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CONFIDENTIAL

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

OCT 11 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 5481-144. 2,4-D.
Letter of 2/22/89: Product Chemistry Data Submitted
in Response to the Registration Standard.
DEB#: 5546 HED#: 9-1745 MRID#: 410150-01,-02,-03

FROM: Maxie Jo Nelson, Ph.D., Chemist
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C)

mjn

THRU: Richard D. Schmitt, Ph.D., Chief
Dietary Exposure Branch
Health Effects Division (H7509C)

Richard D Schmitt

TO: C. Grubbs, PM Team 74
Reregistration Branch
Special Review and Reregistration Division (H7508C)

and

Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

Attached is a Registration Standard follow-up review prepared by Dynamac Corporation under supervision of the Dietary Exposure Branch, HED. This submission was Amvac Chemical Corporation's (registrant) response to product chemistry data requirements.

This Dynamac review has undergone secondary and tertiary review in the Dietary Exposure Branch and reflects Branch policies.

Please note that pp 11-16 (Confidential Appendices A-D) of this Dynamac review will receive limited distribution since they contain Confidential FIFRA Trade Secret/CBI information.

Attachment: "2,4-D. (DEB No. 5546). Task 4: Registrant's Response to Product Chemistry Data Requirements", 16 pages.

cc [with Attachment consisting of the **complete** Dynamac review, including the **Confidential** FIFRA Trade Secret/CBI portion, pp. 11-16 (Confidential Appendices A-D)]:

Reading File
2,4-D Registration Standard File
2,4-D Subject File
ISB/PMSD (E. Eldredge)

cc [with Attachment consisting of the **non-Confidential/non-CBI** portion of the Dynamac review only, i.e., pp. 1-10 inclusively]:

DEB Reviewer (M. Nelson)
Circulation (7)
Dynamac (P. Deschamp)

H7509C:DEB:Reviewer(MJN):CM#2:Rm810:557-7423:typist(mjn):
24D-DYN.PC2:9/29/89.

RDI:SecHead:RSQuick(byMJN):9/29/89:BrSrScientist:RALoranger:
10/3/89.

Final Report

2,4-D (DEB No. 5546)
Task 4: Registrant's Response to
Product Chemistry Data Requirements

September 22, 1989

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

2,4-D

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

Task - 4

BACKGROUND

In response to the 2,4-D Guidance Document of September 1988, Amvac Chemical Corp. has submitted three volumes of product chemistry data (DEB# 5546; MRIDs 41015001, 41015002, and 41015003) for the 93% isopropyl ester (IPE) technical (T) formulation (EPA Reg. No. 5481-144).

These data and our conclusions are discussed below.

61-1. Product Identity and Disclosure of Ingredients

Information on the identity of the product along with a confidential statement of formula has been submitted by the registrant for the product (MRID 41015001); the data are presented in Confidential Appendix A. These data do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition for the Amvac 93% IPE T (EPA Reg. No. 5481-144) because: (i) impurities were incorrectly identified as inerts; and, (ii) one impurity identified as an inert is an "active ingredient".

Information concerning the detection of chlorinated dibenzo-p-dioxin and dibenzofuran (CDD/CDF) in the IPE product has been reviewed by the Agency (DEB Memorandum No. 4604, dated January 4, 1988) where it was concluded that Amvac has responded satisfactorily to the Dioxin Call-In of June 15, 1987.

61-2. Description of Beginning Materials and Manufacturing Process

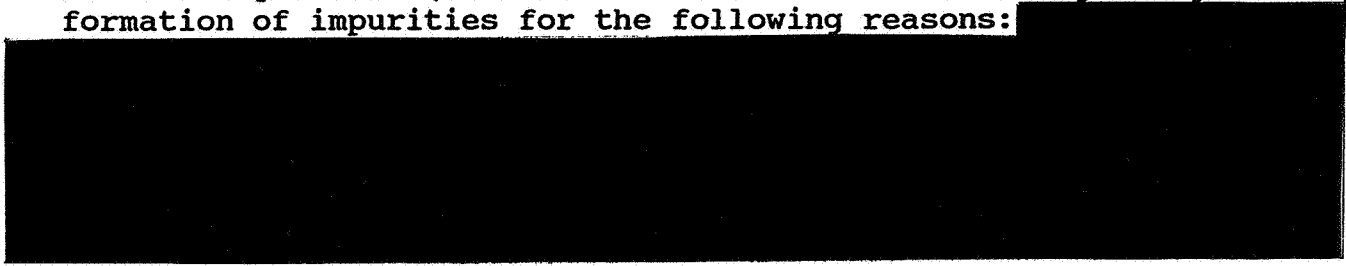
The registrant has submitted the names and addresses of the suppliers of beginning materials along with their specifications; the registrant has also submitted a description of the manufacturing process for the product (MRID 41015001). A discussion of this current manufacturing process is given in Confidential Appendix B. These data satisfy the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding beginning materials and the production process for the 93% IPE T (EPA Reg. No. 5481-144).

