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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

Note to Reader
August 7, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

Recycled/Recyclable • Printed with Vegetable Oil Based Inks on 100% Recycled Paper (40% Postconsumer)

available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack Housenger, Acting Director
Special Review and Reregistration
Division

H SM 25/011 #04107

18PP

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

25

MAY - 9 1996

OFFICE OF
RECEIVED PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

JUL 29 1998
OPP PUBLIC DOCKET

MEMORANDUM

SUBJECT: Acute Dietary Exposure Analysis for Phorate 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

E. A. Doyle
WJB

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).

Recycled/Recyclable • Printed with Vegetable Oil Based Inks on 100% Recycled Paper (40% Postconsumer)

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	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
	PERSON DAYS THAT ARE USER-DAYS	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	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
	PERSON DAYS THAT ARE USER-DAYS	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

0CHILDREN(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
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)
--------------------          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:               99.88                        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

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:               99.96                        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

	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:	99.70	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)

	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:	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)

	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:	99.94	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

6

```
1DETAILED ACUTE ANALYSIS INCLUDING AR'S:  ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION          13:30 Monday, April 22, 1996  28
*****************************************************************************************************************************
*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)
--------------------          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:               99.74                        0.000386                     3.86
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     0     0     0     0     0     0     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:               99.91                        0.000537                     5.37
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     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

DP BARCODE: D220566 RED 11 80 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	
DIV : HED	11/15/95	/ /	ADMIN DUE DATE: 02/27/96
BRAN: TB-2	11/21/95	/ /	NEGOT DATE: / /
SECT: RS-2	/ /	/ /	PROJ DATE: / /
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

This Portion of Document #25 have been classified as a "B" Document. An "Affirmation of Non-Multinational Status" Must be Completed and Approved to View/Copy this Document.

Please See Docket Staff for a Copy of the "Affirmation."