060101

EEE BRANCH REVIEW

DATE: IN 6/13/78 OUT 11/21/78 IN ____ OUT ____ IN ____ OUT ____

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 618-84

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED _____

DATE OF SUBMISSION _____

DATE SUBMISSION ACCEPTED _____

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

DATA ACCESSION NO(S). _____

PRODUCT MGR. NO. WILSON (21)

PRODUCT NAME(S) Mertect LSP Fungicide-30% TBZ

COMPANY NAME Merck & Co. Inc

SUBMISSION PURPOSE Fish and Wildlife Studies

CHEMICAL & FORMULATION _____

Pesticide Name - Mertect LSP (Thiabendazole - 30%)

100 Pesticide Label Information - Refer to review by Larry Turner (4-1-78).

101 Physical and Chemical Properties - Refer to review by Larry Turner (4-1-78).

102 Behavior In The Environment - Refer to Environmental Safety Review by T.F.O`Brien (6-28-77).

103 Toxicological Properties - Refer to Review by T.F.O`Brien (6-28-77)

103.2.1 Avian Acute Oral LD50

Test: Avian Acute Oral LD_{50}
Species: Bobwhite Quail (Colinus virginiatus)
Results: Acute Oral LD_{50} > 4640 mg/kg (Technical)
Validation: Supplemental (See review ES-TBZ-1).

Test: Avian Acute Oral LD_{50}
Species: Bobwhite Quail (Colinus virginiatus)
Results: Acute oral LD_{50} > 4640 mg/kg (Formulated product)
Validation: Supplemental (See review ES-M-LSP-2).

Test: Avian Acute Oral LD_{50}
Species: Mallard Duck(Anas platyrynchos)
Results: LC_{50} > 4640 mg/kg (Formulated Product).
Validation: Supplemental (See review ES-M-LSP-1)

103.2.2 Avian Dietary LC_{50}

Test: Avian Dietary LC_{50}
Species: Bobwhite Quail (Colinus virginiatus)
Results: Avian Dietary LC_{50} > 10,000 ppm (Formulated product).
Validation: Supplemental (See review ES-M-LSP-3).

Test: Avian Dietary LC_{50}
Species: Mallard Duck (Anas platyrynchos
Results: Avian dietary LC_{50} > 10,000 ppm (Formulated product).
Validation: Supplemental (See review ES-M-LSP-4).

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103.2.3 Fish Acute LC50

Test: Acute 96-Hour LC_{50}
Species: Bluegill Sunfish (Lepomis macrochirus Rafinesque)
Results: Acute 96-Hr. LC50=56.3 mg/L (Formulated product).
Validation: Supplemental (See review ES-M-LSP-7).

Test: Acute 96-Hour LC_{50}
Species: Rainbow Trout (Salmo gairdneri Richardson).
Results: Acute 96-Hr. LC_{50} 3.8 mg/L (Formulated product).
Validation: Supplemental (See review ES-M-LSP-6).

103.2.4 Aquatic Invertebrate LC_{50}

Test: Acute Aquatic Invertebrate LC_{50}
Species: Water Flea (Daphnia magna Straus).
Results: Acute 48-Hr. LC_{50} 0.31 mg/L (Technical)
Validation: Core (See review ES-TBZ-2).

Test: Acute Aquatic Invertebrate LC_{50}
Species: Water Flea (Daphnia magna Straus)
Results: Acute 48-Hr. LC_{50} 0.49 mg/L (Formulated Product).
Validation: Supplemental (See review ES-M-LSP-5).

104 Hazard Assessment

104.1 Discussion

The proposed use of Mertect LSP fungicide on wheat seed is a major use addition for this formulation. The proposed maximum application rate of six fluid ounces of formulated product per acre (30% Thiabendazole) converts to 0.13 pounds a.i./acre based on a gallon of the technical product weighing 9.43 pounds.

Wheat seed is generally planted at depths of 1-2 inches, at the 6 oz./ acre application rate (0.13 lbs.a.i.), concentrations of 0.286 ppm at depths of one inch and 0.143 ppm at two inches could be expected.

104.2 Liklihood of Adverse Effects to Non-Target Organisms

Birds

The lack of a valid avian acute oral LD_{50} precludes definitive estimates concerning acute avian toxicity. Turner (4-1-78) estimates a dietary concentration of 2085 ppm for birds eating only treated seeds. This exposure would be well below the dietary LC_{50}.

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Fish

Aquatic species should not be exposed by direct application but contamination may occur through wind drift, leaching and by surface runoff. Even by direct contamination, the maximum expected residues in the top six inches of water would be 0.095 ppm at the six ounce application (0.13 lbs.a.i/acre). Available data for warm and coldwater fish suggests a wide safety margin at this level.

Aquatic Invertebrates

The 48-hour acute invertebrate LC_{50}, using Daphnia magna as the test organism, was 0.31 mg/L. This is the least tolerant of any group yet on which we have data. The low solubility and rapid photolysis of TBZ in water coupled with its low application rate and use pattern, however, indicate minimal danger, even to this group.