Information concerning CDDs and CDFs has been reviewed by the Agency (DEB Memorandum No. 4604, dated January 4, 1988) where it was concluded that Amvac has responded satisfactorily to the Dioxin Call-In of June 15, 1987.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

61-3. Discussion of Formation of Impurities

The registrant has submitted a discussion of impurities formed during the production of the IPE (MRID 41015001). The discussion (see Confidential Appendix C) does not satisfy the requirements of 40 CFR §158.167 (Guidelines Reference No. 61-3) regarding formation of impurities for the following reasons:



We note that the registrant has postulated the presence of an impurity in their 93% IPE product and believes it to be formed from a substance present in the source material. The registrant of the source material has not reported this substance to be present in their product; thus, the information regarding the putative existence of this impurity in the 93% IPE product may not be correct.

Information concerning CDD/CDF impurities has been reviewed by the Agency (DEB Memorandum No. 4604, dated January 4, 1988) where it was concluded that Amvac has responded satisfactorily to the Dioxin Call-In of June 15, 1987.

62-1. Preliminary Analysis

The registrant provided preliminary analyses of five batches of the 93% T (MRID 41015002, see Confidential Appendix D). These data do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis for the 93% IPE T (EPA Reg. No. 5481-144) because the analytical method used to obtain the data was not specified.

62-2. Certification of Limits

The registrant has submitted the lower and upper limits for the active ingredient and upper limits for impurities (MRID 41015001). The data are presented in Confidential Appendix A. These data do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits because: (i) the limits for active ingredient 2,4-D IPE exceeds the range of the standard certified limits as described in 40 CFR §158.175(b)(2) without explanation by the registrant; and (ii) a lower certified limit is required for a residual active ingredient. Furthermore, validation data explaining how limits were established for all ingredients were unavailable for review.

62-3. Enforcement Analytical Methods

Amvac Chemical Corp. (1989; MRID 41015002) submitted a GLC method for the determination of the active ingredient 2,4-D IPE.



PHYSICAL AND CHEMICAL CHARACTERISTICS

The physical and chemical characteristics for the 93% IPE T have been submitted by the registrant (MRID 41015003). These properties are presented in Table 1. Data gaps still exist for solubility, octanol/water partition coefficient, stability, oxidizing or reducing action, and storage stability. No data were presented for oxidizing or reducing action. Solubility determinations were reported only as lower bounds and test temperatures were not provided. Determination of octanol/water partition coefficient must be conducted using PAI rather than TGAI as the test substance and the test temperature must be reported. Stability data on the sensitivity of the active ingredient to metal ions, metals, and sunlight must be provided and the temperature conditions for the longterm stability data must be reported.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

Table 1. Physical and chemical properties of the isopropyl ester of 2,4-D (EPA Reg. No. 5481-144) purified active ingredient (PAI) and technical grade of the active ingredient (TGAI). Data from MRID 41015003.

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Substrate)
63-2. Color	pale amber [Muncell color scale] (TGAI)
63-3. Physical state	liquid (TGAI)
63-4. Odor	mild chemical (TGAI)
63-5. Melting point	5-10 or 20-25 C, two crystal forms (PAI) liquid at ambient temperature (TGAI)
63-6 Boiling point	130 C at 1 mm Hg [Amvac method] (TGAI)
63-7. Specific gravity	1.252 g/ml at 25 C [Amvac hydrometer method] (TGAI)
63-8. Solubility	0.023 g/100 ml water (unspecified temperature) [Amvac method] (TGAI) ≥2.0 g/100 ml in cold (temp. unreported) ethanol, methanol, chloroform, cyclohexane, 53, or kerosene [Amvac method] (TGAI)
63-9. Vapor pressure	1×10^{-3} mm Hg at 26.6 C
63-11. Octanol/water partition coefficient	$K_{ow} = 253.8 \pm 44.4$ (temp. unreported) [Amvac method] (TGAI)
63-12. pH	3.94; 5% 93% T in distilled water 3.84; 10% 93% T in distilled water [Amvac method] (TGAI). Technical IPE is insoluble and nonionizable in water; pH is affected by the presence of residual 2,4-D acid.

