4-25-97

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 25 1997

APR 25 1997

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Thiodicarb in Support of the Reregistration Eligibility Decision.

FROM: Brian Steinwand BS
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head
Dietary Risk Evaluation Section
SAB/Health Effects Division

TO: Mike Metzger, Chief
Risk Characterization Analysis Branch
Health Effects Division (7509C)

Action Requested

Provide a dietary exposure analysis to estimate the acute dietary exposure and risk from thiodicarb for uses which are being supported through reregistration using a maternal NOEL of 10 mg/kg/day.

Discussion

Previously, an acute dietary risk analysis was performed using a developmental endpoint of 3 mg/kg/day. Because the endpoint of concern was a developmental effect, the only analysis of concern was for females of child bearing age. Using the new acute NOEL endpoint, MOE values should be determined for the remaining population subgroups.

1450

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Toxicological Endpoint:

The endpoint for acute dietary risk assessment is the maternal NOEL of 10.0 mg/kg bwt/day.

Residue Information

Tolerances for thiodicarb are published in 40 CFR §180.407 (a), (b), and (c). The available data support the established tolerances in/on sweet corn, the leafy vegetable crop group, cabbage, soybeans, broccoli, and cauliflower; the established tolerances for residues in/on cottonseed should be decreased from 0.4 ppm to 0.2 ppm (See Memo, D. Miller, 11/26/96). Tolerance level residues and 100 percent crop treated assumptions were made for all commodities. No anticipated residue (AR) information was used in this analysis.

Results

Acute Exposure:

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern when results are compared to animal-derived data.

Following the recommendations of CBRS (which includes the reduction of the cottonseed tolerance from 0.4 ppm to 0.2 ppm) results in the following MOEs: U.S. Population = 62; Infants (<1 year old) = 20; Children (1-6 years old) =33 ; Females (13+ years) = 71; and Males (13+ years) = 83 (See Table 1).

These MOEs exceed the Agency's level of concern regarding acute exposure with the proposed decrease in the cottonseed tolerance.

Attachments
cc: DRES; Caswell 900AA

TABLE 1

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 10:18 Tuesday, April 15, 1997 17

	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.
*NAME: THIODICARB (LARVIN)	A	00000.0300	000060.000	000100	Chron-onco	Rat	Systemic	Minimum	0000001820*
*CASWELL NO: 900AA CFR NO: CFR180.407	B								*
*CAS NO: 59669-26-0 SHAUGHNESSY NO: 114501	C								*

*RDV INFO: The LD value used in this analysis is 0.1 MG/KG of BODY WEIGHT/DAY *

FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications

-U.S. POP.--48 STATES

ESTIMATES BASED ON	ESTIMATED % OF POTENTIAL PERSON DAYS THAT ARE USER-DAYS	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	98.46	0.013836	13.84

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	23	10	5	2	1	1	1	0	0	0	0	0	0	0	0	0

0INFANTS(<1 YEAR)

ESTIMATES BASED ON	ESTIMATED % OF POTENTIAL PERSON DAYS THAT ARE USER-DAYS	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	76.87	0.008464	8.46

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	4	3	2	2	2	2	2	2	1	1	1	1	0	0	0	0

OCHILDREN(1-6 YRS)

ESTIMATES BASED ON	ESTIMATED % OF POTENTIAL PERSON DAYS THAT ARE USER-DAYS	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	98.7[illegible]	0.014157	14.16

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	19	11	6	4	3	2	1	1	1	1	0	0	0	0	0	0

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 10:18 Tuesday, April 15, 1997 18

*NAME: THIODICARB (LARVIN)	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.*
*CASWELL NO: 900AA CFR NO: CFR180.407	A	00000.0300	000060.000	000100	Chron-onco	Rat	Systemic	Minimum	0000001820*
*CAS NO: 59669-26-0 SHAUGHNESSY NO: 114501	B								*
*STATUS CODES:	C								*

*RDV INFO: The LD value used in this analysis is 0.1 MG/KG of BODY WEIGHT/DAY *

FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications

-FEMALES(13+ YRS)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	98.35	0.014673	14.67

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	26	11	5	3	1	1	0	0	0	0	0	0	0	0	0	0

0MALES(13+ YRS)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	99.15	0.012226	12.23

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	22	8	3	2	1	0	0	0	0	0	0	0	0	0	0	0

General U.S. Population

Exposure = RDV x X
= 0.1 x 1.6
High End Exposure = 0.16

MOE = Noel + Exposure
= 10 mg/kg/day + 0.16 mg/kg/day
MOE = 62.5

Infants (< 1 year)

Exposure = RDV x X
= 0.1 x 5
High End Exposure = 0.5

MOE = Noel + Exposure
= 10 mg/kg/day + 0.5 mg/kg/day
MOE = 20

Children (1-6 years)

Exposure = RDV x X
= 0.1 x 3
High End Exposure = 0.3

MOE = Noel + Exposure
= 10 mg/kg/day + 0.3 mg/kg/day
MOE = 33

Females (13+ Years):

Exposure = RDV x X
= 0.1 x 1.4
High End Exposure = 0.14

MOE = Noel + Exposure
= 10 mg/kg/day + 0.14 mg/kg/day
MOE = 71

Males (13+ Years):

Exposure = RDV x X
= 0.1 x 1.2
High End Exposure = 0.12

MOE = Noel + Exposure
= 10 mg/kg/day + 0.12 mg/kg/day
MOE = 83

S1

900AA	13002AA10	35.0000	CELERY
900AA	13002AA21	35.0000	CELERY
900AA	13005AA21	7.0000	BROCCOLI
900AA	13005AA31	7.0000	BROCCOLI
900AA	13005AA63	7.0000	BROCCOLI
900AA	13007AA10	7.0000	CABBAGE
900AA	13007AA11	7.0000	CABBAGE
900AA	13007AA21	7.0000	CABBAGE
900AA	13008AA10	7.0000	CAULIFLOWER
900AA	13008AA21	7.0000	CAULIFLOWER
900AA	13010AA10	7.0000	CABBAGE-CHINESE
900AA	13010AA21	7.0000	CABBAGE-CHINESE
900AA	13013AA10	35.0000	LETTUCE-LEAFY
900AA	13014AA63	35.0000	DANDELION
900AA	13015AA10	35.0000	ENDIVE
900AA	13015AA21	35.0000	ENDIVE
900AA	13016AA00	35.0000	FENNEL
900AA	13017AA00	35.0000	CRESS
900AA	13020AA10	35.0000	LETTUCE-UNSPEC
900AA	13022AA10	35.0000	PARSLEY
900AA	13022AA21	35.0000	PARSLEY
900AA	13022AA53	35.0000	PARSLEY
900AA	13023AA10	35.0000	RHUBARB
900AA	13023AA21	35.0000	RHUBARB
900AA	13023AA31	35.0000	RHUBARB
900AA	13023AA62	35.0000	RHUBARB
900AA	13024AA10	35.0000	SPINACH
900AA	13024AA21	35.0000	SPINACH
900AA	13024AA31	35.0000	SPINACH
900AA	13025AA10	35.0000	SWISS CHARD
900AA	13025AA31	35.0000	SWISS CHARD
900AA	13025AA63	35.0000	SWISS CHARD
900AA	13039AA00	35.0000	CRESS,UPLAND
900AA	13045AA10	35.0000	LETTUCE-HEAD
900AA	13045AA21	35.0000	LETTUCE-HEAD
900AA	15005AA10	2.0000	CORN,SWEET
900AA	15005AA21	2.0000	CORN,SWEET
900AA	15005AA31	2.0000	CORN,SWEET
900AA	15029AA00	0.2000	SOYBEAN-SPROUTED
900AA	27003OA18	0.2000	COTTONSEED-OIL
900AA	27003WA18	0.2000	COTTONSEED-MEAL
900AA	27010OA18	0.2000	SOYBEANS-OIL
900AA	28023AA21	0.2000	SOYBEANS-UNSPEC
900AA	28023AB10	0.2000	SOYBEANS-DRY
900AA	28023AB21	0.2000	SOYBEANS-DRY
900AA	28023AB23	0.2000	SOYBEANS-DRY
900AA	28023AB25	0.2000	SOYBEANS-DRY
900AA	28023AB31	0.2000	SOYBEANS-DRY
900AA	28023WA21	0.2000	SOY-FL, FULL FAT
900AA	28023WA22	0.2000	SOY-FL, FULL FAT
900AA	28023WA31	0.2000	SOY-FL, FULL FAT
900AA	28023WB21	0.2000	SOY-FL, LOW FAT
900AA	28023WC10	0.2000	SOY-FL,DEFAT
900AA	28023WC21	0.2000	SOY-FL,DEFAT
900AA	28023WC22	0.2000	SOY-FL,DEFAT
900AA	28023WC51	0.2000	SOY-FL,DEFAT
900AA	28023WC53	0.2000	SOY-FL,DEFAT

File Violate

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 08/22/97 BS PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
THIODICARB Caswell #900AA CAS No. 59669-26-0 A.I. CODE: 114501 CFR No. 180.407	2yr feeding- rat NOEL= 3.3000 mg/kg 60.00 ppm LEL= 12.0000 mg/kg 200.00 ppm ONCO: USED METHOMYL RfD	Increased incidence of extramedullary hemopoiesis in males & decreased RBC ChE in females. Evidence of carcinogenicity in rats & mice.	ADI UF -->100 OPP RfD= 0.030000 EPA RfD= 0.030000	No data gaps.	WHO reviewed 1986 HED complete 11/19/86 HED reviewed 10/30/87 RfD/PR reviewed 01/18/96

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.013642	0.017646	58.819990	13.345320		
U.S. POPULATION - SPRING SEASON	0.014542	0.018271	60.902450	12.429977		
U.S. POPULATION - SUMMER SEASON	0.013965	0.018150	60.499247	13.949927		
U.S. POPULATION - FALL SEASON	0.012773	0.016757	55.858150	13.280380		
U.S. POPULATION - WINTER SEASON	0.013256	0.017245	57.483073	13.295633		
NORTHEAST REGION	0.014735	0.018777	62.591310	13.474707		
NORTH CENTRAL REGION	0.013090	0.017206	57.352070	13.717833		
SOUTHERN REGION	0.011200	0.014748	49.159053	11.826390		
WESTERN REGION	0.017177	0.021577	71.921897	14.664620		
HISPANICS	0.013762	0.018700	62.331860	16.457403		
NON-HISPANIC WHITES	0.014086	0.018198	60.660883	13.705923		
NON-HISPANIC BLACKS	0.010184	0.012847	42.823860	8.876137		
NON-HISPANIC OTHERS	0.017812	0.021298	70.993457	11.621590		
NURSING INFANTS (< 1 YEAR OLD)	0.000954	0.001713	5.708853	2.529683		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.008931	0.011522	38.406843	8.635803		
FEMALES (13+ YEARS, PREGNANT)	0.011385	0.014956	49.853890	11.902300		
FEMALES 13+ YEARS, NURSING	0.018368	0.021863	72.875457	11.648450		
CHILDREN (1-6 YEARS OLD)	0.014079	0.021390	71.301083	24.370820		
CHILDREN (7-12 YEARS OLD)	0.015635	0.021604	72.012147	19.893860		
MALES (13-19 YEARS OLD)	0.011322	0.015584	51.945687	14.207207		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.011618	0.015178	50.593757	11.867123		
MALES (20 YEARS AND OLDER)	0.012376	0.015637	52.124330	10.870830		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.014896	0.018054	60.180717	10.526523		

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 186

[OPP-300541; FRL-5739-7]
RIN 2070-AB78

Thiodicarb; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of thiodicarb and its metabolite methomyl in or on broccoli, cabbage, cauliflower, and leafy vegetables (except Brassica vegetables). The petitioner, Rhone-Poulenc Ag Company, requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170).

DATES: This regulation is effective August 22, 1997. Objections and requests for hearings must be received by EPA on or before October 22, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300541], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ``Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300541], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. If you wish to submit in person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by

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Dated: August 15, 1997.

Stephen L. Johnson,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. By revising Sec. 180.407 to read as follows:

Sec. 180.407 Thiodicarb; tolerances for residues.

(a) General . Tolerances are established for the combined residues of the insecticide thiodicarb (dimethyl N,N'-[thiobis[[(methylimino)carbonyloxy]] bis[ethanimidothioate]) and its metabolite methomyl (S-methyl N-[(methylcarbamoyl) oxy]thioacetimidate) in or on the following food commodities or groups. The time-limited tolerances expire and are revoked on the dates listed in the following table:

Commodity	Parts per million	Expiration/revocation date
~~B~~roccoli	7.0	None
~~C~~abbage	7.0	None
~~C~~auliflower	7.0	None
~~C~~orn, sweet grain (K + CWHR)	2.0	None
~~C~~ottonseed	0.4	None
~~C~~ottonseed hulls	0.8	None
Leafy vegetables (except Brassica vegetables)	35	None
~~S~~oybean hulls	0.8	None
~~S~~oybeans	0.2	None

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. [Reserved]

(d) Indirect or inadvertent residues. [Reserved]

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run (which showed no chronic dietary risks at levels of concern to the Agency), since the Agency's previous DRES analysis showed that chronic risks are not at a level of concern.

2. For the acute analyses performed by Novigen, the Monte-Carlo simulations were performed using consumption data from the 1989-1992 USDA CSFII data, information on the percent of crop treated, and data from field trial studies purported to have been previously reviewed by the Agency.

3. Novigen provided three estimates of percent crop treated obtained from Rhone-Poulenc, the National Agricultural Statistics Service, and The National Center for Food and Agricultural Policy. Novigen used the highest of these estimates as its estimate of the percent crop treated in its Monte-Carlo analysis. CBRS has obtained information from BEAD on percent crop treated and compared these values to those used by Novigen, as shown below:

Commodity		Percent Crop Treated Estimate		
		Novigen	EPA (BEAD)	
			Likely Average	Likely Maximum
Corn, sweet grain	fresh	33	18	35
	processed		<1	2
Cottonseed		16	8	16
Soybeans		<1	<1	<1
Leafy Vegetables (excluding Brassica)	Lettuce, Head	32	15	19
	Lettuce, Leaf and Romaine	32	<1	2
	Celery	20	4	10
	Spinach	20[a]	6	17
	Swiss Chard	20[a]	–	–
	Parsley	20[a]	–	–
	Endive	20[a]	–	–
	Cress	20[a]	–	–
Broccoli		5	<2	3
Cabbage		7	4	7
Cauliflower		5	4	8

[a] Novigen assumed the the percentage of cress, endive, parsley, spinach, and swiss chard acreage treated with thiodicarb was similar to the percentage of celery acreage so treated.

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MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Thiodicarb in Support of the Reregistration Eligibility Decision.

FROM: Brian Steinwand
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head
Dietary Risk Evaluation Section
SAB/Health Effects Division

TO: Mike Metzger, Chief
Risk Characterization Analysis Branch
Health Effects Division (7509C)

Action Requested

Provide a dietary exposure analysis to estimate the chronic, carcinogenic, and acute dietary exposure and risk from thiodicarb for uses which are being supported through reregistration.

Discussion

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.03 mg/kg bwt/day, based on a NOEL of 3.3 mg/kg bwt/day from a two year feeding study in rats with an uncertainty factor of 100 that demonstrated increased incidence of extramedullary hemopoiesis in males and decreased red blood cell cholinesterase activity in females (See RfD Document, 6/18/96). Thiodicarb is classified as a Group B2 - probable human carcinogen. No Q_1^* is required to support registrations (See TES Document, 6/14/96). However, the Cancer Peer Review Committee (CPRC) recommends that a non-linear methodology (MOE) be applied for the estimation of human cancer risk, based on the hepatocellular combined adenoma/carcinoma in male mice, with the point of departure set at the 5 mg/kg/day

dose (NOEL) (See TES Document, 6/14/96).

The endpoint for acute dietary risk assessment is the developmental NOEL of 3.0 mg/kg bwt/day based on skeletal variations and decreases in pup body weights at 10 mg/kg/day (See TES Document, 6/14/96).

