10-31-90

Shaughnessy No.: 81901

Date Out of EFGWB: _____

TO: Lewis/Stone
Product Manager # 21
Registration Division (H7505C)

FROM: Michael R. Barrett, Acting Head
Ground-Water Technology Section
Environmental Fate & Ground-Water Branch/EFED (H7505C)

THRU: Henry Jacoby, Chief
Environmental Fate & Ground-Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of:

Reg./File #: 50534-7

Chemical Name: chlorothalonil

Type Product: fungicide

Product Name: Bravo, N-96, Daconile

Company Name: SDS Biotech Corp., Fermenta Plant Protection Co., et al.

Purpose: Evaluation of Ground-Water Contamination Potential. Respond to Registrant's Correspondence (attached).

Date Received : 4/04/90 (by EFED) Action Code: 401

Date Completed: 10/31/90 EFGWB # (s): 90-0491

Monitoring study requested: X Total Review Time: 3-days

Monitoring study voluntarily: ____

Deferrals To: ____ Ecological Effects Branch

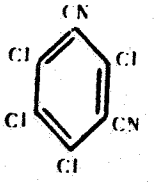
__X__ Health Effects Division

1. CHEMICAL: Common name: chlorothalonil

Chemical name: 2,4,5,6-tetrachloroisophthalonitrile

Trade name: Bravo®

Structure:



Chlorothalonil

2. TEST MATERIAL: N/A

3. STUDY/ACTION TYPE: Respond to registrant's statement that chlorothalonil parent has not been found in ground water to date.

4. STUDY IDENTIFICATION: Letter from Fermenta ASC Corp. dated 3/22/90

5. REVIEWED BY: John H. Jordan, Ph.D.
Microbiologist
OPP/EFED/EFGWB Ground-Water Section

Signature: John H. Jordan Date: 10/31/90

6. APPROVED BY: Michael R. Barrett, Ph.D.
Acting Head
OPP/EFED/EFGWB Ground-Water Section

Signature: Michael R. Barrett Date: 10/31/90

7. CONCLUSION:

The parent compound (chlorothalonil) has a very low potential for leaching into ground water except on sand soils where the potential is moderate. The major degradate 4-hydroxy 2,5,6, trichlorophthalonitrile (SDS 3701) has a potential to leach in clay soils as well as in sandy soils. The major degradate and some minor degradates have been found in ground water at levels from 2.8 to 12.6 ppb.

Chlorothalonil (parent) has not been reported in ground water at or above the 2 ppb level of quantitation. The registrant stated in their 3/22/90 letter that the Agency was in error, because the Ground-Water Section reported that the parent compound had been found in ground water. The evidence shows that the registrant is correct. The Ground-Water Section either received erroneous information or recorded the information incorrectly. One of the values (12.6 ppb) in the EPA Pesticides in Ground-Water Data Base which was recorded as parent, is the value for degradate residue SDS 46851 reported in the references cited by the registrant. It is clear that there has been no report of parent in ground water.

8. RECOMMENDATIONS:

Small scale prospective studies are required to elucidate which of the current uses may result in an impact of chlorothalonil parent or degradate on ground water. Monitoring studies are required regardless of whether there are any toxicological concerns for these compounds. Before a small scale monitoring study is initiated, the registrant must send EFGWB a proposed protocol including proposed sites, site selection criteria, soil, soil pore water, and ground-water sampling procedures.

9. BACKGROUND:

On January 22, 1990 The Ground-Water Section stated (Reg. File # 50534-7) that parent chlorothalonil had been reported in ground water because it was recorded in our OPP Pesticides in Ground-Water Data Base. Since that time it has been determined that only degradates have been reported in ground water; we either received or interpreted the data erroneously. Three references were cited by the registrant which showed that degradates and not parent are ground-water contaminants. The parent has been shown to have a potential for leaching in sand soils only. The major degradate has a potential to leach in sandy and in clay soils and was found in ground water with some of the minor degradates.

