079401
SHAUGHNESSY NO.

12
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 7/3/85 OUT 8/23/85

FILE OR REG. NO. 8340-13

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 1/9/85

DATE RECEIVED BY HED 7/2/85

RD REQUESTED COMPLETION DATE 8/30/85

EEB ESTIMATED COMPLETION DATE 8/23/85

RD ACTION CODE/TYPE OF REVIEW 661/Registration Standard Follow-up

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

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Thiodan Technical

COMPANY NAME American Hoescht Corporation

SUBMISSION PURPOSE Submission of Avian Reproduction Study (1) in Response to Registration Standard; Avian and Mammal Hazard Assessment

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
079401	Endosulfan, Technical	97

100 Submission Purpose and Label Information

The purpose of this submission is to submit avian reproduction studies on bobwhite quail and mallard duck in response to requirements of the Registration Standard for endosulfan published by EPA in April 1982. These studies test the technical grade of the active ingredient.

EEB notes that these data were required to be submitted within 14 months. These data are approximately two (2) years late.

No label was submitted with these data.

101 Hazard Assessment

101.1 Discussion

Endosulfan products are registered for a wide variety of sites, including large and small acreage commercial field and food crops, fruit trees, nuts, and ornamental trees, shrubs, and plants. Several greenhouse uses are also registered.

Outdoor uses of particular concern for birds and mammals include, but are not limited to: alfalfa, beans, sweet and field corn, cotton, fruit and fruit trees, lettuce, macadamia nuts, pecans, potatoes, soybeans, small grains, sugarcane, tobacco, tomatoes and vegetables.

While submitted studies are not sufficient to fully assess the environmental fate and mobility of endosulfan at this time, a consideration of several of its known physico-chemical characteristics is essential to this hazard assessment. Endosulfan and its metabolites are persistent in soils, with hydrolysis in this medium strongly pH dependent. It is most stable in slightly acidic soils with hydrolysis to endosulfan diol occurring over six (6) months at 27 °C. Oxidation, a minor degradative pathway, causes slow transformation to endosulfan sulfate.

In partial fulfillment of the leaching study requirement, it was shown that endosulfan binds strongly to sand and sandy loam. Although other soils must be tested it is assumed that binding will be strong for silt loams, clay loams, and clays as well.

From the preliminary data reviewed in the Registration Standard, we know that endosulfan is quite persistent in soil. When applied in aerobic and anaerobic soils as much as 20 to 70 percent remained 15 weeks after treatment. A rough

estimate then for a soil half-life is 15 weeks. Endosulfan was oxidized to its major transformation product, endosulfan sulfate (which is the most acutely toxic metabolite tested in mammalian systems). Generally then, soil oxidation will not appreciably reduce the toxicity of endosulfan residues.

Available field studies reviewed by the Registration Standard indicate that annual applications or several applications during the same growing season (as allowed by many of the registrations which either direct repeat applications or leave to the discretion of the user), can result in accumulated residues of the parent and sulfate metabolite in soils. Severe inhibition of soil microflora has been demonstrated for up to 20 days after a single application so that these effects may be prolonged for an unknown period of time after directed or user determined repeat applications.

The environmental fate data base is considered inadequate to determine the dissipation rate of endosulfan.

101.2 Likelihood of Adverse Effects to Nontarget Organisms

A mallard acute oral LD_{50} study was performed with technical endosulfan and found LD_{50} = 34.4 mg/kg (Hudson et al. 1972, 05003462). A study on starlings (Schafer, 1972, BA007916) found LD_{50} = 35 mg/kg. Technical endosulfan is therefore considered highly toxic to avian species.

One (1) dietary study tested several species with technical endosulfan, (Hill et al. 1975, BA007911) and resulted in the following LC_{50} values: Bobwhite quail = 805 ppm; Japanese quail = 1250 ppm; Ring-necked pheasant = 1275 ppm; Mallard duck = 1053 parts per million. Technical endosulfan is therefore considered moderately to slightly toxic to upland game species and waterfowl when administered in subacute dietary tests.

Dietary Hazards - Birds

Table I (below) presents expected maximum initial residues on items causing exposure to birds and mammals, after a single application of endosulfan at the rates specified in the table. All rates shown are allowed by at least one registered label. Half-lives on these items are not established.

Many registered labels are unclear on the number of repeat applications or the frequency of applications allowed. Some place no restrictions at all on the number and frequency of allowed applications. Hazards resulting from these registered uses will probably be underestimated.

Table I. Selected Application Rates and Maximum Expected Terrestrial Residues (PPM) Following a Single Application

Rate lbs. ai per acre	Short Range-Grass	Long Grass	Foliar	Forage or Insects	Seeds	Fruit	Soils 0.1"	Soils 0.5"
10	2400	1100	1200	600	120	70	220.5	44.1
8	2000	900	100	450	90	55	176.4	35.3
4	1000	450	500	225	45	25	88.2	17.6
3	725	320	370	180	36	21	66.1	13.2
2	480	230	255	120	25	14	44.1	8.8
1	240	110	125	58	12	7	22.0	4.4

Although tobacco registrations carry an application rate of 12 lb ai/A, other labels such as field crops (vegetables) may be as low as 1 lb ai/A. Cotton, a very extensive use with particular concern for avian exposure, is registered for 1.5 lb ai/A. Tree fruits and nuts, another particular concern for avian exposure, are registered for typical applications of 4 lbs ai/A (cherries at 5 lbs ai/A), but can go as high as 10 lb ai/A (pecans). Many labels permit aerial application of EC's and WP's with repeat applications.