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Substrate)
63-13. Stability	hydrolyzes in the presence of strong acids or bases; transesterifies in the presence of strong acids; stable in presence of water and alcohols as long as no acid is present (TGAI)
63-15. Flammability	Flashpoint = 156 F (69 C) [TCC closed cup] (TGAI)
63-17. Storage Stability	≤0.6% loss (2 samples) over 14 months [enforcement analytical method] (TGAI)
63-18. Viscosity	41.6 centipoise at 22 C [Amvac method] (TGAI)
63-20. Corrosion Characteristics	Corrosive to mild steel due to presence of 2,4-D acid, but not to stainless steel; has no effect on high density polypropylene or glass containers [Amvac method; no specific values were reported] (TGAI)

TABLE A. GENERIC DATA REQUIREMENTS FOR THE 2,4-D: ISOPROPYL ESTER (AMVAC CHEMICAL CORP.) TECHNICAL GRADE OF THE ACTIVE INGREDIENT.¹

Data Requirement	Test Substance ²	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes] [No]	Reference (MRID No.)
<u>40 CFR §158.155-190 Product Chemistry 2,4-D: ISOPROPYL ESTER (AMVAC CHEMICAL CORP.)</u>				
<u>Product Composition</u>				
61-2. Beginning Materials & Production Process	TGAI	R	X	41015001
61-3. Formation of Impurities	TGAI	R	X ³	41015001
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis	TGAI	CR	X ⁴	41015002
<u>Physical and Chemical Characteristics</u>				
63-2. Color	TGAI	R	X	41015003
63-3. Physical State	TGAI	R	X	41015003
63-4. Odor	TGAI	R	X	41015003
63-5. Melting Point	TGAI	R	X	41015003
63-6. Boiling Point	TGAI	R	X	41015003
63-7. Density/Specific Gravity	TGAI	R	X	41015003
63-8. Solubility	TGAI or PAI	R	X ^{5,6}	41015003
63-9. Vapor pressure	TGAI or PAI	R	X	41015003
63-10. Dissociation Constant	TGAI or PAI	R	X	41015003
63-11. Octanol/Water Partition Coefficient	PAI	CR	X ^{5,7}	41015003
63-12. pH	TGAI	CR	X	41015003
63-13. Stability	TGAI	R	X ^{5,8}	41015003
<u>Other Requirements:</u>				
64-1. Submittal of Samples	TGAI or PAI	CR	X ⁹	

1. Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for 2,4-D Manufacturing-Use Products", for registered technical products.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

TABLE A. (Continued).

2. Test substance: MP = manufacturing-use product; PAI = purified active ingredient; TEP = typical end-use product; TGAI = technical grade of the active ingredient.
3. [REDACTED]
4. Information on the analytical method used to obtain preliminary analysis data is required.
5. As required by 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-13, data must be submitted on physicochemical characteristics (solubility, octanol/water partition coefficient, and stability). There are additional data requirements listed in Table B pertaining to physicochemical characteristics of those technical products which are also manufacturing-use products.
6. Temperatures for all solubility measurements must be reported. In addition, actual solubilities in organic solvents, rather than lower bounds, must be reported.
7. Temperature for the measurements of the octanol/water partition coefficient must be reported. In addition, measurements must be conducted using the PAI rather than the TGAI.
8. Information on stability must include consideration and discussion of the sensitivity of the active ingredient to metal ions and metals, the stability of the active ingredient at normal and elevated temperatures, and the sensitivity of the active ingredient to sunlight.
9. If samples are required, the Agency will request them.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR 2,4-D: ISOPROPYL ESTER (AMVAC CHEMICAL CORP.)
MANUFACTURING-USE PRODUCTS.

