090301

December 7, 1982

MEMORANDUM

TO: Emil Regelman, (Acting Chief)
Review Section No. 1
Environmental Fate Branch
Hazard Evaluation Division (TS-769)

Attached herewith please find Section 3's responses to DuPont's requests for waivers of testing required by the Registration Standard for Methomyl.

Hudson Boyd

Hudson Boyd
Chemist,
Review Section No. 3
Environmental Fate Branch
Hazard Evaluation Division (TS-769)

cc: Dr. Severn
Dr. Richardson
Correspondence Files

Date Out EFB: DEC 8 1982

INIT.

To: Jay Ellenberger
Product Manager 21
Registration Division (TS-767)

From: Hudson Boyd,
Acting Chief, Review Section No. 3
Environmental Fate Branch
Hazard Evaluation Division (TS-769)

Attached please find the environmental fate review of:

Reg./File No.: 352-361

Chemical: Methomyl

Type Product: I

Product Name:

Company Name: DuPont

Submission Purpose: response to standard

ZBB Code: 10/13/82

Date in:

Date Completed DEC 8 1982

ACTION CODE: 606

EFB # 9

TAIS (level II) 46 Days 2

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

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DEC 7, 1982

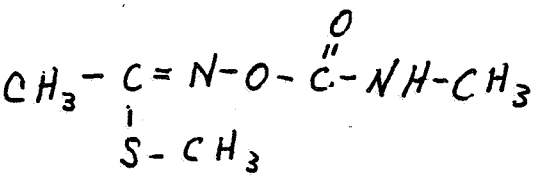
1.0 INTRODUCTION

Chemical Name: S-Methyl-N-[(methylcarbamoyl) oxy] thioacetimidate

Trade Names: Lannate, Nudrin

Common Name: Methomyl

Chemical Structure:



Reference: DuPont Response to EPA Generic Data Requirements, Specifically, Environmental Fate "Data Gaps",

Memo dated May 26, 1982

2.0 DISCUSSION

Items 4 & 5: Hydrolysis/photolysis. Study referred to by DuPont as # 115397 was invalidated because the hydrolysis study was not run in the dark and the photolysis study did not include dark controls. There were other less important problems. Upon reevaluation of the studies (and data), the fact that only 9% of the initial methomyl appeared to hydrolyze in 168 days (even if a combination of hydrolysis & photolysis) and exposure to sunlight for up to 120 days failed to indicate photolytic decomposition, we agree to to withdraw the request for further testing. This is not meant to "bless" the unscientific methodology followed by the researchers. It is also to be noted that the study Decomposition in Soil, cited by DuPont as having been conducted in sunlight, did not address photolysis.

Item 6. Aerobic Soil Metabolism. Study MRID 0000~8844 gave a half-life prediction for methomyl in silt loam and an unknown (unclassified) California soil. Data gathered from muck and sandy loam soils were unreliable. The Guidelines under which this standard was prepared requested ~~was prepared~~ 3 or more soils. Later editions of the Guidelines

are less stringent. Consequently we are accepting the data for silt loam as being representative for methomyl in agricultural soils.

Item 7. No anaerobic soil metabolism study was found in our literature search. No anaerobic aquatic studies were available. Therefore, either an anaerobic soil or an anaerobic aquatic study will be required.

Item 8 & 9 DuPont to supply leaching and vapor pressure data.

Item 10. Adsorption/Desorption. Study by Fung and Uren was invalidated because the soil was "equilibrated" with saturated Ca SO_4 prior to introduction of methomyl. Ca^{++} may have bound to each anionic site, altering the degree of adsorption of methomyl. Adsorption Coefficients should be determined using one soil sediment and at least 4 concentrations of methomyl in distilled water. DuPont should repeat test as suggested but under an acceptable method.

Item 11. Field dissipation. Although the Agency has specified that "the test substance shall be a typical end-product," e.g., typical of a formulation category, and the studies failed to identify the C^{14} methomyl as belonging to a formulation category, the registrant's argument that the data requirement has been satisfied is accepted.

Item 12. Terrestrial forest field dissipation. Since the environmental conditions in a forest differ from those of the field test sites (11 above), the waiver request for terrestrial forest field dissipation studies is denied.

Item 13. Rotational crops. Because of the apparent rapid aerobic soil metabolism of methomyl, we agree to waive the requirement for this test.