104.3 Endangered Species Considerations
No hazard to protected species is anticipated

104.4 Adequacy of Toxicity Data

Nine studies were included in this submission. Seven used the formulated product; two the technical product. Studies using the formulated product are required only if "the product will be introduced directly into an aquatic environment when used as directed". These seven studies were therefore classified as supplemental. Five studies are repairable to core studies should studies using the formulated product be necessary. Two studies are not repairable since protocol was not followed.

The Avian Acute Oral LD_{50} study using Technical TBZ (ES-TBZ-1) could not be classified as core and is not repairable since required protocol was not followed.

The Acute Invertebrate 48-Hr. LC_{50} Study (ES-TBZ-2) met all requirements and was classified as Core.

104.5 Additional Data Required
1. An Avian Acute Oral LD_{50} (Bobwhite Quail or Mallard Duck) using technical grade Thiabendazole.
2. Avian reproductive studies on Bobwhite Quail and the Mallard Duck using technical Thiabendazole are still outstanding. These were requested by T.F.O'Brien (6-28-77).

105 Classification - None; data evaluation only.

106 RPAR Criteria - None

107 Conclusions

The Environmental Safety Staff objects to the proposed registration of MERTECT LSP for wheat seed treatment. Data gaps do not allow a complete determination of hazard.

Additional testing may be required depending on the results of studies still outstanding, additional environmental data and/or any change in use pattern.

The registrant may wish to contact the Environmental Safety Section to clarify any requirements or protocols.

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Study Validation

DATA REVIEW NUMBER: ES-TBZ-1

TEST: Avian Acute Oral LD_{50}

SPECIES: Bobwhite Quail- Colinus virginiatus

RESULTS: Acute Oral LD_{50} > 4640 mg/kg

* This is the same study validated by J. Tice (5-12-78) Review No. ES-C-2

CHEMICAL: Thiabendazole Technical, 98.5% AI

TITLE: Acute Oral LD_{50}-Bobwhite Quail-Thiabendazole-Final Report Project No. 105-119

ACCESSION NO.

STUDY DATE: 7-28-77 (Date of Initiation)

RESEARCHER: Prep. By Joann Beavers - Submitted by Robert Fink

REGISTRANT: Merck Chemical Division

VALIDATION CATEGORY: Supplemental

CATEGORY REPAIRABILITY: No! The study used 14-day-old birds instead of 16-week-old birds as required and was conducted for only 8 days instead of the required 14-day minimum.

ABSTRACT:

Study Validation

DATA REVIEW NUMBER: ES-TBZ-2

TEST: Acute Invertebrate LC_{50} - 48-Hr.

SPECIES: Water Flea, Daphnia magna Straus

RESULTS: The 48-Hr. LC_{50} is 0.31 mg/l - no effect level is 0.18 mg/l - 95% conf. limits are 0.26 to 0.36 mg/l

The study followed acceptable protocol using the technical material.

CHEMICAL: Thiabendazole Technical

TITLE:The Acute Toxicity of Thiabendazole Technical To The Water Flea, Daphnia magna Straus.

ACCESSION NO.

STUDY DATE: 9-1-77 to 9-3-77

RESEARCHER: UCES

REGISTRANT: Merck and Co. Inc.

VALIDATION CATEGORY: Core

CATEGORY REPAIRABILITY: NA

Study Validation

DATA REVIEW NUMBER: ES-M-LSP-1

TEST: Avian Acute Oral LD_{50}

SPECIES: Mallard Duck (Anas platyrynchos)

RESULTS: LD_{50} > 4640 mg/kg

CHEMICAL:Mertect LSP 30% Thiobendazole

TITLE: Final Report Acute Oral LD_{50} Mallard Duck Project No. 105 - 126 - WI Iden. No. WI 501

ACCESSION NO.

STUDY DATE:January 4, 1978 (Initiation date)

RESEARCHER:Prep. by Joann Beavers - Submitted by Robert Fink

REGISTRANT:Merck Chemical Division

VALIDATION CATEGORY:Supplemental

CATEGORY REPAIRABILITY:No. The study used 14 days old birds instead of 16 week old birds and was conducted for only 8 days instead of the required minimum 14 days.

ABSTRACT:

Study Validation

DATA REVIEW NUMBER: ES-M-LSP-2

TEST: Avian Acute Oral LD_{50}

SPECIES: Bobwhite Quail (Colinus virginiatus)

RESULTS: Avian Acute Oral LD_{50} > 4640 mg/kg

CHEMICAL: Mertect LSP - 30% Thiobendazole

TITLE: Final Report - Acute Oral LD_{50} - Bobwhite Quail Project No. - 105-125: WI-501

ACCESSION NO.