Considering the potential of persistence and accumulation of terrestrial residues of endosulfan and its toxic metabolites assessed by the environmental fate data, EEB expects that residues in Table 1 (single application) can be expected to increase in proportion to the number of applications made at a particular site, with an expected degradation half-life of 15 weeks. Thus, if two (2) applications are made 7.5 weeks apart to the same site, at the same rates, we expect that the residues estimated in table 1 will accumulate:

Example:

A - Application on Day 0 to orchard at 4.0 lb ai/A results in . . . . . 88 ppm (soil residue)

B - Residue on Day 52.5 . . . . . 44 ppm (half-life of 15 weeks)

C - Same application on Day 52.5 - additional. . 88 ppm

Final Residue on Day 52.5 . . . . . 132 ppm (Add B and C)

The above example is for soil which has minimal expected initial residue - but a very long half-life is expected in this medium. Endosulfan may degrade more rapidly on leaves or grass, but these media have very much higher initial residues. The above example is considered conservative because it allows for 52 days between applications. Applications made more frequently will of course accumulate to a greater degree.

At this time applications of $\geq$ 3.3 lbs active ingredient per acre must carry RESTRICTED use classification under the Sec. 3 regulations based strictly on the avian dietary LC_{50} data. The attached tables[2,3] calculate: 1) actual (bobwhite chick) and theoretical (all others) values for: LC_{50}; 2) expected environmental concentrations (maximum and those expected in avian diets of the appropriate species); 3) RESTRICTED triggers and expected daily pesticide burdens for the appropriate species (among other useful values indicated on the tables).

Note that daily pesticide burdens of three (3) species (including the actual values for bobwhite chicks) are equal to or exceed the RESTRICTED use triggers in three cases (indicated by footnote 7 on table 2). Only the bobwhite chick case used actual data for calculations, however.

Reproductive Hazards - Birds

Note that the above determination does not include consideration of the avian reproduction information recently obtained. These data, although only partially acceptable, indicate that, in addition to being a subacute dietary hazard, endosulfan causes the impairment of reproduction in birds (at this time satisfactorily demonstrated by the study of mallard ducks). Moreover, the acceptable reproduction data show that statistically significant reproductive impairment (particularly of the production of eggs by hens) occurs in mallard ducks at the lowest dose tested, i.e., 30 parts per million. A "no-effect" level has not been demonstrated at this time. (Reproductive data required for bobwhite quail were unacceptable for use in a hazard assessment - see section 101.4.)

At this time endosulfan applications to alfalfa, cotton, corn, tree fruit and nut crops, tobacco, tomato, lettuce, felled logs, strawberries, macadamia nuts, pineapples, and some minor field crops are expected to result in residues in avian food items exceeding the levels causing reproductive impairment in mallard ducks. Residue accumulation caused by repeat applications of this persistent pesticide can only

Table 2.

Calculated LC_{50} Values and Estimated Toxicant Exposure (MG/KG/DAY and MG/ANIMAL/DAY) for Seven Species of Non-target Birds.

SPECIES	BODY WGT. (GMS)	FOOD CONS. (GMS.)	F. CONS./ B. WGT (%)	CALCULATED LC50[6] (PPM)	TOXICANT MG/KG/DAY	CONSUMED[4] MG/ANIMAL/DAY	1/5 CALCULATED LC50[5] PPM)	1/5 LC_{10} (PPM)[7]
1. Bobwhite Quail (Young)	16[1]	4[2]	25.00	805.0[3]	201.3	3.2	161.0	87.0
2. Bobwhite Quail (Adult)	170.00	15.20	8.9	2251	201.3	34.2	450.2	243.4
3. Robin	81	8.11	10.00	2010	201.3	16.3	402.0	217.2
4. Mourning Dove	100.00	11.20	11.20	1797	201.3	20.1	359.4	194.2
5. Eastern Cowbird	50.00	7.00	14.00	1438	201.3	10.1	287.5	155.3
6. Field Sparrow	13.90	4.6	33.1	608.1	201.3	8.0	121.6	65.7
7. Grasshopper Sparrow	13.90	4.6	33.1	608.1	201.3	8.0	121.6	65.7
8. Carolina Wren	19.00	6.5	34.2	588.3	201.3	8.0	117.7	63.5

1/ Milligrams body WGT. (Average) for 9 day old bobwhite (Patuxent Wildlife Research Center bioassay).

2/ Average 5-day food consumption.

3/ LC_{50} determined by testing facility.

4/ MG/ANIMAL/DAY = MG/KG/DAY X Body weight (kg)

5/ 1/5 LC_{50} value for classification labeling criteria.

6/ $LC50(ppm) = \frac{201.30 \text{ mg/kg/day}}{\text{F. Con.(g) /B. WGT (g)}}$

7. 1/5 LC10 value for hazard evaluation to endangered species(dose-mortality slope = 4.796)

Table 3.

Dietary Contamination and Total Estimated Residues for Eight Species of Non-target Birds.

SPECIES	CALCULATED LC_{50} (PPM)	1/5 CALC. 2/ LC_{50} (PPM)	FOOD CONSUMED 3/ Animal (%)	Plant	MAXIMUM EXPECTED RESIDUES 4/ Animal (PPM)	Plant	MAXIMUM ADJUSTED RESIDUES 5/ Animal (PPM)	Plant	TOTAL 6/ RESIDUES (PPM) Plant/Animal
Bobwhite Quail (9-day)	805.0	161.0	80% Beetles Weevils Grasshoppers Etc.	20% Seeds: Ragweed Lespedeza Corn Etc.	191.4	39.6	153.1 8	7.9 9	161 7
Bobwhite Quail (Adult)	2251	450.2	27% Beetles Weevils Grasshoppers etc.	73% Seeds: Ragweed Lespedeza Corn etc.	191.4	39.6	51.7	28.9	80.6
Robin	2010	402	40% Caterpillars Beetles Weevils Earthworms Etc.	60% Seeds/ Fruits: Cherry Dogwood Holly	191.4	39.6	76.6	23.8	100.3
Mourning Dove	1797	359.4	0%	100% Seeds: Corn Pigweed Etc.	191.4	39.6	0.0	39.6	39.6

See footnotes on last page.

TABLE 3 (cont.)

Dietary Contamination and Total Estimated
Residues for Eight Species of Non-target Birds.

SPECIES	CALCULATED LC_{50} (PPM)	1/5 CALC. LC_{50} (PPM) [2]	FOOD CONSUMED(%) [3] Animal	Plant	MAXIMUM EXPECTED RESIDUES [4] (PPM) Animal (PPM)	Plant	MAXIMUM ADJUSTED RESIDUES [5] Animal (PPM)	Plant	TOTAL [6] RESIDUES(ppm) Plant/Animal
Eastern Cowbird (Adult)	1438	287.6	52% Grasshoppers Beetles Caterpillars	48% Seeds: Bristlegrass Oats	191.4	39.6	99.5 [8]	19.0 [9]	118.5
Field Sparrow (Adult)	608.1	121.6	51% Beetles Grasshoppers Caterpillars Etc.	49% Seeds: Crabgrass Bristlegrass Panicograss Etc.	191.4	39.6	97.6	19.4	117.0
Grasshopper Sparrow (Adult)	608.1	121.6	61% Grasshoppers Caterpillars Ants Etc.	39% Seeds: Bristlegrass Ragweed Knotweed Etc.	191.4	39.6	116.8	15.4	132.2 [7]
Carolina Wren (Adult)	588.3	117.6	99% Ants Flies Millipedes Etc.	1% Seeds Poison-Ivy Pine Oaks Etc.	191.4	39.6	189.5	0.4	189.9 [7]

FOOTNOTES FOR TABLES 3.

1/ Refer to table 1 (Footnote 6) for an explanation of how the "calculated LC_{50}'s" were obtained.

2/ Application of Sec. 162.11(c)(2)(iii)(B) criterion of Sec. 3 Regulations.

3/ This information is taken from:

Martin, Alexander C., et al., American Wildlife and Plants; A Guide to Wildlife Food Habits, Dover Publ., Inc., N.Y., 1951

4/ Based upon a 3.3 lbs. active ingredient per acre, application to expected food items using following references:

(a) Hoerger, F.D. and E.E. Kenaga, Pesticide Residues on Plants. Correlation of Representative Data as a Basis for Estimation of Their Magnitude in the Environment. Environmental Quality, Academic Press, New York, I: 9-28, 1972.

(b) Kenaga, E.E., Factors to be Considered in the Evaluation of the Toxicity of Pesticides to Birds in Their Environment, Environmental Quality and Safety, Academic Press, N.Y., II: 166-181, 1973.

5/ Residue values adjusted to reflect % animal/plant matter consumed. Examples:

(a) Bobwhite Quail, Adult:

191.4 ppm x 0.27 (27%) = 51.7 ppm
39.6 ppm x 0.73 (73%) = 28.9 ppm

(b) Robin, Adult:

191.4 ppm x 0.40 (40%) = 76.6 ppm
39.6 ppm x 0.60 (60%) = 23.8 ppm

6/ Reflects total dietary residues expected : total of residues on animal and plant food items. Examples:

(a) Robin (Adult):
76.6 + 23.8 = 100.3 ppm total for animal and plant foods.

(b) Mourning Dove (Adult):
39.6 ppm total expected in food items consumed (i.e., 1.00 (100%) x 39.6 ppm = 39.6 ppm).

7/ The RESTRICTED classification trigger value of $\geq$ 1/5 X calculated LC_{50} of this species is achieved at 3.3 lbs. a.i./A. (Application of Sec. 162.11 (c) (2) (iii) (B) criterion of Sec. 3 Regulations.)

8/ Daily expected pesticide burden resulting from ingested animal items.

9/ Daily expected pesticide burden resulting from ingested plant items.

increase the reproductive hazard observed in laboratory tests. Exposure of breeding birds and other wildlife is illustrated below for typical uses.

I. Cotton - 1.5 lbs ai/A with multiple sprays registered for every 3 to 5 days; aerial; ground; for bollworm; boll weavil; stinkbugs.

Cotton seed is usually planted at a depth of 1 to 2 inches. Rows are generally 38 to 40 inches apart on ridges or beds. In the lower Rio Grande area of Texas and in Arizona, planting starts as early as March 1. No wildlife use of cotton field is reported for Arizona in March (Gusey & Maturgo, 1972). In Texas, sandhill cranes use cotton fields for feeding at this time. In the Imperial Valley of California, planting first occurs on about April 1, but again California does not recommend these products for cotton. In southern States north and east of Texas, planting can start as early as March 21 (Florida, southern Louisiana) through April 21 (all the rest).

Wildlife usage of cotton fields is reported for many mammal and bird species. Quail feed in fields all year long in Alabama, with rabbits using fields for "loafing" from September through December (missing most applications). In Arkansas birds such as quail and dove use cotton for feeding from May through November; rabbits use these fields for "loafing" from May through August and for cover from September through December. Raccoons are reported to feed in Arkansas cotton in July and August. Cotton fields in Arizona see use by birds from June through August for cover, and for feeding and cover from September through November.

Georgia cotton fields receive the heaviest use by wildlife as cover from October through March and for feeding and nesting by birds from April through June, with bird feeding again from June through October. Deer, wild turkey, raccoon and oppossum often use Georgia cotton (all year long) for cover. Songbirds use cotton in Georgia for cover November through April and for feeding from April through October.

