DATE	3-31-89	4-4-89	4-18-89					

May, 1983, it would not be considered acceptable by today's standards. It is still considered to provide useful exposure information, and no new studies for field crops are considered necessary. The deficiency of the study was not so much in its performance, but in the fact that only one site was studied. It did not provide for potential variation between sites both locally and in other regions. Therefore, EEB used modeling to estimate exposure in their discussion of hazard to aquatic organisms from field crops.

Corrections Necessary:

Once EEB has verified that the numbers provided by the registrant are the same as the RIOCHL06 provided by EEB, add them to the data table after 72-7 where EEB had referenced RIOCHL06. No change in hazard assessment required.

Page 71, paragraph 2:

The registrant suggests that the Registration Standard has incorrectly stated certain fish LC50's.

EEB Response:

According to EEB's records, MRID No. 30393 is a study by Buccafusco performed in 1977 using bluegill to determine toxicity of DS-3701 (degradate of chlorothalonil). The study providing information on channel catfish to which the registrant refers is probably referred to in the standard as 30390. The EEB used the raw mortality data to conduct independent statistics. The result, using the binomial probability method, was an LC50 of 43 ppb. Since there was less than two test concentrations with percent mortality between 0 and 100, neither the moving average nor the probit method can give statistically sound results.

When reviewing 56486, EEB realized there had, indeed, been an error in taking numbers from the Data Evaluation Report dated March 7, 1980. In that review, EEB used the "reported" LC50 of 47 ppb. However, the raw data were used to perform independent statistical analysis. The result, using the binomial probability method, was an LC50 of 42.3 ppb (Rainbow trout, chlorothalonil). Since there were less than two concentrations at which the percent dead was between 0 and 100, neither the moving average nor the probit method can give statistically sound results.

The LC50 for bluegill, 51 ppb, was not taken from the reference identified as 41439. Indeed, that reference reported an LC50 of 62 ppb. The reference used by EEB was identified as Pitcher, 1976, RIOCHL09 and reported an LC50 of 51 ppb.

Corrections Necessary:

On page 39, paragraph under Aquatic, second sentence should read, "...while other studies showed LC50's of 43, 42.3 and 51 ppb for channel catfish, rainbow trout and bluegill, respectively."

Hazard assessment conclusions do not change.

Page 71, Paragraph 3:

The registrant questions the need for a fish bioaccumulation study.

EEB Response:

This data requirement may be triggered by either EEB or EFGWB, and EEB uses the information in their hazard assessment. In either case, it is EFGWB that evaluates the study to determine its acceptability. If EFGWB has concluded that the available data do not satisfy that requirement, then EEB will not use the information.

The bioaccumulation study identified as a requirement by EEB is different than the fish accumulation study. It would involve determining accumulation in marine organisms including mollusks. This study is specifically required for the marine anti-fouling paint and the cranberry use.

Corrections Necessary:

This will, of course, depend on the response by EFGWB. If they decide that the available data are now acceptable, then the statements on bioaccumulation on page 39 of the draft standard do not need to be changed. However, if the bioaccumulation data are still determined to be invalid, delete reference to bioaccumulation data (paragraph 4, page) 39 of draft standard and indicate (on page 41 second paragraph) that bioaccumulation data are necessary for EEB to complete their risk assessment.

Also at top of page 41, indicate that the aquatic organism bioaccumulation test required for the marine anti-fouling paint use is to be conducted with organisms other than fish, and especially must include mollusks.

Footnote number 14, page 99 should be modified to indicate that the bioaccumulation study with species other than fish is required for both the marine antifouling paint use and the cranberry use.

Page 217, Paragraph 1:

The registrant indicates that the avian reproduction studies have been submitted and that they were performed voluntarily.

EEB Response:

The avian reproduction studies were not available at the time of the writing of the EEB science chapter. These studies have not been reviewed.

The EEB does have records showing that EEB specifically required that new avian reproduction studies be performed on both waterfowl and upland gamebirds using chlorothalonil. This requirement was imposed in the EEB science chapter prepared in 1983. The rationale was that the first tests only tested up to 50 ppm and the use rates as low as 1 lb. ai/acre result in residue concentrations on avian food items exceeding this level, and multiple applications are permitted. In a meeting on April 30, 1987, attended by Norm Cook and Dan Rieder of EEB, Lois Rossi of RD and representatives of Fermenta Plant Protection Company, Fermenta representatives indicated that they were conducting the avian reproduction studies with both chlorothalonil and DS-3701, as requested. Therefore, whether a time frame was imposed or not, the registrant, Fermenta Plant protection Company, formerly SDS and before that, Diamond Shamrock, was aware that additional avian reproduction testing was necessary as early as 1984.