STUDY DATE: Dec 30, 1977 (Initiation Date)

RESEARCHER: Prep: by Joann Beavers - Submitted by Robert Fink

REGISTRANT: Merck Chemical Division

VALIDATION CATEGORY: Supplemental

CATEGORY REPAIRABILITY: No. The study used 14-day-old birds instead of the required 16-week-old birds and was conducted for only 8 days instead of the required minimum 14 days.

ABSTRACT:

Study Validation

DATA REVIEW NUMBER: ES-M-LSP-3

TEST: Avian Dietary LC_{50}

SPECIES: Bobwhite Quail (Colinus virginiatus)

RESULTS: Eight-day Dietary LC_{50} > 10,000 ppm

CHEMICAL: Mertect - LSP - 30% Thiabendazole

TITLE: Final Report - Eight-day Dietary LC_{50} - Bobwhite Quail

ACCESSION NO.

STUDY DATE: Dec 30, 1977

RESEARCHER: Prep. by Joann Beavers: Submitted by Robert Fink

REGISTRANT: Merck Chemical Division

VALIDATION CATEGORY: Supplemental

CATEGORY REPAIRABILITY: Yes. The study was classified supplemental because the formulated product was used instead of the technical material. If a study using the formulated product is necessary, it may be categorized as core.

ABSTRACT:

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Study Validation

DATA REVIEW NUMBER: ES-M-LSP-4

TEST: Avian Dietary LC_{50}

SPECIES: Mallard Duck (Anas platyrhynchos)

RESULTS: Eight-day dietary LC_{50} > 10,000 ppm

CHEMICAL: Mertect LSP- 30% Thiabendazole

TITLE: Final Report-8-day dietary LC_{50} - Mallard Duck

ACCESSION NO.

STUDY DATE: Dec. 27, 1977

RESEARCHER: Prep. by Joann Beavers: Submitted by Robert Fink

REGISTRANT: Merck Chemical Division

VALIDATION CATEGORY: Supplemental

CATEGORY REPAIRABILITY: Yes. The study was classfied supplemental because the formulated product was used instead of the technical material. If a study using the formulated product is necessary, it may be categorized as core.

ABSTRACT:

Study Validation

DATA REVIEW NUMBER: ES-M-LSP-5

TEST: Acute LC_{50} - Water Flea

SPECIES: Water Flea (Daphnia magna Straus)

RESULTS: 48-Hr. LC_{50} is 0.49 mg/l - observed no-effect level is 0.10 mg/l
95% Conf. intervals: (0.40-0.59) mg/l

CHEMICAL: Mertect LSP- 30% Thiabendazole

TITLE: The Acute Toxicity of Mertect LSP to the Water Flea

ACCESSION NO.

STUDY DATE: 12-30-77 to 1-1-78

RESEARCHER: UCES Toxicity Lab. - Project 11506-42-06

REGISTRANT: Merck and Co.,Inc.

VALIDATION CATEGORY: Supplemental

CATEGORY REPAIRABILITY: Yes. The study was classfied supplemental because the formulated product was used instead of the technical material. If a study using the formulated product is necessary, it may be categorized as core.

ABSTRACT:

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Study Validation

DATA REVIEW NUMBER: ES-M-LSP-6

TEST: Acute LC_{50}-Rainbow Trout

SPECIES: Rainbow Trout (Salmo gairdneri Richardson)

RESULTS: 96-Hr. LC_{50} is 3.8 mg/l - observed no effect level is < 0.56 mg/l - 95% conf. intervals (3.0 to 4.7) mg/l

CHEMICAL: Mertect LSP

TITLE: The Acute Toxicity of Mertect LSP to the Rainbow Trout, Salmo gairdneri Richardson.

ACCESSION NO.

STUDY DATE: 12-13-77 to 12-17-77

RESEARCHER: UCES

REGISTRANT: Merck and Co., Inc.

VALIDATION CATEGORY: Supplemental

CATEGORY REPAIRABILITY: Yes. The study was classified supplemental because the formulated product was used instead of the technical material. If a study using the formulated product is necessary, it may be categorized as core.

ABSTRACT:

Study Validation

DATA REVIEW NUMBER: ES-M-LSP-7

TEST: Acute LC_{50} - Bluegill Sunfish

SPECIES: Bluegill Sunfish, Lepomis macrochirus Rafinesque

RESULTS: The 96-Hr. LC_{50} is 56.3 mg/l and the observed no-effect level is 42.0 mg/l.
95% Conf. Intervals (51.3-61.8) mg/l

CHEMICAL: Mertect LSP

TITLE: The Acute Toxicity of Mertect LSP to the Bluegill Sunfish Lepomis machrochirus Rafinesque.

ACCESSION NO.

STUDY DATE: 12-13-77 to 12-17-77

RESEARCHER: UCES

REGISTRANT: Merck and Co., Inc.

VALIDATION CATEGORY: Suppplemental

CATEGORY REPAIRABILITY: Yes. The study was classified supplemental because the formulated product was used instead of the technical material. If a study using the formulated product is necessary, it may be categorized as core.

ABSTRACT: