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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

114501

Subject: Toxicology Review for the Reregistration Eligibility Document on THIODICARB

From: Linda L. Taylor, Ph.D. Linda Lee Taylor 8/13/96
Toxicology II Branch, HED (7509C)

Thru: K. Clark Swentzel, Head, Section K. Clark Swentzel 8/13/96
Toxicology II Branch, HED (7509C)

Ioannou Yiannakis, Ph.D., Acting Chief K. Clark Swentzel for 8/14/96
Toxicology II Branch, HED (7509C)

To: Michael S. Metzger, Acting Chief
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Chemical: **THIODICARB**; dimethyl N,N'-[thiobis[(methyliminocarbonyl)oxy]bis]ethanimidothioate **or** 3,7,9,13-tetramethyl-5,11-dioxa-2,8,14-trithia-4,7,9,12-tetraazapentadeca-3,12-diene-6,10-dione; Case 819468 [2675]; Chemical No. 114501; CAS Reg No. 59669-26-0; Submission S504096; DP Barcode D225379.

Products: **food and non-food applications:** a carbamate insecticide for control of insects on cotton, soybeans, corn (sweet), leafy vegetables, broccoli, cabbage, cauliflower, peanuts, ornamentals, non-crop areas, seed treatment, tomatoes, peppers.

cc: Kathy Davis [B. Adler], SRRD/ARB w/ ATTACHMENT
Dennis Edwards, RD [PM 19] w/ ATTACHMENT

1. Toxicology Data Base

The toxicological data base on THIODICARB is adequate and will support reregistration eligibility.

a. Acute Toxicity

Acute toxicity values and categories for Thiodicarb are summarized in Table 1.

TABLE 1. Acute Toxicity of THIODICARB

Guideline	Study Type	MRID #	Results	Toxicity Category
81-1	Acute Oral - rat	00025791 00115604 00115607	LD_{50} = ♂♂ 46.5/♀♀ 39.1 to ♂♂ 398/♀♀ 248 mg/kg	I II
	- mouse	43784501	LD_{50} = ♂♂ 73/♀♀ 79 mg/kg	II
81-2	Acute Dermal - rabbit	92185010 92185011 44025501	LD_{50} > 2000 mg/kg	III
81-3	Acute Inhalation - rat	00041432 00045467	LC_{50} = ♂♂ 0.126/ ♀♀ 0.115 mg/L > 0.32 mg/L [dust]	II II
81-4	Primary Eye Irritation - rabbit	44025502	slight irritant	III
81-5	Primary Skin Irritation - rabbit	44025503	Non-irritant	IV
81-6	Dermal Sensitization - guinea pig human	41891004 43373201	weak dermal sensitivity reaction	-
81-8	Acute Neurotoxicity	044962	negative	-

In several acute oral toxicity studies with rats, the LD_{50} ranged from 46.5 mg/kg for males and 39.1 mg/kg for females, which is toxicity category I, to 398 mg/kg for males and 248 mg/kg for females, which is toxicity category II [Guideline 81-1; MRID 00025791, 00115604, 00115607]. In the mouse, the LD_{50} was 73 mg/kg in males and 79 mg/kg in females [Guideline 81-1; MRID 43784501]. The LD_{50} in an acute dermal toxicity study with rabbits was found to be greater than 2000 mg/kg. This is toxicity category III [Guideline 81-2; MRID 44025501, 92185010, 92185011]. In an acute inhalation toxicity study with rats, the LC_{50} was ♂♂ 0.126/♀♀ 0.115 mg/L and greater than 0.32 mg/L for dust. These are toxicity category II [Guideline 81-3; MRID 00041432, 00045467].

In a primary eye irritation study with rabbits, the test material was a slight irritant. This is toxicity category III [Guideline 81-4; MRID 44025502]. The test material was shown to be a non-irritant in a primary dermal irritation study in rabbits. This is toxicity category IV [Guideline 81-5; MRID 44025503].

In a dermal sensitization study in guinea pigs, Thiodicarb induced a weak dermal sensitization reaction [Guideline 81-6; MRID 41891004, 43373201]. In a delayed neurotoxicity study in hens, Thiodicarb was administered once at a dose level of 660 mg/kg [LD_{50}]. Thiodicarb was not a delayed neurotoxin in this study [Guideline 81-7; MRID 00044961, 00053253].

b. Subchronic Toxicity

In a subchronic toxicity study, Fisher 344 [COBS CD F/Crl BR] rats [10/sex/group] were administered Thiodicarb [≈97% a.i.] via the diet at dose levels of 1, 3, 10, and 30 mg/kg/day for 13 weeks. The NOEL was 3 mg/kg/day, and the LOEL was 10 mg/kg/day, based on decreased body-weight gain, RBC cholinesterase activity, and hemoglobin [Guideline 82-1(a); MRID 00044965]. In a subchronic feeding study in Beagle dogs, Thiodicarb was administered via the diet at dose levels of 0, 15, 40, and 90 mg/kg/day for 13 weeks. The high dose was lowered to 76 mg/kg/day in females after day 36 due to the deaths of 2 high-dose females. The NOEL was 15 mg/kg/day, and the LOEL was 45 mg/kg/day, based on decreased hemoglobin parameters [Guideline 82-1(b); MRID 00044966]. In another subchronic toxicity study in dogs, Thiodicarb was administered via the diet at dose levels of 0, 5, 15, and 45 mg/kg/day for 6 months. The NOEL was 15 mg/kg/day, and the LOEL was 45 mg/kg/day, based on liver effects [Guideline 82-1(b); MRID 00079474].

In a 21-day dermal toxicity study, New Zealand White rabbits were administered Thiodicarb via the skin at dose levels of 1, 2, and 4 grams/kg for 6 hours a day, 5 days a week for 3 weeks. The NOEL was 1 mg/kg/day, and the LOEL was 2 mg/kg/day, based on macrocytic anemia, erythema, and edema [Guideline 82-2; MRID 00043737, 00044967]. In a 16-dose dermal toxicity study, New Zealand white rabbits were administered Thiodicarb via the skin at dose levels of 1 and 4 grams/kg for 6 hours a day, 5 days a week for 3 consecutive weeks. The NOEL was 1 mg/kg/day, and the LOEL was 4 grams/kg/day, based on decreased erythrocytes and hemoglobin and decreased body weight [Guideline 82-2; MRID 00043738].

In a 9-day dust inhalation study, Sprague-Dawley rats were administered Thiodicarb particulates via the inhalation route at dose levels of 4.8 [both sexes], ♂♂ 17.7/♀♀ 19.6, ♂♂ 59.5/♀♀ 54.0 mg/m^3 [mean measured atmospheric concentrations] for 6 hours a day for 9 days. The NOEL was not determined. At 4.8 mg/m^3, two clinical signs typically associated with cholinesterase effects [pinpoint pupils and tremors] were observed in both sexes. There were no significant body-weight effects at this dose level in either sex, and no statistically significant effects were observed in any cholinesterase measurement [plasma, RBC, and brain] at 4.8 or 17.7/19.6 mg/m^3 in either sex [non-guideline; MRID 00045467, 00053252].

In a 4-week feeding study, CD-1 mice of both sexes were administered Thiodicarb via the diet at dose levels of 0, 30 [♂♂ 6.2/♀♀ 8.3 mg/kg/day], 1750 [♂♂ 346/♀♀ 491 mg/kg/day], 3500 [♂♂ 734/♀♀ 954 mg/kg/day], and 7000 [♂♂ 1538/♀♀ 2030 mg/kg/day] ppm for 4 weeks. The NOEL was 30 ppm [♂♂ 6.2/♀♀ 8.3 mg/kg/day], and the LOEL was 1750 ppm [♂♂ 346/♀♀ 491 mg/kg/day], based on increased liver weight in females and increased spleen weight in both sexes [non-guideline; MRID 43611701].

In a subchronic feeding study, Fischer 344 rats of both sexes were administered Thiodicarb via the diet at dose levels of 0, 1.0, 3.0, 10.0, and 30.0 mg/kg/day for 28 days. The NOEL for effects on cholinesterase activity was 10 mg/kg/day, and the LOEL was 30 mg/kg/day, based on decreased plasma and RBC cholinesterase activity [non-guideline; MRID 00098292].

c. Chronic Toxicity and Carcinogenicity

Beagle dogs were administered Technical Thiodicarb via the diet at dose levels of 0, 164 [♂♂ 4.4/♀♀ 4.5 mg/kg/day], 487 [♂♂ 12.8/♀♀ 13.8 mg/kg/day], and 1506 [♂♂ 38.3/♀♀ 39.5 mg/kg/day] ppm for one year. The NOEL is ♂♂ 4.4/♀♀ 4.5 mg/kg/day, and the LOEL is ♂♂ 12.8/♀♀ 13.8 mg/kg/day, based on cholinesterase inhibition. The systemic NOEL is ♂♂ 12.8/♀♀ 13.8 mg/kg/day and the systemic LOEL is ♂♂ 38.3/♀♀ 39.5 mg/kg/day, based on reduced hematology parameters (including erythrocytes, hemoglobin, and hematocrit). [Guideline §83-1(b); MRID 00159813]

In a chronic toxicity/carcinogenicity study, Sprague-Dawley rats of both sexes were administered Thiodicarb via the diet at dose levels of 0 ppm, 60 ppm [♂♂ 3.3/♀♀ 4.5 mg/kg], 200 ppm [♂♂ 12/♀♀ 15 mg/kg], and 900 ppm [♂♂ 60/♀♀ 80 mg/kg] for 104 weeks. The systemic NOEL was 60 ppm [♂♂ 3.3/♀♀ 4.5 mg/kg/day] and the LOEL was 200 ppm [♂♂ 12/♀♀ 15 mg/kg/day], based on the increased incidence of extramedullary hemopoiesis in males and decreased RBC cholinesterase in females. There were no compound-related tumors observed in the females. The high-dose males displayed an increased incidence of interstitial cell tumors in the testes compared to the concurrent control males, and the incidence was greater than the historical control also. [Guideline 83-5; MRID 43308201, 43405001, 43596401].

In a carcinogenicity study, Charles River CD-1 mice of both sexes were administered Thiodicarb via the diet at dose levels of 0, 5, 70, and 1000 mg/kg/day for 97 weeks. The NOEL was 70 mg/kg/day, and the LOEL was 1000 mg/kg/day, based on increased mortality in females, decreased body-weight gain in males, decreased hemoglobin, hematocrit, and erythrocytes, increased alanine aminotransferase and total bilirubin, increased liver and spleen weights, and increased incidences of kidney, liver, and spleen lesions [Guideline 83-2(b); MRID 43000501, 43619301].

In another carcinogenicity study, Charles River CH:COBS CD-L (ICR)BR mice of both sexes were administered Thiodicarb via the diet at dose levels of 1, 3, and 10 mg/kg/day for 104 weeks. The NOEL was 3 mg/kg/day, and the LOEL was 10 mg/kg/day, based on mortality in females [Guideline 83-2(b); MRID 00041407].

d. Developmental Toxicity

In a rat developmental toxicity study, pregnant Charles River CD COBS rats were administered Thiodicarb via gavage [days 6-19 of gestation] at dose levels of 0 [vehicle 0.5% methocel], 10, 20, and 30 mg Thiodicarb/kg body weight/day. In another rat developmental toxicity study, pregnant Fisher 344 rats were dosed via the diet on (1) gestation days 6 to 15 or (2) gestation days 0-20 at dose levels of 0.5, 1.0, 3.0, and 100 mg Thiodicarb [>99%]/kg body weight/day. When these two studies are considered together, the maternal toxicity NOEL is 10 mg/kg/day, and the maternal toxicity LOEL is 20 mg/kg/day, based on clinical signs [tremors, inactivity]. The developmental toxicity NOEL is 3 mg/kg/day, and the LOEL is 10 mg/kg/day, based on decreased fetal body weights and increased incidence of litters and fetuses with developmental variations (unossification of sternebrae #5 and/or #6 and other sternebrae) [Guideline 83-3(a); MRID 00043739, 00043740, 00043741, 00053254, 00053255, 00053256].

In a developmental toxicity study, artificially-inseminated New Zealand white rabbits were administered Thiodicarb via gavage on gestation days 6 through 19 at dose levels of 0 [vehicle, 0.5% aqueous methylcellulose], 5, 20, and 40 mg Thiodicarb [93%]/kg body weight/day. The maternal toxicity NOEL was 20

mg/kg/day, and the maternal toxicity LOEL was 40 mg/kg/day, based on reduced body-weight gain and food consumption. The developmental toxicity NOEL was 40 mg/kg/day, the highest dose tested [Guideline 83-3(b); MRID 00159814, 40280001].

In a developmental toxicity study, Charles River CD-1 mice were administered Thiodicarb on gestation days 6 through 16 via gavage at dose levels of 0 [vehicle 0.5% methocel], 50, 100, and 200 mg Thiodicarb/kg body weight/day. The maternal toxicity NOEL was 100 mg/kg/day, and the maternal toxicity LOEL was 200 mg/kg/day, based on increased mortality. The developmental toxicity NOEL was 200 mg/kg/day, the highest dose tested [Guideline 83-3(a); MRID 00043742, 00043743, 00053257, 00053258].