Necessary Changes: None

Page 217, Paragraph 3 (Field Testing with Mammals and Birds:

The registrant feels certain that the reserved terrestrial field testing will not be required and that the final standard should so note that change.

EEB Response: It is unlikely that EEB will complete the review of the avian studies and make a final determination concerning the need for terrestrial field testing before the final standard is published.

Necessary Changes: None

Page 218, Paragraph 1:

The registrant questions the need for testing with the end use product registered for cranberries.

EEB Response:

The EEB believes that cranberries are grown in areas such that there is a high probability that pesticides sprayed on them will

settle directly on water. Aerial application is used to treat cranberries in some states. The EEB concluded from the field study that was conducted that even when ground applied, chlorothalonil will drift into adjacent waterbodies. Because of this, it is essential that data on the end use products be provided. Without it, EEB will be unable to conclude safety for, or quantify the adverse effects of, this use. Further, the label may prohibit release of water, but rainfall could force an unscheduled "release" of water. With regards to previous testing with other formulations, EEB has determined that testing with the 75% formulation will not suffice for the 40.4% formulation.

Necessary Changes: None

Page 218, Paragraph 3:

The registrant opposes performing monitoring adjacent to orchards and cranberry fields because they are not aquatic sites.

EEB Response:

A crop or use site need not necessarily be an "aquatic use site" to trigger concern for hazards to aquatic organisms and the need for monitoring or a field study. However, as discussed above, EEB considers cranberry use to involve application immediately adjacent to waterways and thus exposure to aquatic habitat is highly likely. Furthermore, according to the Department of Fisheries, Wildlife and Environmental Laws, Division of Marine Fisheries, Commonwealth of Massachusetts, the major sources of pesticides are agricultural run-off from uplands and bogs and individual use on lawns and gardens. They further indicate that the major agricultural activity in the coastal region of Southeastern Massachusetts and on Cape Cod is the cranberry industry. Also, most major watersheds in Buzzards Bay and on Cape Cod drain large areas of cranberry bogs. Pesticides from bogs are carried by these rivers and streams into the coastal waters resulting in exposure to fish and shellfish and other marine species. Chlorothalonil is acutely toxic to mollusks with an EC50 of 3.6 ppb. It is imperative that EEB obtain information on the aquatic and marine exposure from the cranberry use. Because of the expressed concern expressed by the Commonwealth of Massachusetts, the monitoring for cranberry uses in Massachusetts must extend downstream and into estuarine environments to determine exposure to shellfish and other marine biota.

The study previously performed was conducted with a field crop (soybeans). It does not suffice for, or show exposure from, use sites such as cranberries or orchards. Based on estimations presented in the EEB science chapter, concentrations in water adjacent to orchards treated at 3.15 lb. ai/acre will exceed the fish LC50 of 23 ppb. This is sufficient to trigger field testing.

The requirement for field monitoring with orchards and cranberry growing areas remains.

Necessary Changes:

Footnote number 15 (page 99) should be expanded to include the following wording.

"The monitoring for cranberries must include sites in Massachusetts (≥ 5) as well as sites in the midwest and west. In Massachusetts, monitoring must extend from the treated cranberry bog, downstream to an estuarine habitat where mollusks and other marine organisms occur."

Summary

With this memorandum, the EEB has responded to the comments on the draft registration standard of chlorothalonil. In summary, chlorothalonil is persistent and toxic to aquatic organisms and EEB is unable to conclude safety from its use on cranberries and orchards. The EEB concludes that the study performed (Shults, RIOCHL06) showed that even with ground application, chlorothalonil will drift into adjacent ponds. This was evidenced by the presence of chlorothalonil in the control pond which was "uphill" from, and could not have received runoff from, the treated area.

The changes, due to the response from the registrant, are minor and do not alter the conclusions. If you have any questions, contact Dan Rieder.

Addendum: I have verified that the study I referred to as RIOCHL06 is the same as either 00127862 and 00137146. It is sufficient to replace the RIOCHL06 (in my Table A across from 72-7 Aquatic Field Testing) with 00127862. Note that in the Draft Standard Table, even my "RIOCHL06" was not referenced.

Dan Rieder

4.6.89