Item 14. Fish accumulation. The study cited by DuPont was not available to the reviewer. If, as DuPont contends, data are available to show that the octanol-water partition coefficient is 1.08, and those data are supplied, we will withdraw the requirement for this test.

Item 15. Reentry. The Agency maintains that the registrant must propose an acceptable reentry interval which may be based upon any of the following:

a. Existing state reentry intervals;

b. data on dissipation of foliar residues (decline curve);

c. determination of that time beyond which there are no detectable foliar residues, under appropriate climatic conditions.

Note that the California Department of Food and Agriculture methomyl reentry interval is 2 days (48 hours).

Conclusions: Conclusions are given following the discussion of each item in the registrant's memo.

Hudson Boyd

Hudson Boyd, Chemist
Section No. 3
Enviromental Fate Branch
Hazard Evaluation Division (TS-769)

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information – Does Not Contain National Security Information (E.O. 12065)

4/87

1. CHEMICAL NAME METhomyl 10/13/82

2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
352-361	606	—	5. RECORD NUMBER 80562
			6. REFERENCE NUMBER 2
			7. DATE RECEIVED (EPA) 5-27-82
			8. STATUTORY DUE DATE
			9. PRODUCT MANAGER (PM) 12
			10. PM TEAM NUMBER

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☐ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☐ Seasonal Concern
- ☐ Review Requires Less Than 4 Hours

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TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS 10/13/82

12. PRIORITY NUMBER 12

13. PROJECTED RETURN DATE 12/13/82

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☑ Chemical Undergoing Active Registration Standards Review

C. ☐ BFSD

D. ☐ TSS/RD

E. ☐ Other

F. INSTRUCTIONS

Scrapie Standard – Rebuttal

16. RELATED ACTIONS

17. 3(c)(1)(D)

- ☐ Use Any or All Available Information
- ☐ Use Only Attached Data
- ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

- ☐ TB
- ☐ EEB
- ☐ EF
- ☐ PL
- ☐ RCB
- ☐ EFB
- ☐ CH
- ☐ BFSD

19.	To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED		TOXICOLOGY								
		ECOLOGICAL EFFECTS								
		RESIDUE CHEMISTRY								
	✓	ENVIRONMENTAL DATE	✓							
RD/TSS		CHEMISTRY								
		EFFICACY								
		PRECAUTIONARY LABELING								
BFSD		ECONOMIC ANALYSIS								6

20.	21.	22.	23.	24.
☐ Label Submitted with Application Attached	☐ Confidential Statement of Formula	☐ Representative Labels Showing Accepted Uses Attached	Date Returned to RD (to be completed by HED)	Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information — Does Not Contain National Security Information (E.O. 12065)

4/87

1. CHEMICAL NAME Methomyl 10-13-82

2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
352-361	606	—	5. RECORD NUMBER 40562
			6. REFERENCE NUMBER 2
			7. DATE RECEIVED (EPA) 5-27-82
			8. STATUTORY DUE DATE
			9. PRODUCT MANAGER (PM) 12
			10. PM TEAM NUMBER

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☐ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☐ Seasonal Concern
- ☐ Review Requires Less Than 4 Hours

nh

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS 10/13/82

12. PRIORITY NUMBER 13

13. PROJECTED RETURN DATE 12/13/82

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☒ Chemical Undergoing Active Registration Standards Review

C. ☐ BFSD

D. ☐ TSS/RD

E. ☐ Other

F. INSTRUCTIONS

Semanic Standard — Rebuttal

16. RELATED ACTIONS

17. 3(c)(1)(D)

☐ Use Any or All Available Information ☐ Use Only Attached Data
☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

☐ TB ☐ EEB ☐ EF ☐ PL
☐ RCB ☐ EFB ☐ CH ☐ BFSD

19.	To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED		TOXICOLOGY								
		ECOLOGICAL EFFECTS								
		RESIDUE CHEMISTRY								
	✓	ENVIRONMENTAL DATE	✓							
RD/TSS		CHEMISTRY								
		EFFICACY								
		PRECAUTIONARY LABELING								
BFSD		ECONOMIC ANALYSIS								7

20.	21.	22.	23.	24.
☐ Label Submitted with Application Attached	☐ Confidential Statement of Formula	☐ Representative Labels Showing Accepted Uses Attached	Date Returned to RD (to be completed by HED)	Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

EPA Form 8570-13 (Rev. 11-81) PREVIOUS EDITIONS ARE OBSOLETE.