10. DISCUSSION:

Results from the registrant's acceptable field dissipation study indicated that chlorothalonil has a half-life of 30 to 60 days. The registrant's laboratory soil metabolism study on four soils resulted in half-lives of 7 to 31 days. No half-life has been determined for the major degradate which represents up to 69% of the applied radioactivity. However, it was stated that the major degradate showed no degradation in four test soils after 90 days, but no data were presented to confirm. The parent and the major degradate (SDS 3701) 4-hydroxy 2,5,6, trichlorophthalonitrile, are both stable to photolysis and hydrolysis.

Batch equilibrium (Freundlich) tests indicated that parent has a relatively low mobility on silty clay loam (K=26), silt (K=29) and sandy loam (K=20) but was intermediately mobile in a sand soil (K=3). TLC studies showed that parent chlorothalonil was immobile (Rf=0.0) but the major degradate (SDS 3701) has a low to intermediate mobility (R_f= 0.25 - 0.43) in two silt loam and three silty clay loam soils. The major degradate leached in sandy, silty clay loam and clay soils, but the parent is immobile to low in mobility except in sands where it is moderately mobile. Chlorothalonil and all degradates were moderately mobile in sand soils.

The Storet (1988) data base indicates that parent chlorothalonil was not detected in 633 ground-water samples from 627 locations.

Review of the studies in the registrant's letter of 3/22/90 revealed that no parent (chlorothalonil) was detected in any of the three studies[1]. However, the following degradates were detected:

3.6 ppb of SDS - 3701 (4-hydroxy 2,5,6, trichlorophthalonitrile)
2.8 ppb of SDS - 19221 (3,cyano-2,4,5,6, tetrachlorobenzamide)
12.6 ppb (max) of SDS - 46851 (trichloro-3- carboxybenzamide) detected in 7 of 24 samples
5.0 ppb (max) of SDS - 47525 (3-cyanotrichlorohydroxybenzamide) detected in 3 samples

Only SDS- 46851 was confirmed by gas chromatography; no other degradate was confirmed by another method.

HCB Contaminant

The 1984 Registration Standard stated that compliance with FIFRA means that technical chlorothalonil cannot contain more than 0.05% (500 ppm) as a manufacturing contaminant and that the registrant must develop a valid method for HCB analysis that is acceptable to the Agency. The present lowest detection limit for HCB is 3 ppb. The registrant has been required to develop a method to detect 1 ppb.

The maximum application, e.g., for onions is 9 pounds/Ac of 75% W.P. per season.

75% of 9 lbs. ai = 6.75 lbs. ai/Ac (total)

6.75 lbs./Ac x 0.05% HCB = 0.003375 lbs. HCB/Ac

0.003375 lbs. HCB on 1 Ac (2M lbs. 6.7" deep) = 0.001687 ppm

0.001687 ppm = 1.69 ppb HCB /Ac

[1]Determination of Chlorothalonil and its Degradation Products in Water from Suffolk Co. Long Island, New York, 1981. MRID 00149204.
Determination of tetrachloroisophthalonitrile (chlorothalonil) SDS-2787, SDS-3701 SDS-46851 in Water from Long Island Wells - 1985. MRID 00164514.
Cohen, S.Z., et al.1990.A Ground-Water Monitoring Study for Pesticides and Nitrates Associated with Golf Courses on Cape Cod. Ground Water Monitoring Review,10(1)

Use this form for individual studies & to submit pesticide applications.

United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain National Security Information (E.O. 12065)

Pack Number	Date Received
50317 EFED	4-4-90

1. Product Name: Chlorothalonil Technical

Chemical Name: Chlorothalonil

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
50534-7	242133	401	—	—

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
28	3/30/90	Lewis/Stone	21	4/4/90	7/4/90	

Instructions

Fermenta tsc response to John H. Sorden's review dated 1/22/90

This Section Applies to Review of Studies Only

14. Check Applicable Box

- ☐ Adverse 6(a)(2) Data (405)
- ☐ Special Review Data (870)
- ☐ Generic Data (Reregistration)(660)
- ☐ Product Specific Data (Reregistration)(655)

15. No. of Individual Studies Submitted

16. Have any of the above studies *(in whole or in part)* been previously submitted for review?

☐ Yes *(Please identify the study(ies))* ☐ No

17. Related Actions

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	SAC, PC	A. Policy Note No. 31
		Toxicology/HFA	TOX/HFA, PL	
		Toxicology/IR	TOX/IR	☐ 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
		Dietary Exposure	DEB, EA	
		Nondietary Exposure	NDE, AC	
EFED		Ecological Effects	BA	☐ 2 = data of particular concern from registration standard
	X	Environmental Fate & Groundwater	EEB	
SRRD		Special Review	EFGWB	☐ 3 = data necessary to determine tiered testing requirements
		Reregistration		
		Generic Chemical Support	SR	
RD		Insecticide-Rodenticide	RER	
		Fungicide-Herbicide	GSC	B. Section 18
		Antimicrobial		☐ 1 = data in support of section 3 in lieu of section 18
		Product Chemistry	IR	
		Precautionary Labeling	FH	
BEAD		Economic Analysis	AM	C. Inert Ingredients
		Analytical Chemistry		☐ 1 = data in support of continued use of List 1 inert
		Biological Analysis		

☐ Confidential Statement of Formula (EPA Form 8570-4) Attached *(Trade Secrets)*

☐ Label Attached

EPA Form 8570-17 (Rev. 11-88)
Previous editions are obsolete.

White - Data Coordinator
Yellow - Data Review Section
Pink - PM/RM/DCI
Green - Return with completed review

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FERMENTA ASC

March 22, 1990

Ms. Susan Lewis (21)
Fungicide-Herbicide Branch
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Lewis:

Subject: -Response to Your Letter Dated January 31, 1990
-Chlorothalonil Potential for Leaching Into Groundwater
-Technical Chlorothalonil (EPA Reg. No. 50534-7)

This is in response to your above subject letter and its accompanying EPA internal review dated January 22, 1990 regarding the potential leaching of chlorothalonil and degradates into groundwater.

The letter and review contained two serious misinterpretations of the facts concerning the potential for chlorothalonil to leach into groundwater.

1) The conclusions concerning the detection of chlorothalonil/ parent compound in groundwater in Suffolk County, New York and Cape Cod, Massachusetts are not supported by the published data for those studies.

2) It is not correct to equate the detection of chlorothalonil metabolites with detection of chlorothalonil in groundwater.

In the EFGWB review dated January 22, 1990 the reviewers state (p. 2, 9. BACKGROUND),

> "Chlorothalonil and degradates were reported in the ground water of Suffolk County, New York at the 16.3 ppb level; no range was given. Parent was found in Massachusetts ground water ranging from 0.22 ppb to 0.38 ppb.
>
> The Suffolk County Department of Health and the Fermenta Plant Production Co. recently cooperated in sampling private drinking water wells. The Suffolk County Health Department reported that 11 of 67 wells tested positive for chlorothalonil; the highest positive test was 12.6 ppb. Contamination was attributed to normal agriculture use practices."

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These conclusions are not supported by the published results for these studies. The analyses of groundwater samples from Suffolk County, New York were conducted by our company and showed only occasional detections of two soil metabolites of chlorothalonil. **There were no detectable residues of the chlorothalonil parent compound in any of the samples analyzed.** The results of those studies were summarized in a report titled "Status Report Pesticide Sampling Program 1980-1987," Suffolk County Department of Health Services, Bureau of Drinking Water, May 1988. (Identified as NY 009 in "Pesticide in Ground Water Data Base 1988 Interim Report).

In that report, the summary for chlorothalonil stated,

> "Metabolites of chlorothalonil were detected in 11 out of 67 samples. The concentration ranged from 1.1 - 12.6 ppb for each individual breakdown product. The highest combined concentration of chlorothalonil degradation compounds found was 16.3 ppb. The contamination was found primarily in shallow private wells but was also detected in a 97-foot public water supply well."

Those results are also contained in the Fermenta reports "Determination of Chlorothalonil and Its Degradation Products in Water From Suffolk County, Long Island, New York, 1981," MRID No. 00149204 and also "Determination of Tetrachloroisophthalonitrile (Chlorothalonil, SDS-2787), SDS-3701 and SDS-46851 in Water From Long Island Wells - 1985," MRID No. 00164514.

The data in those reports demonstrate the absence of detectable residues of chlorothalonil and also confirm that the values cited in the EPA review (16.3 ppb, 11 of 67 wells tested positive, highest positive test was 12.6 ppb) apply to the detections of the soil metabolites SDS-3701 and SDS-46851.

A detailed report on the Cape Cod study was only recently published - "A Ground Water Monitoring Study for Pesticides and Nitrates Associated with Golf Courses on Cape Cod" Ground Water Monitoring Review, 10 (1) 160-173 (1990). Stuart Z. Cohen, Susan Nickerson, Robert Maxey, Aubry Dupuy, Jr., and Joseph A. Senita. Two of the authors are scientists with EPA, and one was the Water Resources coordinator for the Cape Cod Planning and Economic Development Commission (CCPEDC) during the study.

Previously the only information available on this study was a Draft Project Summary dated April 1987 "Cape Cod Gold Course Ground Water Monitoring" (Identified as MA 002 in "Pesticides in Ground Water Data Base 1988 Interim Report").

It is clear from the information presented in the paper that the results reported do not constitute a valid finding of chlorothalonil in groundwater. The authors report (Table 4 - "Pesticide Application Data") that there was chlorothalonil

applied at Bass River 1984 through 1987 and Falmouth 1986 and 1987 (no information given for prior years). However, it is clear from both the Methods and Discussion sections of the report that improper well construction techniques were used. Therefore, the contamination resulting in the two reported detections could have occurred either form the "drive and wash" well installation procedure or from the use of native soil to backfill the annular space either of which procedure could mechanically transfer previously applied parent chlorothalonil from the soil surface to the well water. The applicable excerpts from the Methods (p. 165-166) and Discussion (p. 169) sections are as follows:

"Monitoring Well Construction

Nineteen ground water monitoring wells were installed for this study. At each of the four golf course participating in the study, wells were placed at one tee, one green, and one fairway, and one well was placed upgradient of all treated areas to establish background water quality conditions (Table 1). Sixteen of the wells were installed in 1985 using the drive-and-wash technique. Three additional wells were installed in 1987 using a hollow-stem auger, in response to concern that the drive-and-wash method may have caused cross contamination between surface soils and the aquifer. All of the wells are flush mounted and made of 2-inch PVC. The wells were screened at or just below the water table. Equipment during drive-and-wash installation was cleaned with water between boreholes. Hollow-stem auger equipment was steam cleaned between holes.

A sand pack was placed 1 to 2 feet above the top of the screen, followed by a bentonite seal. Native soil was then backfilled into the annular space in wells completed by the drive-and-wash method. This was done contrary to the well construction protocol, but according to standard practice in that area, and may have caused cross contamination (see the discussion section). The wells were developed by bailer until the water was clear." and

"This trend is consistent with the possibility of cross contamination during well installation. Due to a scheduling mix-up, the 16 drive-and-wash wells were installed without the presence of a practicing geologist. A 2 to 3 foot plug of bentonite was used to seal the borehole above the well screens, but native soil was used to backfill the annular space above the bentonite plug. Thus, it might be possible for pesticides to desorb from contaminated surficial soil and leach to ground water, especially if the bentonite seal is not complete. (Note the high surficial chlordane concentrations in Table 6.) In addition, the wash-and-drive techniques itself have introduced cross contamination.

The purpose of bringing this to the Agency's attention is to point out that as shown in the above mentioned reports, chlorothalonil was not detected in groundwater and thus it is requested the EPA correct this significant error or misinterpretation.

It is also pertinent for the Agency to be aware that the toxicological characteristics of the parent chlorothalonil and its metabolites are markedly different. Long term toxicological studies have been conducted on SDS-3701, which have clearly demonstrated that this metabolite is not carcinogenic in laboratory animals. Subchronic, teratogenicity and mutagenicity studies have been conducted with SDS-46851. The results of these studies show SDS-46851 to be relatively non-toxic and the target organ for toxicity of this metabolite (liver) to be different than that of chlorothalonil (kidney). Thus, it has been demonstrated that the metabolites of chlorothalonil are not toxicologically similar to chlorothalonil.

Based on the above information, it is requested the Agency reconsider their position on requesting a retrospective groundwater study prior to an official request for such a study via FIFRA Section 3(c)(2)(B).

Sincerely,

FERMENTA ASC CORPORATION

Jerry R. Lucietta
Manager, Regulatory Affairs

JRL:jmh