New Mexico reports heavy feeding use from May through December for quail, pheasant, doves, songbirds and rabbit (some feeding by deer late in the year). Quail and pheasant use cotton for brood-rearing and cover from May through August.

The attached chart indicates the total time span over which egg production in the field has been observed in various species. The majority of egg production occurs prior to mid-July, however, my sample of nine field and edge species clearly indicates that reproduction will continue into August and, in some cases, September. Late season breeders generally include those birds producing multiple clutches and year-old birds which often breed late in their first nuptial season (The Life of Birds, J. Welty, 1975).

Avian Egg Dates*

(Comprehensive Field Collection Dates)

March	April	May	June	July	August	September	October	November	December
		Mourning Dove (Texas) - Feb. 30-Sept. 24							
		Mourning Dove (Calif.) - Records for every month but Oct. & Nov.							
	Song Sparrow - (Arizona) April 9- Aug. 22								
		Vesper Sparrow- (Md) May 5-Aug. 1							
	Vesper Sparrow- (Calif.) April 2 -July 8								
		Grasshopper Sparrow- (Ala.) May 11-July 15							
		Grasshopper Sparrow (Md.) May 15-Aug. 19							
Blue Jay - (Florida) March 17-August 29									
		Barn Swallow - (Va.) May 21-July 15							
	Barn Swallow- (Calif) April 9-July 24								
		Meadow Lark-La.) May 3-June 4							
		Red-wing- (Texas) May 1-July 5							
	Bobwhite (South Carolina & Georgia) April 24-Sept. 16								

* Bent, Arthur C. Life Histories of North American Birds, vol. 1-26

California - applications for control of cotton bollworm in southern California usually commence in mid-July.

Texas - bollworm is a late season pest, generally appearing in mid to late July, however, its appearance is highly variable with treatments for early infestations not uncommon.

Louisiana - applications for cotton bollworm may begin as early as July 4 and extend through October.

It is concluded that applications for control of the bollworm, a major pest on registered endosulfan EC's and WP's, commence in mid-July, however, applications in late June and early July will occur in some areas depending on local planting schedules and levels of infestations.

Boll weevil infestations can severely impact cotton fields from 30 to 50 days postplanting, all the way through defoliation.

Considering that multiple applications (every 3-5 days is allowed) may be made to control economic pests, such as the bollworm (boll appears after 11 weeks postplanting) and boll weevil, there appears to be potential continuous exposure for breeding birds immediately prior to and during nesting and breeding (April through June) in most cotton producing States.

II. Alfalfa - 2.0 lbs ai/A; aerial; ground; for aphids, lygus bugs and stinkbugs (insecticidal treatments, esp. for weevil, March through September). Information obtained for use in Wisconsin is illustrative.

In central and southern Wisconsin the majority of alfalfa attains a height of 2 to 4 inches between April 1 and 15 in most years. Alfalfa is an early and fast growing plant and shows early response to spring.

Pheasants

Hen pheasants prefer wetland areas bordering marshy areas of cattails and sedges for nesting sites. They will also nest in fence rows, residual cover and hay fields. First eggs are dropped in mid to late April but rarely hatch as they are unattended. Between 2/3 to 3/4 of Wisconsin pheasant nests are begun during May in an average year. Peak nest initiation is usually between May 10 through 15. Predators often break up nests requiring new nest sites. New nests are sometimes in hay fields or alfalfa. Hay needs to be at least 6 inches high for renesting so that the hen and nest have cover.

Once a nest is decided upon eggs are deposited for 10 to 14 days (one a day) and then incubated for 23 days. Peak egg hatch is about June 18. Insect life is the primary food of young pheasants. Feeding starts shortly after birth and usually occurs in the early morning about sunrise.

Bobwhite Quail

No heavy use of alfalfa in Wisconsin (however, see table 4). Bobwhite quail exhibit a lengthy hatching distribution in Wisconsin. Average hatching date is about July 18 with a range of July 9 to August 3. Insect life is the main food of young birds. As birds mature they eat weed, crop seeds, and insects.

Mallard Duck

The mallard duck prefers open grassy and herbaceous areas adjacent to water for nesting sites. This duck will adapt to many types of nesting sites, including wild hay meadows, brushy areas interspersed with grass, various crops - as long as water is close by. Some renesting attempts are made in alfalfa fields when the alfalfa is over 6 inches high and the field is near water. First eggs of mallards are deposited in successful nests as early as March 27 to April 2 and as late as July 3 to July 9. Egg hatch extends from May 1 to May 7 to August 7 to August 13. About 80 percent of broods appear before July 3. About 95 percent of young mallards are flying by September 15.

Upon hatching young ducks immediately head for water. The food of young ducks is aquatic insect life.

Prairie Chicken and Sharptail Grouse

Prairie chickens utilize alfalfa for feeding and nesting cover. Sharptail grouse utilize alfalfa for feeding (limited distribution of these species).

Table 4. Use of Alfalfa By Bird Species For Nesting and/or Brood Rearing

Arkansas	- B.W. Quail	- May, June
Alabama	- Ring-necked Pheasant	- April, May
Idaho	- Pheasant	- April through August
	Hungarian Partridge	- May, June, July, August
	Mourning Dove	- May, June, July
	Quail	- May, June, July, August
	Ducks	- June, July
	Canada Goose	- June, July
Illinois	- Pheasants	- May through August
Indiana	- Pheasant	- June through August
	Quail	- June through August
	Turkey	- April through July
Iowa	- Pheasant	- April through August
	Quail	- June through August
	Hungarian Partridge	- April through June
	Ducks	- April through July
Kansas	- Pheasant	- April through June
	B.W. Quail	- May through June
	Greater Prairie Chicken	- May through June
	Wild Turkey	- April through June
Kentucky	- Quail	- April through September
	Songbirds	- May through October
Maryland	- R.N. Pheasant	- April through June
	Mallard & Black Duck	- April through June
	Wild Turkey	- May through September
	Ruffed Grouse	- May through August
Michigan	- R.N. Pheasant	- April through August
	B.W. Quail	- June through September
	Waterfowl	- April, May
	Sandhill Crane	- May through August
Minnesota	- R.N. Pheasant	- May through July
	Sharptailed Grouse	- May through September
	Ducks	- May through July
Missouri	- R.N. Pheasant	- April through June
	Wild Turkey	- April through June
	Prairie Chicken	- May, June

