

US EPA ARCHIVE DOCUMENT

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To: G. Werdig/S. Lewis
Product Manager (50)
Registration Division (TS-767)

From: Carolyn K. Offutt, Chief *Carolyn K. Offutt*
Environmental Processes and Guidelines Section
Exposure Assessment Branch, HED (TS-769)

Attached please find the environmental fate review of:

Reg./File No.: 580001

Chemical: Azinphos-Methyl

Type Product: Insecticide

Product name: GUTHION

Company name: Mobay

Submission Purposes: Response to the 2/28/85 Reentry Data Call

In Notice: Mobay is submitting a protocol & proposing to combine the required studies with studies on ®METASYSTOX-R, ®DI-SYSTON, and ®DYRENE and is asking for an extension of the due date.

Data In: 8/22/85

Action Code 400

Date Completed: 6/11/86

EAB #: 5892

TAIS (Level II) Days

60

7

Deferrals To:

- Ecological Effects Branch
- Residue Chemistry Branch
- Toxicology Branch

REVIEW OF REENTRY DATA

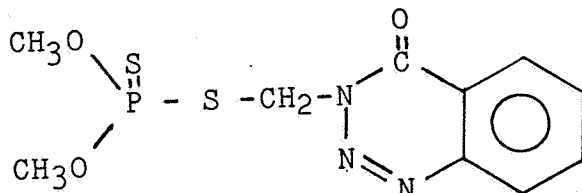
1. CHEMICAL:

Common name: Azinphos-methyl

Product name: ®GUTHION

Chemical name: O,O-Dimethyl S-(3,4-dihydro-4-oxobenzo[d][1,2,3]-triazin-3-ylmethyl) phosphorodithioate

Structure:



Other names: CAS 86-50-0, GUSATHION, AZATHION, etc.

2. TEST MATERIAL:

Not applicable, No studies were submitted.

3. STUDY/ACTION TYPE:

Response to Registration Standard Guidance Package and Data Call In for Azinphos-methyl. See the related submissions for Anilazine (EAB # 5847), Oxydemeton-methyl (EAB # 5802), and Disulfoton (EAB # 6213, 6214, 6215, 6216) also registered by Mobay. There are three parts to this submission: the first is a waiver request for delay of the required date for data submission to December 1987; second is a request for waiver of soil residue data; and third is a request for review/approval of proposed protocols.

4. STUDY IDENTIFICATION:

Accession No. 156,978. Letter to Geraldine Werdig, RD, from G. E. Brussels, Mobay, dated June 28, 1985 containing attachments: I. "Proposed Worker Re-entry Exposure Studies"; II. Protocol, Dislodgeable and Soil Surface Residue Study"; and III. "Comparison of EPA Reentry Guidelines to Proposed Mobay Reentry Protocol".

5. REVIEWED BY:

James D. Adams, PhD

Chemist

Environmental Processes and Guidelines Section

6/11/1986

James D. Adams

6. APPROVED BY:

Carolyn K. Offutt, Chief

Environmental Processes and Guidelines Section

Exposure Assessment Branch, HED (TS-769)

6/11/1986

Carolyn K. Offutt

7. CONCLUSIONS:

The requested extension date is reasonable given that they are considering employment of a contractor to gather the data and that they plan to combine Azinphos-methyl data with data from other studies (Anilazine and Disulfoton) that will not be available until December 1987 by Agency agreement. The protocols are acceptable with a few minor changes in the crop groupings. The request for waiver from submission of data on Azinphos-methyl in soil where potato culture is involved is not acceptable.

8. RECOMMENDATIONS:

The due date for azinphos-methyl reentry-data submission should be extended to December 1987. The request for waiver of requirement of residues in soil should be denied.

9. BACKGROUND:

Notice of the Azinphos-methyl Reentry Data-Call-In was received by the Registrant on April 16, 1985. This date was clearly too late for completion of study planning, Agency review of protocols, and other preparations for initiation of the required studies during the 1985 growing season. Loss of the 1985 growing season delayed the studies' completion at least to the fall of 1986. The Registrant will need additional time for other tasks such as chemical analysis, data analysis, and report writing.

In other registration actions, the Registrant is being required to submit reentry data for three other pesticides; Disulfoton (®DI-SYSTON), Oxydemeton-methyl (®METASYSTOX-R), and Anilazine (®DYRENE). The Registrant proposes to combine the data acquisition and analysis for the four pesticides.

10. DISCUSSION OF SUBMITTED PROTOCOLS:

A. Crop Grouping Scheme

The question of grouping crops arises in connection with the conversion of dislodgeable residues to fieldworker exposure levels. Azinphos-methyl and the Registrant's three other pesticides are registered for a number of crops. The Registrant has proposed to perform human-exposure monitoring studies with the crops grouped into 6 groups [Azinphos-methyl is not registered for a crop in Group A]. These are ranked for anticipated exposure levels at similar residue levels. See the submission's attachment I and my reviews for Anilazine [EAB # 5847] and Oxydemeton-methyl [EAB # 5802]. I suggested several changes to the crop groupings in those reviews.

B. Exposure Monitoring

The Agency has, heretofore, suggested that fieldworker exposure levels be estimated from dislodgeable residues by use of a correlation published by Dr. W. Pependorf of the University of California, Berkeley. Pependorf's correlation, based on citrus harvesting, is expected to give worst-case exposure levels for other, non-tree-fruit crops; and the Registrant's proposal to monitor fieldworker exposure is appropriate for crops where less exposure is expected.

The Registrant proposes to monitor exposure of fieldworkers to Azinphos-methyl residues during the harvesting of corn [for estimation of exposure in Group B crops] and during the tying of cauliflower leaves [for estimation of exposure in Group D crops]. Data on fieldworker exposure to Anilazine residues on tomatoes would be used in conjunction with dislodgeable residue data for Azinphos-methyl to estimate exposure to those residues on crops in Group E.

The Registrant is proposing to use dislodgeable residue data in conjunction with published data on exposure for estimation of fieldworker exposure in tree fruit [Group F] and in berry crops [Group C]. That data is derived from Pependorf's correlation and from Zweig et al. [J. Agric. Food Chem 32:1232 (1984)] and from Davis et al. [Bull. Environ. Contam. Toxicol. 27:592 (1982)]. These proposals for exposure monitoring are acceptable.

I suggest that the Registrant consider monitoring workers for pesticide residue exposure during the hand-harvesting of potatoes. The monitoring data in conjunction with edaphic residue levels could be used to develop a residue transfer coefficient for the estimation of fieldworker exposure from residue levels. This study could be done with Azinphos-methyl or Disulfoton and in conjunction with the soil residue dissipation study.

C. Residue Dissipation Studies

The Registrant's protocols for the quantification of dislodgeable residues of Azinphos-methyl are, in general, acceptable. However, the request for waiver from submission of data on Azinphos-methyl in soil where potato culture is involved is not acceptable.

11. COMPLETION OF ONE-LINER:

Not Applicable

12. CBI APPENDIX:

Attachments I, II, and III and Tables I, II, III, IV, and V have been duplicated and attached to EAB's file copy of the review no. 5802 for Oxydemeton-methyl. These will be maintained in EAB's Secure File for reference in future actions/data-reviews for Anilazine, Azinphos-methyl, Oxydemeton-methyl, and Disulfoton.