



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

CONFIDENTIAL

MAR 12 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#9F3743. Clethodim Product Chemistry Data Submitted
in Support of Registration.

DEB#: 5681 HED#: 9-1969 MRID#s: 409745-01 thru -05

FROM: Maxie Jo Nelson, Ph.D., Chemist
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Dietary Exposure Branch
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mjn

THRU: Richard D. Schmitt, Ph.D., Chief
Dietary Exposure Branch
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Richard D Schmitt

TO: J. Miller/M. Erumsele, PM Team 23
Herbicide-Fungicide Branch
Registration Division (H7505C)

and

Toxicology Branch - HFA Support
Health Effects Division (H7509C)

Attached is a review of the Product Chemistry data for clethodim, submitted in support of registration. This review was prepared by Dynamac Corporation under supervision of the Dietary Exposure Branch (DEB).

The review has undergone secondary review and revision within DEB and reflects current Branch policies.

Please note that pp 17-45 (Confidential Appendices A-E) of this Dynamac review will receive limited distribution since they contain Confidential FIFRA Trade Secret/CBI information.

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Attachment: "CLETHODIM. Task 5 - DEB No. 5681: Product
Chemistry Data Submitted Under PP#9F3743 in
Support of Registration", 45 pages.

cc (pp. 1-45; CBI): PP#9F3743, RF, Clethodim Reg. Std. File,
Clethodim Subject File, ISB/PMSD (E. Eldredge).

cc (pp. 1-16; non-CBI): Circ. (7), M. Nelson.

H7509C:DEB:Reviewer(DYN/mjn):CM#2:Rm810:557-7423:typist(DYN/mjn):
CLET3743.PC:1/17/90.

RDI:SecHead:RSQuick:1/26/90:BrSrScientist:RALoranger:1/26/90.

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Final Report

CLETHODIM
Task 5 - DEB No. 5681: Product
Chemistry Data Submitted Under
PP#9F3743 in Support of Registration

November 13, 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

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CLETHODIM

PRODUCT CHEMISTRY DATA SUBMITTED IN SUPPORT OF REGISTRATION

Task - 5

Chevron Chemical Company is currently seeking registrations for a 90.5% technical (T) manufacturing use product (MUP), and a 2 lb/gal (26.6%) emulsifiable concentrate (EC) end-use product (EUP), which contain the herbicidal active ingredient clethodim. In support of the registration of these products, Chevron Chemical Company has submitted 5 volumes of product chemistry data, MRIDs 40974501, 40974502, 40974503, 40974504, and 40974505, dated 1988-1989 (DEB No. 5681).

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA §3(c)(2)(A)] requires the Environmental Protection Agency to establish guidelines for registering pesticides in the United States. The Agency, in turn, requires registrants to provide quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products to be registered, the Agency requires detailed information on the manufacturing and/or formulation processes and a discussion on the formation of manufacturing impurities. Furthermore, to assure that the composition of the product as marketed will not vary from that evaluated at the time of registration, prospective pesticide registrants are required to propose certified upper and lower composition limits for the added ingredients, and upper limits for toxicologically significant impurities. Standard certified limits for pesticide product ingredients are established according to 40 CFR §158.175(b)(2); these limits may be modified with appropriate and acceptable explanation by the registrant.

The Agency also requires data on the physical and chemical properties of the pesticide active ingredient and its formulations, such as melting and boiling points, ambient vapor pressure, and solubility in various solvents. Corresponding to each of the topical discussions listed below are the Guideline Reference Numbers from "Pesticide Assessment Guidelines - Subdivision D - Product Chemistry," referred to in Title 40 of the Code of Federal Regulations (40 CFR), Part 158, "Data Requirements for Registration," Subpart C, "Product Chemistry Data Requirements." These regulations and guidelines explain the minimum data that the Agency needs to adequately assess the product chemistry of clethodim.

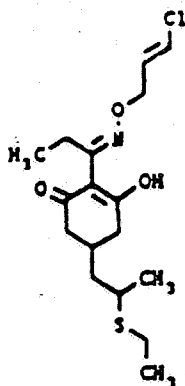
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Guidelines Reference No.
from 40 CFR §158.155-190

Product Composition and Manufacture	61-(1-3)
Analysis and Certification of Product Ingredients	62-(1-3)
Physical and Chemical Characteristics	63-(2-20)

61-1. Product Identity and Disclosure of Ingredients

Clethodim is the common name for the herbicidal active ingredient in the 90.5% technical (T) and 2 lb/gal (26.6%) emulsifiable concentrate (EC) formulations produced by Chevron Chemical Co. The molecular structure of the active ingredient is illustrated below:



The company identification number assigned to this active ingredient is RE-45601. The CAS naming of clethodim is 2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one.

Other identifying characteristics and codes are:

Empirical Formula:	C ₁₇ H ₂₆ ClNO ₃ S
Molecular Weight:	359.92
CAS Registry No.:	99129-21-2

Chevron Chemical Company (1988; MRID 40974501) submitted product identity data and a Confidential Statement of Formula (CSF) for the 90.5% T. Refer to Confidential Appendix A for the disclosure of ingredients. The submitted data do not satisfy the requirements of 40 CFR §158.155 (Guidelines Reference No. 61-1) regarding product composition for the Chevron 90.5% T because individual impurities present at ≥0.1% by weight of the technical, as determined by preliminary analysis, were not listed on the CSF. The following additional information must be submitted:

- o Each impurity determined to be present at $\geq 0.1\%$ by weight of the 90.5% technical must be individually listed on the CSF, and a nominal concentration must be provided for each of the impurities listed. For any impurity determined to be of toxicological concern, a nominal concentration and an upper certified limit are required, regardless of the amount present. In accordance with §158.175, an explanation as to how the certified limits for the active ingredient were determined is needed. A corrected CSF must be submitted on EPA Form 8570-4 (Rev. 2-85).

