UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 29 1995

MEMORANDUM

SUBJECT: Acute Dietary Exposure Analysis for Chlorethoxyfos.

FROM: Brian Steinwand
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
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 (NOEL/exposure = 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 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

TABLE 1

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION   13:44 Wednesday, June 28, 1995   7

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********************************************************************************
                         STUDY   RDV   NOEL   SF   STUDY TYPE   SPECIES   EFF. LEV.   CORE GRADE   DOC. NO.*
*NAME: FORTRESS          CFR NO: CFR        STUDY  A                                                         *
*CASWELL NO: 663P        SHAUGHNESSY NO: 129006 B                                                            *
*CAS NO:                                        C                                                            *
*STATUS CODES:                                                                                               *
*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*
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-U.S. POP.--48 STATES

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:	98.40	0.000006	5.92

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

0INFANTS(<1 YEAR)

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:	65.14	0.000018	17.52

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

0CHILDREN(1-6 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:	99.29	0.000014	14.46

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

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************************************************************************************************
*NAME: FORTRESS                 STUDY    RDV    NOEL    SF    STUDY TYPE    SPECIES    EFF. LEV.    CORE GRADE    DOC. NO. *
*CASWELL NO: 663P.    CFR NO: CFR          A                                                                              *
*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                                     *
*FILE INFO: No Tolerance Data Are Used--Without User Modifications.              AR DATA:  No User Modifications*
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-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:	98.33	0.000004	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	0
TOLERANCES:																	
0	100	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:																	

OMALES(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:	99.23	0.000004	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	0
TOLERANCES:																	
0	100	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:																	

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TABLE 2

General U.S. Population

Exposure = RDV x X
$$= 0.0001 \times 0.8$$
High End Exposure = 0.00008

MOE = Noel ÷ Exposure
$$= 0.06 \text{ mg/kg/day} \div 0.00008 \text{ mg/kg/day}$$
MOE = 750

Mean MOE = NOEL ÷ Mean
$$= 0.06 \div 0.000006$$
$$= 10,000$$

Infants (< 1 year)

Exposure = RDV x X
$$= 0.0001 \times 1.6$$
High End Exposure = 0.00016

MOE = Noel ÷ Exposure
$$= 0.06 \text{ mg/kg/day} \div 0.00016 \text{ mg/kg/day}$$
MOE = 375

Mean MOE = NOEL ÷ Mean
$$= 0.06 \div 0.000018$$
$$= 3,333$$

Children (1-6 years)

Exposure = RDV x X
$$= 0.0001 \times 1.2$$
High End Exposure = 0.00012

MOE = Noel ÷ Exposure
$$= 0.06 \text{ mg/kg/day} \div 0.00012 \text{ mg/kg/day}$$
MOE = 500

Mean MOE = NOEL ÷ Mean
$$= 0.06 \div 0.000014$$
$$= 4,286$$

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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