Residue Information

Tolerances for thiodicarb are published in 40 CFR §180.407 (a), (b), and (c). The available data support the established tolerances in/on sweet corn, the leafy vegetable crop group, cabbage, soybeans, broccoli, and cauliflower; the established tolerances for residues in/on cottonseed should be decreased from 0.4 ppm to 0.2 ppm (See Memo, D. Miller, 11/26/96). Tolerance level residues and 100 percent crop treated assumptions were made for all commodities. No anticipated residue (AR) information was used in this analysis.

Results

Chronic Exposure:

A summary of the residue information considered in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Table 2 and 3.

Existing tolerances (and pending tolerances on peppers, tomatoes and peanuts; and the higher tolerance level for cottonseed result in a TMRC which represents 58.8% of the RfD for the U.S. general population. The highest subgroup, Females (13+ years, Nursing) occupies 72.8% of the RfD.

The analysis for thiodicarb is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with thiodicarb. Even including the pending tolerances and the higher tolerance for cottonseed, it appears that chronic dietary risk from the uses recommended through reregistration, is not of concern.

Acute Exposure:

Two acute analyses were performed. Table 4 shows the results of the analysis using all presently registered commodities. Table 5 demonstrates results which would occur

following the recommendations of CBRS.

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern when results are compared to animal-derived data. Because the endpoint of concern was a developmental effect, the only analysis of concern is for females of child bearing age. The MOE values demonstrate that there is cause for concern regarding the acute dietary exposure from thiodicarb both for existing and proposed uses:

Presently registered commodities result in the following MOE: Females (13+ years) = 20.

Following the recommendations of CBRS (which includes the reduction of the cottonseed tolerance from 0.4 ppm to 0.2 ppm) results in the following MOE: Females (13+ years) = 20.

These MOEs exceed the Agency's level of concern regarding acute exposure for both existing published tolerances and with the proposed decrease in the cottonseed tolerance.

Thiodicarb Carcinogenic Exposure:

As no Q_1^* is required to support registrations, it is recommended that a non-linear methodology (MOE) be applied for the estimation of human cancer risk. Cancer MOEs are estimated by dividing the carcinogenic NOEL by the chronic exposure. The assessment was conducted for the Total U.S. Population only.

Exposure = TMRC
= 0.014 mg/kg/day

MOE = NOEL ÷ Exposure
= 5mg/kg/day ÷ 0.014mg/kg/day
= 357

Attachments

cc: DRES; Caswell 900AA

TABLE 4

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 13:40 Wednesday, December 18, 1996 18

*NAME: THIODICARB (LARVIN)	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.*
*CASWELL NO: 900AA CFR NO: CFR180.407	A	00000.0300	000060.000	000100	Chron-onco	Rat	Systemic	Minimum	0000001820*
*CAS NO: 59669-26-0 SHAUGHNESSY NO: 114501	B								*
*STATUS CODES:	C								*

*RDV INFO: The LD value used in this analysis is 0.01 MG/KG of BODY WEIGHT/DAY *

FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications

-FEMALES(13+ YRS)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	98.35	0.014673	146.73

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	55	49	44	40	37	34	32	29	27	26	18	11	8	1	0	0

→

Females (13+ Years:

Exposure = RDV x X
= 0.01 x 15
High End Exposure = 0.15

MOE = Noel ÷ Exposure
= 3.0 mg/kg/day ÷ 0.15 mg/kg/day
MOE = 20

TABLE 5
RED

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 14:10 Wednesday, December 18, 1996 18

*NAME: THIODICARB (LARVIN)	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.*
*CASWELL NO: 900AA CFR NO: CFR180.407	A	00000.0300	000060.000	000100	Chron-onco	Rat	Systemic	Minimum	0000001820*
*CAS NO: 59669-26-0 SHAUGHNESSY NO: 114501	B								*
*STATUS CODES:	C								*

*RDV INFO: The LD value used in this analysis is 0.01 MG/KG of BODY WEIGHT/DAY *
FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications

-FEMALES(13+ YRS)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	98.35	0.014670	146.70

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	55	49	44	40	37	34	32	29	27	26	18	11	8	1	0	0

→

Females (13+ Years:

Exposure = RDV x X
= 0.01 x 15
High End Exposure = 0.15

MOE = Noel ÷ Exposure
= 3.0 mg/kg/day ÷ 0.15 mg/kg/day
MOE = 20