B-11001

DUPONT
ESTABLISHED 1802

E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

BIOCHEMICALS DEPARTMENT

May 26, 1982

OCT 14 REC'D

Mr. Jay Ellenberger (PM 12)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Ellenberger:

DU PONT RESPONSE TO THE METHOMYL REGISTRATION STANDARD

Attached is a document delineating the position of the Du Pont Company regarding the Methomyl Registration Standard, and Methomyl Registration.

I would like to note that we have received your April 30, 1982 letter to Mr. J. J. Trexel of our Legal Department granting a 30-day extension for this response. We are unable at this time to provide all the information specified in the guidance package for the six-month deadline as you requested. Several points about data requirements and label changes should be clarified first.

The Du Pont response is a point-by-point discussion of these label changes and data requirements as listed in the Standard. We noted several inaccuracies regarding the extent of our submitted data base for methomyl. In addition we believe several of the requests for data and label changes are open to discussion. Consequently, we will be unable to supply all the information you have requested until we have a more concrete understanding of what data and label changes actually will be needed to reregister methomyl.

Since the Standard listed many new requirements, the Du Pont response is necessarily long. In order to save time and manpower for both Du Pont and EPA I suggest a meeting be set up to discuss Methomyl reregistration once the Agency has had time to review our attached response. Such a meeting would help our respective organizations find the common ground between our positions on the Standard. It would also help clarify any issues where our opinions may differ, and hopefully would aid in seeking a prompt and reasonable resolution of those differences. All interested Methomyl registrants should be invited to participate, since they will all be affected through proposed label changes or data compensation.

I look forward to hearing from you. In the meantime, please do not hesitate to call me if you have any questions.

Sincerely,

Robert B. Fugitt
Agrichemicals Product Registration

cc: J. J. Trexel - Du Pont Legal Dept.

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E. I. DU PONT DE NEMOURS & COMPANY (INC.)

RESPONSE TO

METHOMYL REGISTRATION STANDARD

E. I. du Pont de Nemours and Company
Biochemicals Department
Wilmington, DE 19898
May, 1982

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DU PONT RESPONSE TO THE METHOMYL REGISTRATION STANDARD

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PART I: Discussion of the Methomyl Standard, Du Pont Position.....Part I

PART II: Required Forms.....Part II

- FIFRA 3(c)(2)(B) Summary Sheets - All Du Pont Methomyl Products
- Data Compensation Statement: Reregistration - All Du Pont Methomyl Products

DISCUSSION OF THE METHOMYL STANDARD

DU PONT POSITION

This document is the official response of E. I. du Pont de Nemours and Company, Inc. to the October, 1981 Methomyl Registration Standard (received in Wilmington Jan. 26, 1982). Du Pont will support the reregistration of our technical and formulated methomyl products.

Methomyl has been registered in the U.S. since 1968. Foreign sales began that year also. Since then, methomyl has come to be one of the world-wide standards by which insect control products are judged. Throughout this time, methomyl has caused no harm to man or the environment when used in accord with good agricultural practices.

This "record of good behavior" is acknowledged by the EPA in Chapter II of the Standard document. The EPA states "Available data indicate that the use of methomyl will not result in unreasonable adverse effects to man or the environment." The "available data" referred to must include several million dollars worth of health, safety, and residue data. Du Pont alone has submitted data valued at roughly 2 million (current) dollars. Data from other registrants can only have augmented that figure.

In view of the millions of dollars worth of health and safety data that has already been generated in support of methomyl registrations, and the historical lack of "adverse effects," it is difficult to accept without more justification than is given, the Agency's position that new label restrictions and more than a million dollars worth of new data are needed to support continued registration of methomyl.

However, the methomyl Standard takes that position. Several broad label restrictions are imposed without adequate justification or explanation. In addition "data gaps" are cited with the requirement that they be filled,

even though much of the requested data has either been submitted already, or will not add to the safety evaluation of methomyl.

Label Restrictions

The following label restrictions are to be imposed by the Standard. These restrictions appear to be based on the Agency's "Label Improvement Program" or LIP. Both specific and general comments follow.