Table 4. (Cont'd)

Nebraska	- R.N. Pheasant	- April through May
	Gr. Prairie Chicken	- May through June
	Wild Turkey	- April through June
Nevada	- Pheasants	- April through September
New Mexico	- Pheasants	- May through August
	Quail	- July through August
	Chicken	- July through August
Oklahoma	- B.W. Quail	- May through October
	Wild Turkey	- May through September
	R.N. Pheasant	- May through July
Oregon	- R.N. Pheasant	- April through October
	Valley Quail	- June through September
	Chicken Partridge	- June through September
Pennsylvania	- R.N. Pheasant	- May through July
	B.W. Quail	- June through August
South Dakota	- Pheasant	- April through September
	Dabbling Ducks	- April through August
	Grouse	- April through September
	Mourning Dove	- April through August
	Partridge	- April through September
	Quail	- April through September
Texas	- R.N. Pheasant	- May through August
	B.W. Quail	- May through July
	Lesser Prairie Chicken	- June through August
	Wild Turkey	- May through July
Utah	- R.N. Pheasant	- April through May
	Hungarian Partridge	- April through May
	Quail	- April through June
	Ducks	- May through June
Virginia	- Pheasant	- May through July
	Wild Turkey	- April through August
Washington	- Pheasant	- April through September
	Puddle Ducks	- April through May
	Songbirds	- April through August

III. Tree Fruit

Orchards (2.5 to 5 lbs ai/A) - Bird Nesting/Brood Rearing

Idaho	- Pheasant	- May through September
	Mourning Dove	- April through August
	Hungarian Partridge	- April through June
	Valley Quail	- May through September
Washington	- Pheasant	- April through July
	Valley Quail	- April through June
	Partridge	- April through July
	Grouse	- May through July
	Dove	- April through May
	Songbirds	- April through June

Other Uses of Tree Fruit Orchards for Bird Nesting/Brood Rearing

Apples
Apricots
Cherries
Peaches (Colorado - Mourning doves and songbirds - March through June).

Acute Oral Hazards - Birds

One (1) granular product (Thiodan 3G, 3% ai) is registered for use on sugarcane at 0.45 lb ai/A by a "scatter" technique. Quail and songbirds utilizing these fields for cover, feeding, and nesting would be exposed to the granules. The following calculations refer to the granular product:

Application rate: Thiodan 3G on sugarcane; unspecified frequency; no use restrictions; scatter. 0.45 lb ai/Acre.

Availability: 0.45 lbs ai/A = 15 lbs product/A = 6.80385×10^6 mg/A = 6.80385×10^6 mg/4.356×10^4 ft^2 = 156 mg product/ft^2 available; to be comprised of thousands of granules of various sizes (weights in mg range - specific data on granular sizes is required).

The avian acute oral hazard for the case illustrated in the above calculation is based on a minimum exposure of 156 mg product/ft^2. The actual hazard is dependent on the number of granules to be ingested by a particular quail or songbird as grit, and whether or not that number will achieve an LD_{50} for the species. Considering the numbers of granules necessary to administer an LD_{50} (see Table 5 below), no acute oral hazard for avian populations is expected in the sugarcane use pattern applying a 3 percent ai granule (although individuals may be killed).

An acute oral hazard would appear to exist for EC and WP applications to field and orchard crops. Note that the species in table 5 would require only: duck - 28 mg; quail - 9.45 mg; starling - 3.3 mg; mouse - 0.24 mg - of technical endosulfan to achieve an LD_{50}. Considering the daily feeding amounts shown, such levels could be ingested if feeding in heavily contaminated areas such as orchards or fields receiving aerial spray of up to 5 to 10 lbs ai/A.

Table 5. Comparative Toxicity - Endosulfan

Species	Body Weight (kg)	Daily Feeding (g)	Tech. LD_{50} (mg/kg)	Dietary LC_{50} (PPM)	Number of granules required for product LD_{50} [1/] 2 mg	1 mg	.5 mg	.1 mg
(Adults)								
Mallard duck	1	100	28	1053	466	933	1,866	9,333
Bobwhite Quail	.225	20	42	805	157	315	630	3,150
Starling	.095	19	35	-	55	110	221	1,108
White-Footed Mouse	.03	-	8	-	4	8	16	80

[1/] Technical LD_{50} x kg (body weight)/0.03 x granule weight (mg) = LD_{50} (no. of granules required for LD_{50}).

Acute and Subacute Dietary Hazards for Mammals

The acute oral hazards for small mammal species using agricultural fields and orchards for feeding could be quite significant. The acute oral LD_{50} for the most sensitive species tested (mice) is 8 mg/kg. Thus, using table 5 as a guide, the acute oral hazard would be expected to be about 14 to 116 times greater for small mammals than for birds.

