

US EPA ARCHIVE DOCUMENT



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

HSM 25/01/11/01/01/01/

18PP
18 total pages

MAY - 9 1996

RECEIVED OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

MEMORANDUM

OFF PUBLIC DOCKET

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

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

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

E. A. Doyle
WJD

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 phorate for uses which are being supported through reregistration.

Discussion

A previous analysis which determined the chronic dietary exposure and risk from phorate for uses which are being supported through reregistration was performed (See memo, B. Steinwand, 3/8/96). This analysis demonstrated no chronic dietary risk. At the time of that analysis, DRES was not aware of any Acute toxicity problems related to phorate.

Since that time, phorate was reviewed by the Toxic Endpoint Selection Committee which established an acute NOEL endpoint of 0.05 mg/kg/day (See Tox Endpoint Selection Document, 1/31/96). Using this endpoint, an acute analysis was performed on both the existing file of published tolerances (See Table 1), and all phorate uses which are being supported through reregistration (See Table 2). Both of these analyses resulted in unacceptable acute dietary risks (below a MOE of 100).

Conclusions

In each instance, both the currently registered uses and those uses and reassessed tolerances proposed in reregistration document result in acute dietary risk level which exceed the Agency's level of concern.

TABLE 1
REGISTRATION

DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 10:59 Monday, April 22, 1996 47

 *NAME: PHORATE (THIMET) STUDY RDV NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO. *
 *CASWELL NO: 660 CFR NO: CFR180.206 A 00000.0001 RDV NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO. *
 *CASWELL NO: 00298-02-2 SHAUGHNESSY NO: 057201 B
 STATUS CODES: AR DATA: No User Modifications
 *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.

-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	0.00	0.00														
100	99.84	15.40														
ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=			1	2	3	4	5	10	15	20						
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
ANTICIPATED RESIDUES:			100	24	5	1	0	0	0	0	0	0	0	0	0	0

0 INFANTS(<1 YEAR)

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	94.33	28.01														
ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=			1	2	3	4	5	10	15	20						
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
ANTICIPATED RESIDUES:			100	59	17	7	3	2	1	0	0	0	0	0	0	0

0 CHILDREN(1-6 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	99.97	32.96														
ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=			1	2	3	4	5	10	15	20						
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
ANTICIPATED RESIDUES:			100	71	26	9	4	1	1	0	0	0	0	0	0	0

10:59 Monday, April 22, 1996 48
 DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION

 NAME: PHORATE (THIMET) STUDY RDV NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO.
 *CASWELL NO: 660 CFR NO: CFR180.206 A 00000.0001 NOEL 001000
 *CAS NO: 00298-02-2 SHAUGHNESSY NO: 057201 B C
 *STATUS CODES:
 *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	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0	0	0.00000	0.00
0	0	0.001090	10.90

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

X	1	2	3	4	5	10	15	20								
0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20

TOLERANCES:
 ANTICIPATED RESIDUES: 100 11 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0

 -MALES(13+ YRS)

ESTIMATED % OF POTENTIAL	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0	0	0.00000	0.00
0	0	0.001317	13.17

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

X	1	2	3	4	5	10	15	20								
0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20

TOLERANCES:
 ANTICIPATED RESIDUES: 100 17 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0

General U.S. Population

Exposure = RDV x X
 = 0.01 x .8
 High End Exposure = 0.008

MOE = Noel + Exposure
 = 0.05 mg/kg/day + 0.008 mg/kg/day
 MOE = 6.25

Infants (< 1 year)

Exposure = RDV x X
= 0.01 x 1.4
High End Exposure = 0.014

MOE = Noel + Exposure
= 0.05 mg/kg/day + 0.014 mg/kg/day
MOE = 3.57

Children (1-6 years)

Exposure = RDV x X
= 0.01 x 1.4
High End Exposure = 0.014

MOE = Noel + Exposure
= 0.05 mg/kg/day + 0.014 mg/kg/day
MOE = 3.57

Females (13+ Years):

Exposure = RDV x X
= 0.01 x .6
High End Exposure = 0.006

MOE = Noel + Exposure
= 0.05 mg/kg/day + 0.006 mg/kg/day
MOE = 8.33

Males (13+ Years):

Exposure = RDV x X
= 0.01 x .6
High End Exposure = 0.006

MOE = Noel + Exposure
= 0.05 mg/kg/day + 0.006 mg/kg/day
MOE = 8.33

TABLE 2
RED

DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 13:30 Monday, April 22, 1996 27

 *NAME: PHORATE (THIMET) *****
 *CASWELL NO: 660 CFR NO: CFR180.206 A '00000.0001 *****
 *CAS NO: 00298-02-2 SHAUGHNESSY NO: 057201 B *****
 *STATUS CODES: *****
 *RDV INFO: The LD value used in this analysis is 0.01 *****
 *FILE INFO: No Tolerance Data Are Used--Without User Modifications. *****