A) Reentry Statement. EPA seeks to impose a 2-day reentry interval statement for citrus, grapes, nectarine, and peach use, as well as a statement that application must be in accordance with 40 CFR 170. (Note: This appears to be the EPA position. There seem to be several errors of transposition in the "Required Labeling" sections for each of the end use methomyl categories).
Du Pont Position. The Agency states that these reentry intervals have been adopted from California. No reason is given. No applicable EPA reentry guidelines exist. Furthermore, methomyl is in the second LIP project. According to recent LIP drafts, the only reentry statement to be required of products in this project is "Do not enter treated areas without appropriate protective clothing until sprays have dried and dusts have settled." This is a more rational approach to reentry labeling than trying to apply the standards of the California Department of Food and Agriculture to the other 49 states of the Union. For the record, Du Pont does not agree with the 48-hour reentry interval as required by CDFA for the crops in question.

B) Statement Re-Use or Storage Around Domestic Dwellings. EPA will require a statement "Not for use or storage in or around domestic dwellings" for methomyl in soluble bags.

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Du Pont Position. The statement "not for use or storage in or around the home" was part of our 8/20/81 draft Lannate® labels submitted to EPA for approval on 8/26/81. Via EPA letter of 9/30/81 we were told, exactly, how to revise our storage and disposal statement. The EPA language excluded our home use restriction. Du Pont agrees that such a statement has a worthwhile place on the label.

C) Orchard Grazing Restriction. The EPA seeks to impose a restriction against grazing livestock on cover crops in methomyl-treated orchards. This labeling requirement is imposed without discussion or justification.

Du Pont Position. Methomyl has tolerances for meat, milk, and meat by-products of cattle as well as tolerances for meat and meat by-products of horses, sheep and hogs. Furthermore, methomyl has tolerances for alfalfa, barley (forage, hay and straw) bean forage, corn (fodder and forage), bermudagrass and hay, mint hay, oats (forage, hay, and straw), pea vines rye (forage, hay and straw), sorghum forage, and wheat (forage, hay and straw). In addition, IR-4 has sponsored a pesticide petition (pp OE2276) for all forage grasses. Methomyl is not applied directly to orchard cover crops (such application would be inconsistent with the label). During aerial application to orchard crops, the ground cover is protected by the orchard canopy. During ground application, the spray is directed upward toward the tree crop, and not at the ground cover. In view of the existing and proposed tolerances, and the protected nature of orchard ground cover, the Agency's proposed grazing restriction serves no apparent purpose. Du Pont feels the proposed orchard grazing restriction

Part 4

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is unnecessary. Unless a logical explanation is available, Du Pont suggests this proposal be deleted from the Standard.

Regarding these label restrictions, Du Pont is concerned that the Agency is requiring changes in the labeling of methomyl products before similar changes are required on competitive products within the methomyl I-1 "cluster" (No. 6 priority in EPA standards ranking scheme). Furthermore, based on the Agency's pace with new standards, it appears that methomyl would be required to carry these label restrictions before the same was required of insecticides in the higher priority clusters, I-4 (No. 1 priority) and I-2 (No. 3 priority). This would unfairly place methomyl at a competitive disadvantage. Until products with comparable toxicity and similar exposure potential are required to carry similar label restrictions. Du Pont will oppose the unnecessary label changes.

Data Gaps Cited by EPA

The methomyl Standard records a number of so called "data gaps." These "gaps" appear in reality to be only the differences (as perceived by EPA) between the data requirements and protocols now in use by the Agency, and the findings and protocols of the 1968-1982 methomyl data base. In other words, the "gaps" cited in the standard do not necessarily indicate the absence of data that is essential to show a lack of possible hazard to man or the environment. Furthermore, the numerous requests by EPA for "checklist" types of data appears to be inconsistent with remarks made by Dr. John Todhunter on February 3, during a speech to the Arkansas Agricultural Pesticide Association. At that meeting, Dr. Todhunter said reregistration and registration standards would be "...a process to reasonably reassure the safety of most of the pesticides that our agriculture currently depends upon and to ask the valid questions on the safe use of those pesticides..." (emphasis added) Dr. Todhunter also said, 'The aim of the reregistration program will be to bring old chemicals sufficiently up to the current state of scientific

understanding to insure that they present no unreasonable risk to the environment. This does not mean the same level of proof as a new chemical entering the market for the first time. It means rather an intelligent consideration of the existing history and experience of years of use to make a reasonable reassessment of the chemical." (Emphasis added).

Because most of the "gaps" do not represent a lack of essential data, Du Pont feels a number of the data requirements for reregistration are unjustified, and should be withdrawn or waived. There follows a tabular summary of data gaps as cited in the Standard and the corresponding Du Pont response to each.