1-30-84

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

JAN 30 1984

MEMORANDUM JAN 30 1984

Case #378 A

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: William Miller/Marilyn A. Mautz, PM#16
Insecticide/Rodenticide Branch
Registration Division (TS-767)

THRU: Reto Engler, Acting Section Head
Section II, Toxicology Branch
Hazard Evaluation Division (TS-769) 11/27/84

Edwin R. Budd, Acting Deputy Chief
Toxicology Branch
Hazard Evaluation Division (TS-769) 11/30/84

SUBJECT: Request for waiver of subchronic (21-day) dermal toxicity study.

The 21-day dermal study was listed as one of the toxicity data gaps in the Registration Standard package for MONITOR (methamidophos), completed by Toxicology Branch in March, 1982.

Chevron Chemical Company requested currently a waiver of the 21-day dermal toxicity study for the reasons detailed in the Chevron's memo, dated July 11, 1983 (attached).

Toxicology Branch agrees with Chevron's comments and recommends approval of the requested waiver. Toxicology Branch has, indeed, data to support Chevron's comments regarding the acute dermal toxicity, cholinesterase inhibition, metabolism, absorption and excretion of MONITOR by mammals.

Krystyna K. Locke, Toxicologist
Section II, Toxicology Branch
Hazard Evaluation Division (TS-769)

Attachment

1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 20 1984

MEMORANDUM

SUBJECT: Reevaluation of Reregistrtion Data Requirements for Methamidophos------ACTION MEMORANDUM------

TO: Douglas D. Campt, Director
Registration Division (TS-767)

BACKGROUND:

On September 30, 1982, the Agency issued its Reregistration Guidance Package for methamidophos (Monitor). This document was issued for manufacturing-use products and certain end-use products containing methamidophos as the single active ingredient. Two registrants and their two manufacturing-use products were involved, Chevron Chemical Co. and Mobay Chemical Corp.

REQUEST FOR DATA WAIVER

On July 11, 1983, and November 8, 1983, Chevron submitted the product chemistry, acute toxicology and product-specific data including a request for a data waiver from the requirement of the 21-day subchronic dermal study. Chevron submitted this data waiver request based on the following:

1. The precautionary labeling on all Monitor products are adequate to protect the user from repeated skin contact with methamidophos.

2. Methamidophos is acutely toxic by the dermal route. Since the toxicity and mode of action of this chemical have been well established, no new information would be derived from conducting a subchronic dermal absorption study.

3. The metabolism and excretion of the insecticide in mammals is very rapid and there is no evidence of selective accumulation in any organ system.

CONCURRENCES

SYMBOL	TS-767	TS767C						
SURNAME	W-Miller	[illegible]						(2)
DATE	6/14/84	6/19/84						

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

RECONSIDERATION OF DATA REQUIREMENTS

Hazard Evaluation Division has evaluated Chevron's request for the data waiver and recommends approval of the requested waiver. Toxicology Branch notes in their review of the waiver dated January 30, 1984 that the Branch does have data to support Chevron's comments regarding the acute dermal toxicity, cholinesterase inhibition, metabolism, absorption and excretion of methamidophos by mammals.

ADDITIONAL MODIFICATIONS IN DATA REQUIREMENTS

1. Acute inhalation study

   This study was reviewed by Technical Services Section (TSS) and classified as a core guideline data.

2. General chemistry data

   The following general chemistry data have been reviewed by TSS and found acceptable:

   a. Description of manufacturing process
   b. Product analytical method and data
   c. Melting point
   d. Stability
   e. pH
   f. Oxidizing or reducing action

   The following general chemistry data have been reviewed by TSS and were not satisfactory:

   g. Declaration and certification of ingredient limits
   h. Storage stability

RECOMMENDATION:

Based on an evaluation of Chevron's data waiver request and additional information submitted, we believe the following data requirements should be waived or modified.

Study	Waiver or Modification
163.81-3 Acute inhalation	Data requirement has been satisfied
163.82-2 21-day subchronic dermal	Waived
163.61-4 Description of manufacturing process	Data requirement has been satisfied

3

Study		Waiver or modification
163.61-7	Product Analytical Methods and Data	Data requirement has been satisfied
163.64-5	Melting Point	Data requirement has been satisfied
163.64-12	pH	Data requirement has been satisfied
163.64-13	Stability	Data requirement has been satisfied
163.64-14	Oxidation/Reduction	Data requirement has been satisfied

We have attached a copy of revised Tables A, and B incorporating the corrections listed above. We hereby request that you concur with this recommendation.

Herbert S. Harrison, Chief
Insecticide-Rodenticide Branch (TS-767)

Concur _____

Do not Concur _____

Date JUN 21 1984

TS-767:RD:IRB:MAUtz:gck:Rm211 Cm-2,557-2600:06-15-84

TABLE B-1 (Addendum) (Cont'd)

METHAMIDOPHOS

Product-Specific, Manufacturing-Use Data Requirements: PRODUCT CHEMISTRY * **

1. These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. References cited are applicable only to the currently registered technical product.

2. A declaration and certification of ingredients must be provided.

A. Studies submitted by Chevron Chemical Company. These studies may be compensable.
B. Studies submitted by Mobay Chemical Corporation. These studies may be compensable.
C. These studies may be compensable.

TABLE B-2 (Addendum)

METHAMIDOPHOS

Product-Specific, Manufacturing-Use Data Requirements: TOXICOLOGY * **

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional da be submitted under FIFRA 3(c)(2)(B)?***
163.81-1	Acute Oral Toxicity	Each Product	yes	00014044[A]/, 00014045[A]/ 00014047[A]/, 00014048[A]/	no
163.81-2	Acute Dermal Toxicity	Each Product	yes	00014049[A]/	no
163.81-3	Acute Inhalation Toxicity	Each Product	yes	000140[illegible]1[A]/;GS0043004[A]/	no
163.81-4	Primary Eye Irritation	Each Product	yes	00014221[A]/	no
163.81-5	Primary Dermal Irritation	Each Product	yes	00014220[A]/, 00014222[A]/	no
163.81-6	Dermal Sensitization	Each Product	no	-	yes

* All requirements apply to registration for "Non-domestic, terrestrial, food crop" uses, only. Registration for othe use patterns may involve different data requirements.

** Cited data will be applicable to new registration requests only when requests are for MUP's judged to be "substantially similar" to currently registered products.

*** All data must be submitted within 6 months (due March '83).

FOOTNOTES

A. Studies submitted by Chevron Chemical Company. These studies may be compensable.

B. Studies submitted by Mobay Chemical Corporation. These studies may be compensable.

C. These studies may be compensable.

Addendum - Methamidophos Registration Standard Bibliography

GS0043004 Mobay Chemical Corporation (1983). Acute Inhalation Toxicity Study with Technical Methamidophos (Monitor) in Rats: study number 80-041-12. (Unpublished study received August 3, 1983, with a duplicate copy received November 15, 1983 under 239-2452; prepared by Mobay Chemical Corporation; submitted by Chevron Chemical Co.; EPA Accesssion number 250925.)

GS0043005 Mobay Chemical Corporation (1983). Product Chemistry Data (received August 3, 1983, with a duplicate copy received November 15, 1983, under 239-2452; prepared by Mobay Chemical Corporation; submitted by Chevron Chemical Co.; EPA Accession number 250925.)