Special Note on Avian Sensitivity - Since endosulfan is a lipid soluble pesticide, Hudson et al. (1984), speculated that it could be eliminated from the body in the eggs of laying hens, following the pattern observed for another familiar lipid-soluble compound, DDT. While it has been noted that one-year-old hen pheasants, which were laying or had been recently laying, were particularly resistant to acute oral doses (LD_{50} > 320), young males were acutely affected at much lower doses (LD_{50} = 80 to 160 mg/kg) and young females at LD_{50}'s of nearly 200 mg/kg. Mortalities in pheasants occurred over several days, but both sexes of mallards (LD_{50} = 28 to 45 mg/kg) up to one-year old, died quickly. Thus, it has been speculated that laying hen pheasants may possess an additional route of toxic metabolism providing some protection from acute or subacute dietary hazard.

At this time, we are unable to speculate concerning what, if any, degree of protection could be afforded to other upland species, such as bobwhite quail (young are slightly less sensitive acutely, than young mallards) via the proposed egg elimination mechanism), because the quail reproduction study submitted is not acceptable for hazard assessment (see 101.4).

101.3 Endangered Species Considerations - Birds, Mammals, Insects, Amphibians

On August 4, 1982, EEB obtained the biological opinion of the U.S. Department of the Interior, U.S. Fish & Wildlife Service, Office of Endangered Species (OES), pursuant to a formal consultation under section 7 of the Endangered Species Act.

Based on the data available at the time (through February 1982) OES found "jeopardy" to the following bird, mammal, amphibian, and insect endangered species, resulting from the use of endosulfan:

Birds

- Attwater's Greater Prairie Chicken (Tympanuchus cupido attwateri)

- Aleutian Canada Goose (Branta canadensis leucopareia)

Mammals

- Hawaiian hoary bat (Lasiurus cinereus semotus)

Amphibians

- Pine Barrens Tree Frog (Hyla andersonii)
- Houston Toad (Bufo houstonensis)
- Santa Cruz long-toed salamander (Ambystoma macrodactylum croceum)

Insects
- All listed species.

Fish
- All listed species.

Freshwater mussels
- All listed species

EPA and OES have identified endosulfan as causing "jeopardy" to listed species in the "cluster" opinions for corn, cotton ,soybeans, sorghum, and small grains (wheat, oats, barley, rye). This opinion incorporates the listed species named above.

Based on the new information regarding adverse effects on egg production in birds EEB must reinitiate an endangered species consultation with OES.

101.4 Adequacy of Toxicity Data

101.4.1 Avian Reproduction Studies

A. Roberts, N. L., A. Anderson, S. I. Dawe, and D. O. Charter, 1985. The Effects of Dietary Inclusion of Endosulfan-Technical On Reproduction In the Mallard Duck. Performed by Huntingdon Research Centre, Cambridgeshire, England, submitted by American Hoechst Corp., Somerville, New Jersey. EPA Registration No. 8340-13. Accession No. 257687.

The study is scientifically sound and fulfills the requirements of the Pesticide Assessment Guidelines, Subdivision E. However, the conclusions of the author (NOEL = 60 ppm) are rejected as they are inconsistent with the data obtained.

The study shows that endosulfan impaired the reproductive capacity of the treated mallards, with statistical significance. This was evident through analysis of variance of egg production in the initial one-half of the induced laying period (considered as biologically significant). This occurred at all levels tested (30, 60, and 120 ppm). A "no-effect" level was not established. Until a NOEL is established, it is assumed that these effects could occur at any level of endosulfan. This means there is no assessable margin of safety.

19

Although several mortalities of treatment and control birds occurred during this study, most deaths are attributable to aggression. Enough replacement replicates were available to obtain statistical validity. We emphasize that the mortality observed, while high only in treatment groups, does not invalidate this test because these deaths are clearly attributable to aggression.

B. Roberts, N. L., R. Almond, D. Charter, and S. Cook. 1984. The Effects of Dietary Inclusion of Endosulfan-Technical on Reproduction in the Bobwhite Quail. Performed by Huntingdon Research Centre, Cambridgeshire, England; submitted by American Hoechst Corp., Somerville, New Jersey. EPA Registration No. 8340-13. Accession No. 256129.

The study is not considered scientifically sound because there are an unacceptable number of unexplainable mortalities in all groups tested, including the controls. The authors cite "stress due to handling" as a "possible" cause. Even if this is the case, the excessive mortality is not acceptable. This indicates either poor husbandry, unacceptable operational procedures, or poor quality control.

The authors did not present an explanation of what, if any, tests, procedures, precautions, etc., were taken to investigate the possibilities of microorganism contamination of the the laboratory or toxic contamination of the food or water supply. (N.B.- We note that a mallard duck reproduction study, undertaken at or about the same time, had to be terminated for "physiological and management problems." Circumstantially then, the "stress in handling" theory proposed for the bobwhite study is be dubious.)

Substitution of spare replicates, while allowing for statistical calculations, is not an adequate substitute for very poor test conditions as evidenced by the mortality observed in treatments and controls (the mortality was not treatment-related).

This study may not be used in hazard assessment as the results are considered invalid. It is particularly important that a good study be submitted because adverse effects at all levels tested were observed in the mallard duck study performed at a later date (Roberts, et al., 1985). The requirement of the Pesticide Assessment Guidelines for a reproduction study of an upland game bird is not fulfilled. The registrant is required to submit another study.

101.4.2 Additional Data Required

A. Terrestrial organism requirements -

- Perform an additional avian reproduction study as per 71-4 of the Pesticide Assessment Guidelines, for an upland game species, preferably bobwhite quail; submit completed study within one and one-half years.

- Perform a two-year field study of mammals and birds - as per 163.71-5 "Simulated and Actual Field Testing for Mammals & Birds" (previously held "Reserved" by the Registration Standard is now required). This study must be completed and submitted to EPA within two and one-half years after written approval is obtained for a protocol; the registrants must submit a protocol for EEB's written approval within 3 months of receipt of notification of this requirement.

