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

MAY - 9 1996

RECEIVED OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

OPP PUBLIC DOCKET

MEMORANDUM

SUBJECT: Acute Dietary Exposure Analysis for Phorate 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 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

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 10:59 Monday, April 22, 1996 47

	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.
*NAME: PHORATE (THIMET)									*
*CASWELL NO: 660 CFR NO: CFR180.206	A	00000.0001		001000					*
*CAS NO: 00298-02-2 SHAUGHNESSY NO: 057201	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

-U.S. POP.--48 STATES

	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
ESTIMATES BASED ON TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	99.84	0.001540	15.40

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	24	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0

0INFANTS(<1 YEAR)

	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
ESTIMATES BASED ON TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	94.33	0.002801	28.01

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	59	17	7	3	2	1	0	0	0	0	0	0	0	0	0	0

OCHILDREN(1-6 YRS)

	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
ESTIMATES BASED ON TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	99.97	0.003296	32.96

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	71	26	9	4	1	1	0	0	0	0	0	0	0	0	0	0

(2)

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 10:59 Monday, April 22, 1996 48

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 001000 *
*CAS NO: 00298-02-2 SHAUGHNESSY NO: 057201 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)

ESTIMATES BASED ON	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:	99.88	0.001090	10.90

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	11	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0MALES(13+ YRS)

ESTIMATES BASED ON	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:	99.96	0.001317	13.17

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	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

(5)

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

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 13:30 Monday, April 22, 1996 27

*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		001000					*
*CAS NO: 00298-02-2 SHAUGHNESSY NO: 057201		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*	

-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:	99.70	0.000557	5.57

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	3	0	0	0	0	0	0	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:	90.86	0.000651	6.51

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	6	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0CHILDREN(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:	99.94	0.001115	11.15

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	12	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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 001000 *
*CAS NO: 00298-02-2 SHAUGHNESSY NO: 057201 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)

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:	99.74	0.000386	3.86

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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

OMALES(13+ 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:	99.91	0.000537	5.37

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	2	0	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 .4
High End Exposure = 0.004

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

(2)

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.

D

RED

DP BARCODE: D220566 REREG CASE # 0103

CASE: 818957 DATA PACKAGE RECORD DATE: 11/22/95
SUBMISSION: S496230 BEAN SHEET 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

(11)

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)