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

STUDY NOEL RDV SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO.*
 001000 *****

MG/KG of BODY WEIGHT/DAY
 AR DATA: No User Modifications*

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
99.70	0.000557	5.57

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

X	1	2	3	4	5	10	15	20								
0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
100	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

TOLERANCES:
 ANTICIPATED RESIDUES:

INFANTS(<1 YEAR)

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
90.86	0.000651	6.51

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

X	1	2	3	4	5	10	15	20								
0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
100	6	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

TOLERANCES:
 ANTICIPATED RESIDUES:

CHILDREN(1-6 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
0.00	0.000000	0.00
99.94	0.001115	11.15

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

X	1	2	3	4	5	10	15	20								
0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
100	12	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

TOLERANCES:
 ANTICIPATED RESIDUES:

1 DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 13:30 Monday, April 22, 1996 28

 NAME: PHORATE (THINET) STUDY RDV NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO.
 *CAS#ELL NO: 660 CFR NO: CFR180.206 A 00000.0001 NOEL SF 001000
 *CAS NO: 00298-02-2 SHAUGHNESSY NO: 057201 B C
 *STATUS CODES:
 *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

PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
0.00	0.000000	0.00
99.74	0.000386	3.86

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
0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

TOLERANCES:
 ANTICIPATED RESIDUES:

0 MALES(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
0.00	0.000000	0.00
99.91	0.000537	5.37

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
0	100	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

TOLERANCES:
 ANTICIPATED RESIDUES:

General U.S. Population
 Exposure = RDV x X
 = 0.01 x .4
 High End Exposure = 0.004
 MOE = Noel + Exposure
 = 0.05 mg/kg/day + 0.004 mg/kg/day
 MOE = 12.5

Infants (< 1 year)

Exposure = RDV x X
= 0.01 x .6
High End Exposure = 0.006

MOE = Noel + Exposure
= 0.05 mg/kg/day + 0.006 mg/kg/day
MOE = 8.3

Children (1-6 years)

Exposure = RDV x X
= 0.01 x .6
High End Exposure = 0.006

MOE = Noel + Exposure
= 0.05 mg/kg/day + 0.006 mg/kg/day
MOE = 8.3

Females (13+ Years):

Exposure = RDV x X
= 0.01 x
High End Exposure = 0.

MOE = Noel + Exposure
= 0.05 mg/kg/day + mg/kg/day
MOE =

Males (13+ Years):

Exposure = RDV x X
= 0.01 x .4
High End Exposure = 0.004

MOE = Noel + Exposure
= 0.05 mg/kg/day + 0.004 mg/kg/day
MOE = 12.5

APPENDIX A

Argus International, Incorporated
935 Horsham Road, Horsham, Pa. 19044
(215) 443-8710

REVIEW (November 28, 1989)

TERATOLOGY STUDY IN RATS

THIMET® PHORATE

LBI PROJECT NO. 20819

FINAL REPORT ISSUED MAY, 1978

REVISED MARCH, 1979

Sponsor:

American Cyanamid Company
P.O. Box 400
Princeton, New Jersey 08540

Test Facility:

Litton Bionetics, Inc.
5516 Nicholson Lane
Kensington, Maryland 20795

Reviewer:

Mildred S. Christian, Ph.D., ATS
President
Argus International, Inc.

Ⓟ

DP BARCODE: D220566

Y1
80
REREG CASE # 0103

CASE: 818957
SUBMISSION: S496230

HED
DATA PACKAGE RECORD
BEAN SHEET

DATE: 11/22/95
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 623 INITIATE RED CHAPTER
CHEMICALS: 057201 Phorate 100.00 %

ID#: 057201

COMPANY:

PRODUCT MANAGER: 73 LINDA PROPST 703-308-8165 ROOM: CS1 2B3
PM TEAM REVIEWER: DENNIS MCNEILLY 703-308-8066 ROOM: CS1 3F5
RECEIVED DATE: 10/30/95 DUE OUT DATE: 02/27/96

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 220566 EXPEDITE: N DATE SENT: 10/30/95 DATE RET.: / /
CHEMICAL: 057201 Phorate
DP TYPE: 001 Submission Related Data Package

CSF: N LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 02/27/96
DIV : HED	11/15/95	/ /	NEGOT DATE: / /
BRAN: TB-2	11/21/95	/ /	PROJ DATE: / /
SECT: RS-2	/ /	/ /	
REVR : YYANG	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Prepare TOX Chapter for phorate RED.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
-------	----------------	----------	----------	-----	-----	-------

Portions of this document has been classified as Confidential:

(1) The non-confidential version is enclosed in the file. (pages 1-11)

(2) Releasable to those person that submits an "Affirmation of Non-multinational Status" Form.
(Pages 12-18)