B. Aquatic organism studies required -

Because this review was initiated to evaluate the avian reproduction studies, EEB has not formally addressed the aquatic hazard assessment at this time. However, EEB considers endosulfan to be persistent and very highly toxic. We are making the presumtption that unreasonable adverse effects will occur in aquatic environments contaminated by it. While EEB will address the aquatic hazard assessment in a forthcoming seperate document, we have decided to indicate the outstanding aquatic data requirements below.

- as per 163.72-7, Simulated or Actual Field Studies for Aquatic Organisms. These studies must be completed and submitted to EPA within three (3) years after written approval is obtained for a prototcol; the registrants must submit a proposal for a protocol for EEB's written approval within three (3) months of the receipt of notification of this data requirement.

The above requirement was previously held as "reserved" by the standard but is now required. (Other "reserved" studies under 163.72-5 and 163.72-6 have been fulfilled by testing performed by EPA.)

102 Classification

Birds and Mammals

At this time labels with applications greater than 3 lbs ai/A or which allow repeat applications which could result in equivalent residues (161 ppm; e.g., two applications of 1.5 lb ai/A) require RESTRICTED labeling to reduce avian and mammalian hazards associated with terrestrial applications (see sec. 101.2) based on current classification labeling ($\geq$ 1/5 LD_{50} < LD_{50}).

Aquatic Organisms

RPAR (special review) criteria appear to be exceeded for several uses which include but may not be limited to: watercress, cotton, lettuce, tomatoe, alfalfa, corn, tree fruit and nut crops, strawberries, macadamia nuts, pineapples and other field crops as well as forestry. We will be addressing this topic in a forthcoming aquatic risk assessment.

103 Conclusions

EEB has reviewed the avian reproduction studies submitted in response to the Agency's Registration Standard requirements. We find that the mallard duck study is acceptable and demonstrates statistically significant adverse reproductive effects at all levels tested (30, 60, 120 ppm). We conclude that endosulfan, at any level will impair (reduce) the production of mallard duck eggs as a primary effect. Additionally, we find that the reproduction study of bobwhite quail is not scientifically sound, and must be performed again.

A hazard assessment for mammals and birds finds that most uses of endosulfan result in persistent residues which represent a substantial dietary risk to avian species. Most registered labels are inadequate with respect to reducing this risk. Based on dietary risk criteria, uses of $\geq$ 3 lbs ai/A must carry a "RESTRICTED" use classification at this time.

Endosulfan application to alfalfa, cotton, corn, tree fruit and nut crops, tobacco, tomato, lettuce, felled logs, strawberries, macadamia nuts, pineapples, and other minor field crops are expected to result in endosulfan residues exceeding the levels causing reproductive impairment in mallard ducks. Acute oral hazards appear to be greater for small mammals than for birds. Simulated or actual field testing for mammals and birds (71-5) previously "reserved" is now required. All proposals and protocols for field tests must be reviewed and approved in writing prior to conducting the studies (see sec 101.4 for time lines).

Although EEB has not yet completed an aquatic organism risk assessment at this time (this review was initiated by submission of the two avian reproduction studies), we consider endosulfan to be higly toxic to aquatic organisms both acutely and chronically. We note that endosulfan is persistent in water, reaches water from terrestrial applications, and has been measured in fish-bearing waters at levels exceeding acute and chronic toxicity values. Special review (RPAR) criteria appear to be exceeded for aquatic organisms.

At this time EEB requires that "Simulated or actual field testing for aquatic organisms" (163.72-7), previously "reserved," now be performed. (N.B. - other "reserved" requirements under 72-5 and 72-6 have been fulfilled by testing performed by EPA.) All proposals and protocols for field tests must be reviewed and approved in writing prior to conducting the studies (see section 101.4 for time lines).

Pursuant to Sec. 7 of the Endangered Species Act, as amended, the Agency obtained the biological opinion of the Office of Endangered Species (OES), U.S. Fish & Wildlife Service, U.S.D.I. in 1982. Numerous listed species were found to be "jeopardized" by the registrations of endosulfan, including all listed fish and mussels. Several bird, mammal and amphibian listed species, as well as all listed insects, were found to be "jeopardized." EPA obtained a second jeopardy opinion regarding endosulfan under the "cluster" program which included uses on corn, cotton, soybeans, sorghum, small grains (wheat,oats,barley,rye). Based on new adverse information obtained from avian reproduction studies, EEB must reinitiate a "section 7" OES consultation.

Signature page for EEB review of Endosulfan, dated 8-23-85.

John J. Bascietto

John J. Bascietto, Wildlife Biologist
Ecological Effects Branch
Hazard Evaluation Division TS-769C

Dave Coppage, Supervisory Biologist DGC
Ecological Effects Branch
Hazard Evaluation Division TS-769C

8/30/85

Michael Slimak, Chief
Ecological Effects Branch
Hazard Evaluation Division TS-769C

(HED PROVIDE) CASWELL NO.: 1001

REGISTRATION DIVISION DATA REVIEW RECORD
—TO BE USED FOR REVIEW OF STUDIES PPA ONLY—

Confidential Business Information—
Does Not Contain National Security Info. (E.O. 12065)

(HED PROVIDE) PACK NO.: 1144 7/2/85

CHEMICAL NAME: ENDOSULFAN

(RD PROVIDE) SHAUGNESSY NO. 079401

Identifying Number	Action Code	Reference Number	Record Number	Study Guideline or Narrative Description	Reg. Std. Review Submission Criteria (SEE BELOW)	Accession Number	(RSERB Provide) MRID Number	(HED/BUD/TSS Complete) Review Results: Acceptable (A)/ Unacceptable(U)
8340-13	661	5	154073	158.145 71-4 (Bobwhite Legume)	2	256129		U

PRODUCT MANAGER (PM) or REVIEW MANAGER (RM) AND NUMBER: LA ROCCA PM-15

PM/RM TEAM MEMBER AND NUMBER: DR PILITT 01

DATE RECEIVED (EPA): 1/9/85

RD BRANCH CHIEF INITIALS: HM

CHECK APPLICABLE BOX:

- ☐ Adverse 6(a)(2) Data (405,406)
- ☐ Suspect Data (415,416)
- ☐ IBT Data (485,486)
- ☐ Groundwater Data (495,496)
- ☐ Data Waiver Request (Reregistration) (650,651)
- ☐ Formulation Data and Labeling (Reregistration) (655,656)
- ☒ Generic Data (Reregistration) (660,661)
- ☐ Special Review Data (870,871)

AH

NUMBER OF INDIVIDUAL STUDIES SUBMITTED:

RELATED ACTIONS: AVIAN REPRODUCTION-MALLARD DUCK

INSTRUCTIONS: AVIAN REPRODUCTION-BOBWHITE QUAIL

TO BE COMPLETED BY RSERB

DATE SENT TO HED/BUD/TSS: 7-2-85

PRIORITY NUMBER: 50

PROJECTED RETURN DATE: 8-30-85

DATE RETURNED TO RD (HED/BUD/TSS PROVIDE): 8-30-85

REVIEWS SENT TO:

HED: ☐ SIS ☐ TB ☐ RCB ☐ EAB ☒ EEB RD: ☐ TSS BUD: ☐ EAB ☐ SSB

	TO: TYPE OF REVIEW	NUMBER OF ACTIONS: Reregistration	Special Review	Other
HED	Toxicology			
HED	☒ Ecological Effects	1		
HED	Residue Chemistry			
HED	Exposure Assessment			
RD/TSS	Product Chemistry			
RD/TSS	Efficacy			
RD/TSS	Precautionary Labeling/Acute Tox.			
BUD	Science Support			
BUD	Economic Analysis			

FOR DATA SUBMITTED UNDER A REGISTRATION STANDARD: Review Submission Criter

Policy Note #31

1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria

(2) = data of particular concern

3 = data necessary to determine tiered testing requirements

NOTE TO TSS: Return 1 Copy To RSERB

INCLUDE AN ORIGINAL AND FOUR (4) COPIES OF THIS COMPLETED FORM FOR EACH BRANCH CHECKED FOR REVIEW.

25

(HED PROVIDE) CASWELL NO.: 1001

REGISTRATION DIVISION DATA REVIEW RECORD
—TO BE USED FOR REVIEW OF STUDIES PPA ONLY—

Confidential Business Information—
Does Not Contain National Security Info. (E.O. 12065)

(HED PROVIDE) PACK NO.: 11131 7/2/85

CHEMICAL NAME: ENDOSULFAN

(RD PROVIDE) SHAUGNESSY NO. 079401

Identifying Number	Action Code	Reference Number	Record Number	Study Guideline or Narrative Description	Reg. Std. Review Submission Criteria (SEE BELOW)	Accession Number	(RSERB Provide) MRID Number	(HED/BUD/TSS Complete) Review Results: Acceptable (A)/ Unacceptable(U)
83402-13	661	5	154081	158.145 71-4 (Mallard)	2	257687		A

PRODUCT MANAGER (PM) or REVIEW MANAGER (RM) AND NUMBER: LA ROCCA PM-15

PM/RM TEAM MEMBER AND NUMBER: D.R PILLITT 01

DATE RECEIVED (EPA): 4/19/85

RD BRANCH CHIEF INITIALS: MM

CHECK APPLICABLE BOX:

- ☐ Adverse 6(a)(2) Data (405,406)
- ☐ Suspect Data (415,416)
- ☐ IBT Data (485,486)
- ☐ Groundwater Data (495,496)
- ☐ Data Waiver Request (Reregistration) (650,651)
- ☐ Formulation Data and Labeling (Reregistration) (655,656)
- ☒ Generic Data (Reregistration) (660,661)
- ☐ Special Review Data (870,871)

AH

NUMBER OF INDIVIDUAL STUDIES SUBMITTED:

RELATED ACTIONS: AVIAN REPRODUCTION — BOBWHITE QUAIL

INSTRUCTIONS: AVIAN REPRODUCTION - MALLARD DUCK

TO BE COMPLETED BY RSERB

DATE SENT TO HED/BUD/TSS: 7-2-85

PRIORITY NUMBER: 50

PROJECTED RETURN DATE: 8-30-85

DATE RETURNED TO RD (HED/BUD/TSS PROVIDE): 8-30-85

REVIEWS SENT TO:

HED: ☐ SIS ☐ TB ☐ RCB ☐ EAB ☒ EEB RD: ☐ TSS BUD: ☐ EAB ☐ SSB

	TO: TYPE OF REVIEW	NUMBER OF ACTIONS: Reregistration	Special Review	Other
HED	Toxicology			
HED	☒ Ecological Effects	1		
HED	Residue Chemistry			
HED	Exposure Assessment			
RD/TSS	Product Chemistry			
RD/TSS	Efficacy			
RD/TSS	Precautionary Labeling/Acute Tox.			
HED	Science Support			
HED	Economic Analysis			

FOR DATA SUBMITTED UNDER A REGISTRATION STANDARD: Review Submission Criteri

Policy Note #31

1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria

(2) = data of particular concern

3 = data necessary to determine tiered testing requirements

NOTE TO TSS: Return 1 Copy To RSERB

INCLUDE AN ORIGINAL AND FOUR (4) COPIES OF THIS COMPLETED FORM FOR EACH BRANCH CHECKED FOR REVIEW.

24