Data Requirement	Test Substance ²	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c) (2) (B)? [Yes] [No]	Reference (MRID No.)
<u>40 CFR §158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-1. Product Composition	MP	R	X ³	41015001
61-2. Beginning Materials & Production/Formulation Process	MP	R	X	41015001
61-3. Formation of Impurities	MP	R	X ⁴	41015001
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis	MP	CR	X ⁵	41015002
62-2. Certified Limits	MP	R	X ⁶	41015002
62-3. Enforcement Method	MP	R	X ⁷	41015002
<u>Physical and Chemical Characteristics</u>				
63-2. Color	MP	R	X	41015003
63-3. Physical State	MP	R	X	41015003
63-4. Odor	MP	R	X	41015003
63-7. Density/Specific Gravity	MP	R	X	41015003
63-12. pH	MP	CR	X	41015003
62-14. Oxidizing/Reducing Action	MP	CR	X ^{8,9}	41015003
62-15. Flammability	MP	CR	X ¹⁰	41015003
63-16. Explodability	MP	R	X ¹¹	41015003
63-17. Storage Stability	MP	R	X	41015003
63-18. Viscosity	MP	CR	X	41015003
63-19. Miscibility	MP	CR	X	41015003
63-20. Corrosion Characteristics	MP	R	X	41015003

(Continued, footnotes follow)

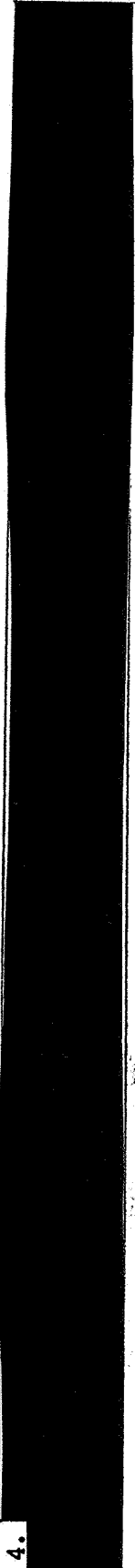
TABLE B. (Continued).

Data Requirement	Test Substance	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Reference (MRID No.)
<u>Other Requirements:</u>				
64-1. Submittal of Samples	MP	CR	X ¹²	41015003

1. Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the 2,4-D Technical Grade of the Active Ingredient", for those manufacturing-use products which consist only of the TGA1.

2. Test substance: MP = manufacturing-use product; PAI = purified active ingredient; TEP = typical end-use product; TGA1 = technical grade of the active ingredient.

3. Components must be correctly identified as impurities or active ingredients rather than inerts.

4. 

5. Information on the analytical method used to obtain preliminary analysis data is required.

6. Validation data explaining how upper and lower limits were established for active ingredient residual 2,4-D IPE and upper limits were established for the active ingredient residual 2,4-D acid must be submitted. A lower certified limit is also required for residual 2,4-D acid. In addition, because the upper limit for the active ingredient 2,4-D IPE exceeds the upper range of the standard certified limits as described in 40 CFR §158.175 (b) (2), the registrant must submit an explanation for the discrepancy.

7. Validation data concerning precision and accuracy for the analysis of the active ingredients 2,4-D IPE and the residual 2,4-D acid must be submitted.

8. As required in 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-20, data must be submitted on physicochemical characteristics of each manufacturing-use product (oxidizing or reducing action and storage stability). Additional data requirements regarding physicochemical properties of manufacturing-use products which

TABLE B. (Continued).

contain only the technical grade of the active ingredient are listed in Table A, "Generic Data Requirements for the 2,4-D Technical Grade of the Active Ingredient."

9. Data are required if the product contains an oxidizing or reducing agent.
10. Data are required if the product is potentially explosive.
11. Storage conditions under which the test was conducted (e.g., temperature, type of packaging) must be reported.
12. If samples are required, the Agency will request them.

2,4-D (AMVAC CHEMICAL CORP.)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDICES

Appendix A: 2 Pages
Appendix B: 1 Page
Appendix C: 1 Page
Appendix D: 1 Page

Confidential Appendices to the Scientific Review of the Followup Report for the pesticide 2,4-D by the Dietary Exposure Branch [Confidential FIFRA Trade Secret/CBI].

2,4-D product chemistry review dated 10/11/89

Page _____ is not included in this copy.

Pages 15 through 19 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients
 - Identity of product impurities
 - Description of the product manufacturing process
 - Description of product quality control procedures
 - Identity of the source of product ingredients
 - Sales or other commercial/financial information
 - A draft product label
 - The product confidential statement of formula
 - Information about a pending registration action
 - FIFRA registration data
 - The document is a duplicate of page(s) _____
 - The document is not responsive to the request
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
