



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

6-29-95

JUN 29 1995

MEMORANDUM

SUBJECT: Acute Dietary Exposure Analysis for Chlorethoxyfos.

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

Through: Elizabeth Doyle, Section Head *E. A. Doyle*
Dietary Risk Evaluation Section
SAB/Health Effects Division

TO: Karen Whitby, Acting Chief *KW*
Risk Characterization and Analysis Branch
Health Effects Division H7508C

Action Requested

Provide a dietary exposure analysis to estimate the acute dietary exposure and risk from chlorethoxyfos using tolerances and neurotoxicity data endpoints.

Discussion

Toxicological Endpoint:

The endpoint for acute dietary risk assessment is the plasma cholinesterase NOEL (0.06 mg/kg/day) from a six month ocular toxicity study in dogs. The effect level in this study (0.578 mg/kg/day) is based upon plasma cholinesterase inhibition.

Residue Information

As a new chemical, tolerances for chlorethoxyfos residues in/on agricultural and animal commodities have yet to be published in the CFR. The acute dietary analysis used tolerance level values on all published commodities. Anticipated residues for acute analysis were not provided. Information on percent crop treated was not used.



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Results

Summaries of the acute dietary risk for the subgroups U. S. Population, Infants (<1 year old), Children (1-6 years old), Females (13+ years) and Males (13+ years) are attached as Tables 1 and 2.

Acute Exposure:

The DRES detailed acute analysis estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of chlorethoxyfos in the commodity supply.

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 ($\text{NOEL/exposure} = \text{MOE}$). Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern when the data are compared to an endpoint from an animal study. The highest MOE for high end exposure in this analysis is ~~10,000~~^{1,000} for Males (13+ years). The lowest MOE for any sub group is 375 for Infants (<1 year). The results of this analysis indicate that chlorethoxyfos in the diet represents no serious risk concern for acute exposure.

Attachments

cc: DRES; Caswell 663P

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TABLE 1

DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 13:44 Wednesday, June 28, 1995 7

 NAME: FORTRESS STUDY RDV NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO.
 *CASWELL NO: 663P CFR NO: CFR A SHAUGHNESSY NO: 129006 B *
 *CAS NO: SHAUGHNESSY NO: 129006 B *
 *STATUS CODES: C *
 RDV INFO: The LD value used in this analysis is 0.0001 MG/KG of BODY WEIGHT/DAY AR DATA: No User Modifications
 *FILE INFO: No Tolerance Data Are Used--Without User Modifications. *****

 -U.S. POP.--48 STATES *****

ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0.00	0.000000	0.00
98.40	0.000006	5.92

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

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	8	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0

ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0.00	0.000000	0.00
65.14	0.000018	17.52

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

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	24	15	9	4	1	1	1	0	0	0	0	0	0	0	0	0

ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0.00	0.000000	0.00
99.29	0.000014	14.46

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

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	9	4	2	1	0	0	0	0	0	0	0	0	0	0	0

ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0.00	0.000000	0.00
99.29	0.000014	14.46

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

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	9	4	2	1	0	0	0	0	0	0	0	0	0	0	0

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1 DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 13:44 Wednesday, June 28, 1995 8

 *NAME: FORTRESS
 *CASWELL NO: 663P
 *CFR NO: CFR A
 *SHAUGHNESSY NO: 129006 B
 *STATUS CODES: C
 *RDV INFO: The LD value used in this analysis is 0.0001 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														
PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV														
0	0.00	0.00														
100	98.33	3.76														
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
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

TOLERANCES:
 ANTICIPATED RESIDUES:
 OMALES(13+ YRS)

ESTIMATED % OF POTENTIAL		MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY														
PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV														
0	0.00	0.00														
100	99.23	4.44														
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
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

TOLERANCES:
 ANTICIPATED RESIDUES:

TABLE 2

General U.S. Population

Exposure = RDV x X
= 0.0001 x 0.8
High End Exposure = 0.00008

MOE = Noel + Exposure
= 0.06 mg/kg/day + 0.00008 mg/kg/day
MOE = 750

Mean MOE = NOEL + Mean
= 0.06 + 0.000008
= 10,000

Infants (< 1 year)

Exposure = RDV x X
= 0.0001 x 1.6
High End Exposure = 0.00016

MOE = Noel + Exposure
= 0.06 mg/kg/day + 0.00016 mg/kg/day
MOE = 375

Mean MOE = NOEL + Mean
= 0.06 + 0.000016
= 3,333

Children (1-6 years)

Exposure = RDV x X
= 0.0001 x 1.2
High End Exposure = 0.00012

MOE = Noel + Exposure
= 0.06 mg/kg/day + 0.00012 mg/kg/day
MOE = 500

Mean MOE = NOEL + Mean
= 0.06 + 0.000012
= 4,286

Females (13+ Years):

Exposure = RDV x X
= 0.0001 x .4
High End Exposure = 0.00004

MOE = NOEL + Exposure
= 0.06 mg/kg/day + 0.00004 mg/kg/day
MOE = 1,500

Mean MOE = NOEL + Mean
= 0.06 + 0.000004
= 15,000

Males (13+ Years):

Exposure = RDV x X
= 0.0001 x .6
High End Exposure = 0.000006

MOE = NOEL + Exposure
= 0.06 mg/kg/day + 0.000006 mg/kg/day
MOE = 10,000 MOE = 1,000

Mean MOE = NOEL + Mean
= 0.06 + 0.000004
= 15,000

8/21/14

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