e. Reproductive Toxicity

In a two-generation reproduction study, Crl:CD®BR/VAF/Plus® rats were fed doses of 0, 100 [5 mg/kg/day], 300 [15 mg/kg/day], and 900 [45 mg/kg/day] ppm Thiodicarb. The reproductive/developmental toxicity NOEL is 100 ppm (5 mg/kg/day), and the reproductive/developmental toxicity LOEL is 300 ppm)15 mg/kg/day), based on decreased fetal body weight and viability. The systemic NOEL is 5 mg/kg/day and the systemic LOEL is 15 mg/kg/day, based on decreased body weight/gain and food consumption in both sexes [Guideline 83-4; MRID 42381301, 42381302, 42735101].

f. Mutagenicity

Thiodicarb did not induce a mutagenic response in the Ames assay, with or without metabolic activation [Guideline 84-2; MRID 00044872, 00135792]. Thiodicarb induced dose-related increased mutant frequencies in mouse lymphoma $TK^{+/-}$ cells, with or without metabolic activation and is considered to have an equivocal weak effect in the mouse lymphoma forward mutation assay [Guideline 84-2; MRID 00151574]. Thiodicarb, with or without metabolic activation, did not cause a clastogenic response in the chromosomes of Chinese hamster ovary cells [Guideline 84-2; MRID 00151572]. Thiodicarb is considered inactive in the primary rat hepatocyte unscheduled DNA synthesis [UDS] assay [Guideline 84-2; MRID 00151573].

g. Metabolism

Metabolic studies were performed in rats using single low and single high doses of radiolabeled Thiodicarb. The major routes of elimination were expired CO_2, expired acetonitrile, and urine. Tissue residues were 7-9% of the dose at 7 days post dose and may reflect the metabolism of ^{14} acetonitrile into the body's C-2 and C-1 pools and subsequent interaction with, or incorporation into natural products. The major metabolites of Thiodicarb in the rat are CO_2 and acetonitrile. The major urinary metabolite is a labile unknown that represents 50% of the urinary radiolabel. No acetamide was detected in any of the tissues. The RBCs contained only residue that cannot be extracted by organic solvents or water, indicating the presence of radiolabel incorporated into natural products or of material tightly bound to hemoglobin [Guideline 85-1; MRID 41250006, 41250007].
In a metabolism study in monkeys, Thiodicarb [syn, syn-isomer] undergoes in vivo metabolism to syn-methomyl and subsequent isomerization to anti-methomyl, with ≈0.8-1.0% [lower limit] to 2.6-3.3% by weight [upper limit] of Thiodicarb being converted to acetamide and excreted in the urine [non-guideline study; MRID 42667601, 43228901].

2. DOSE-RESPONSE ASSESSMENT

a. Reference Dose (RfD)

The Health Effects Division RfD/Peer Review Committee met on January 18, 1996. The RfD for Thiodicarb was determined to be 0.03 mg/kg/day, based on the NOEL of 60 ppm [equivalent to 3.3 and 4.5 mg/kg/day in males and females, respectively] in the chronic rat toxicity study. An uncertainty factor of 100 was used to account for the interspecies extrapolation and intraspecies variability [Ghali, 1996]. WHO/FAO Joint Meeting on Pesticide Residues [JMPR] reviewed Thiodicarb in 1986, and an Acceptable Daily Intake [ADI] of 0.03 mg/kg/day has been established.

b. Cancer Classification

The Carcinogenicity Peer Review Committee of the Health Effects Division classified Thiodicarb as Group B2 - probable human carcinogen - and recommended that for the purpose of risk characterization, a Margin of Exposure [MOE] methodology be used for the estimation of human risk. This decision was based on statistically significant increases in hepatocellular adenomas, carcinomas, and combined adenoma/carcinoma in both sexes of the CD-1 mouse and statistically significant increases in testicular interstitial cell tumors in male Sprague-Dawley rats. The Committee recommended that the MOE be based on the point of departure for liver tumors in mice [5 mg/kg/day].

c. Other Toxicity Information

Based upon the review of the toxicology database for Thiodicarb, toxicological endpoints and dose levels of concern were identified in the **Toxicology Endpoint Selection Document** [meeting on 4/23/96]. An Acute Dietary [one day] risk assessment is required. The NOEL is 3.0 mg/kg/day, based developmental toxicity study in rats. Neither a Short [1 to 7 days] or an Intermediate [1 week to several months] Term Occupational or Residential risk assessment for dermal exposure is required since no appropriate endpoint was identified. An inhalation [any time period] risk assessment is required, based on a 9-day dust inhalation study in rats. A Chronic [several months to lifetime] Occupational or Residential risk assessment for dermal exposure is required. The RfD is based on the NOEL of the chronic toxicity study in rats, and the MOE is based on the point of departure for liver tumors in mice, which is recommended for cancer risk.

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