081901
SHAUGHNESSEY NO.

48
REVIEW NO.

EEB REVIEW

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PETITION OR EXP. NO.

DATE OF SUBMISSION 2-05-86

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RD ACTION CODE/TYPE OF REVIEW 650

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

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. H. Jacoby (21)

PRODUCT NAME(S) Chlorothalonil

COMPANY NAME SDS Biotech Corporation

SUBMISSION PURPOSE Registrant response concerning data requirements of registration standard

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

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EEB REVIEW

100 Submission Purpose:

The registrant, SDS Biotech Corporation, has requested a waiver for a data requirement identified in the Chlorothalonil Registration Standard (August 31, 1983). The data requirements were avian reproduction studies using SDS-3701, primary degradate of Chlorothalonil. These studies are required for all outdoor uses because the degradate is more persistent and more toxic than the parent. The following rationale is presented by SDS Biotech to justify the waiver:

1. Avian reproduction studies have been submitted previously for chlorothalonil which reported no reproductive effects in bobwhite quail or mallard duck.

2. SDS-3701 is the primary metabolite of chlorothalonil. Numerous crop residue studies have included assays for SDS-3701. It is concluded from these studies that SDS-3701 residues present in the environment are expected to be at extremely low (no more than 5-10% of the total crop residue) and generally non-detectable level, which are believed to pose no toxicological hazard to avian species.

3. Presently approved use patterns for chlorothalonil do not employ rates approaching the high rates proposed for use on apples, which apparently prompted EPA's request for this study on SDS-3701.

4. Most applications of chlorothalonil are made to non-nesting sites such as peanuts, tomatoes, potatoes, and other vegetable crops. Early season applications are made to stone fruits -- apricots, cherries, nectarines, peaches, plums, and prunes -- at or prior to shuck split. No applications are approved for use between shuck split and harvest during the period when nesting occurs. Thus, there would be little, if any, chance of direct application to nesting birds.

5. SDS-3701 does not bioaccumulate in animal tissues. Poultry and egg residue studies (EPA Acc. No. 071551, pp. 1263 and 1348) involving ^{14}C-chlorothalonil and ^{14}C-SDS-3701 demonstrated fairly rapid depuration of residues after cessation of dosing.

101 Hazard Assessment

The registration standard (8-31-83) divided the existing uses into two categories, the low use rate (2 lbs a.i. per acre) and the higher use rate (5.7 lbs a.i. per acre). It is estimated that the degradate SDS-3701 will occur on vegetation at 5 to 10 percent of the parent. Using an average and applying that factor to typical estimated residues on terrestrial wildlife food items, the following levels are calculated:

ESTIMATED RESIDUES OF CHLOROTHALONIL IMMEDIATELY AFTER APPLICATION

Application Rate: lbs/A	Short Grass	Long Grass	Leafy Crops	Insects Forage	Seed Pods	Fruit
2	250	184	70	66	6	3
5.7	712	524	200	188	17	9

ESTIMATED RESULTS OF SDS-3701 AFTER DEGRADATION

Application Rate: lbs/A	Short Grass	Long Grass	Leafy Crops	Insects Forage	Seed Pods	Fruit
X 7.5%	19	14	5	5	0.5	0.2
X 7.5%	53	39	15	14	1	0.7

Response to registrant comment 1: While it is true that the avian reproduction study did not show adverse effects, it is important to note that it only tested up to 50 ppm. Without a Lowest Observed Effect Level, EEB assumes reproduction may be affected at any levels greater than 50 ppm. Based on this assumption along with the fact that SDS-3701 is substantially more toxic (acutely) than chlorothalonil to birds and is more persistent, EEB still requires the avian reproduction studies with the degradate.

Response to registrant comment 2: The test results show that SDS-3701 is toxic at substantially lower levels than chlorothalonil.

COMPARISON OF ACUTE TOXICITIES

	Avian LD_{50}	Avian LC_{50}	Acute Rat
Chlorothalonil	4640 mg/kg	> 10,000 ppm	> 10,000 mg/kg
SDS-3701	158 mg/kg	1746 ppm	242 - 422 mg/kg

SDS-3701 is more toxic reproductively to mammals than Chlorothalonil.

3-Generation Rat Reproduction Study

Chlorothalonil	NEL	15,000 ppm (reproduction)
Chlorothalonil	NEL	15,000 ppm (lactation)
SDS-3701*	50 ppm	(mortality)
	100 ppm	(fertility F_2)
	50 ppm	(F_3 litter size)
	100 ppm	(Offspring weight)

* December 6, 1974 review by Eleanor Long of Toxicology Branch.

Note that 100 ppm is 1/150 of 15000 so SDS is at least 150 times more toxic to mammals reproductively than chlorothalonil.

Furthermore, there are no test data to support a statement of toxicological hazard to avian species with regards to chronic hazard.

Response to registrant comment 3: Based on EEB's estimation of concentrations at presently approved use rates, chlorothalonil and SDS-3701 are expected to occur at levels high enough to pose an adverse chronic effect.

The environmental behavior of SDS-3701 (see Rieder 5-1-80 review) is as follows:

No dissipation in soils within 90 days.

SDS-3701 is stable to hydrolysis
SDS-3701 is stable to photodegradation
Chlorothalonil does not hydrolyze under acid or neutral conditions but hydrolyzes in basic solution (t1/2 35 days)
Chlorothalonil is stable to photodegradation

Response to registrant comment 4: As far as timing of bird nesting, it begins in early spring and continues into the early summer with some species producing late, if not two broods, per season. As far as locations of use, nesting birds feed in use areas even if the actual nests are not exposed.

Response to registrant comment 5: Bioaccumulation is not the main issue when concerns for possible avian reproduction effects exist. SDS-3701 may cause reproductive effects without bioaccumulating.

Additional Data Requests: Furthermore, in addition to the required avian reproduction tests with SDS-3701, EEB requires that the registrant conduct another set of avian reproduction tests with Chlorothalonil since it too is persistent and expected to occur on terrestrial food items at greater than 50 ppm.

The registrant must also conduct residue monitoring to determine actual levels of chlorothalonil and SDS-3701 on terrestrial food items. Samples should include short grass, long grass, leafy plants, forage, insects, seed pods, fruit. See conclusions for further details.

103 Conclusion

EEB has considered the waiver request by SDS Biotech concerning the requested avian reproduction studies with SDS-3701, primary degradate of chlorothalonil. Based on available data and use information, EEB rejects the waiver and considers the data requirements necessary. Further, upon the review of the available data, EEB requires the following studies:

Two avian reproduction studies (bobwhite quail or mallard duck) with the parent, chlorothalonil, are required because chlorothalonil is expected to persist on avian food material at levels greater than the highest level tested in the previous studies.

Also, EEB requires SDS Biotech to conduct field residue monitoring for various terrestrial food items at both 2 lbs a.i. per acre and 5.7 lbs a.i. per acre. The following items must be sampled: short grass, long grass, leafy plants, insects, forage, seed pods and fruit. The material must be sampled and residues determined for at least 3 months or until levels of chlorothalonil drop to less than 50 ppm and levels of SDS-3701 drop to less that 0.03 ppm (50/150 = 0.3 ppm). The sampling must be conducted at ten different sites throughout the use area of chlorothalonil. Five sites where it is applied at 2 lbs. ai per acre and five sites where it is applied at 5.7 lbs. ai per acre. These sites must be representative

of the habitats which are exposed to chlorothalonil.

Samples must be collected from each treated field and from adjacent areas on four sides. These samples (field and each of four sides) must be analyzed separately to determine effects of drift as compared to direct application on residues on adjacent vegetation.

The registrant, SDS Biotech, must submit a proposed protocol for this residue monitoring for EEB comment and approval.

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