Chevron Chemical Company (1988; MRID 40974502) has submitted a Confidential Statement of Formula (CSF) for the 2 lb/gal (26.6%) EC formulation. Refer to Confidential Appendix A for the disclosure of ingredients. These data satisfy the requirements of 40 CFR §158.155 (Guidelines Reference No. 61-1) regarding disclosure of ingredients for Chevron 2 lb/gal (26.6%) EC formulation. No additional data are required for this product. ✓

61-2. Description of Beginning Materials and Manufacturing Process

Chevron Chemical Company (1988; MRID 40974501) submitted the details of the manufacturing process for the 90.5% T, and the names and addresses of the suppliers along with specifications concerning the beginning materials. Also included in this submission are descriptions of the analytical methods employed to monitor the various reactions and quality control measures, and the chemical equations of each intended reaction occurring at each step of the process. These data are discussed in Confidential Appendix B. The submitted data satisfy the requirements of 40 CFR 158.160-162 (Guideline Reference No. 61-2) regarding beginning materials and the production process for the Chevron 90.5% T. No additional data are required. ✓

Chevron Chemical Company (1988; MRID 40974502) submitted a description of the formulation process, material specification sheets for each starting material, the relative amounts of material and the order in which they are added, a description of the equipment and the conditions that are controlled during the process, quality control procedures, and container and packaging specifications for the 2 lb/gal (26.6%) EC. These data are discussed in Confidential Appendix B. The submitted data satisfy the requirements of 40 CFR 158.160-165 (Guideline Reference No. 61-2) regarding beginning materials and the formulation process for the Chevron 2 lb/gal (26.6%) EC. No additional data are required.

61-3. Discussion of Formation of Impurities

Chevron Chemical Company (1988; MRID 40974501) submitted a discussion regarding the formation of impurities for the 90.5% T. This discussion covered: (i) impurities which may be found at levels >0.1% by weight of the technical; (ii) impurities which may be found at levels consistently below 0.1% by weight of the technical; and (iii) impurities which, theoretically, could be formed in the 90.5% technical product, but are not found to be present. These discussions are presented in Confidential Appendix C. In addition, a list of these impurities, their CAS Reg. Nos. and names are also contained in this same Appendix. These discussions do not fully satisfy the requirements of 40 CFR 158.167 (Guideline Reference No. 61-3) regarding formation of impurities in the 90.5% T because the following additional discussions must be submitted:

- o Discussions of the possible degradation of the ingredients in the product after its production but prior to its use, postproduction reactions between the ingredients in the product, possible migration of components of packaging materials into the pesticide, and possible carryover of contaminants from use of production equipment previously used to produce other products or substances.

Chevron Chemical Company (1988; MRID 40974502) submitted a discussion concerning the formation of impurities for the 2 lb/gal (26.6%) EC. This discussion appears in Confidential Appendix C. This discussion does not fully support the requirements of 40 CFR 158.167 (Guideline Reference No. 61-3) regarding formation of impurities in the 2 lb/gal (26.6%) EC. The following additional data are required:

- o Discussion of the possible migration of components of packaging materials into the pesticide and possible carryover of contaminants from use of production equipment previously used to produce other products or substances.

62-1. Preliminary Analysis

Chevron Chemical Company has submitted preliminary analysis data for the 90.5% T (1988; MRID 40974503), and for the active ingredient in the 2 lb/gal (26.6%) EC (1988; MRID 40974502). These data are discussed in Confidential Appendix D. The submitted data satisfy the requirements of 40 CFR 158.155 (Guideline Reference No. 62-1) regarding preliminary analysis for the Chevron 90% T and the 2 lb/gal (26.6%) EC. No additional data are required.

62-2. Certification of Limits

Chevron Chemical Company (1988; MRID 40974501) submitted a CSF for the 90.5% T which furnishes certified limits for each component in the technical grade of the active ingredient. These data are reported in Confidential Appendix A. The submitted data do not satisfy the requirements of 40 CFR §158.175 (Guidelines Reference No. 62-2) regarding certified limits for Chevron 90.5% T because no explanation was provided as to how the certified limits for the active ingredient were determined. An explanation is required because the certified lower limit is substantially less than the lower limit which would be obtained by using the standard certified limits, as described in 40 CFR §158.175 (b)(2). We note that the upper certified limits for starting materials (impurities related to the active) greatly exceed the mean \pm standard deviation as determined by the preliminary analysis. The following information is required:

- o An acceptable explanation must be provided as to how the certified limits for the active ingredient were determined. If an acceptable explanation cannot be provided, more precise limits will be required. If new limits are required, a corrected CSF will need to be submitted on EPA Form 8570-4 (Rev. 2-85).

Chevron Chemical Company (1988; MRID 40974502) submitted a CSF for the 2 lb/gal (26.6%) EC which furnishes certified limits for each component in the formulation; a discussion of how these limits were established was also included with this submission. The submitted data are presented in Confidential Appendix A. These data satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits. No additional data are required. However, should new data be required concerning the certified limits for the active ingredient in the technical product, a submission of new limits for this end-use product may be necessary.

62-3. Analytical Methods to Verify Certified Limits

Chevron Chemical Company has submitted a reverse phase high performance liquid chromatography (HPLC) method for the determination of clothodim in the 90.5% T (1988; MRID 40974503) and in the 2 lb/gal (26.6%) EC formulation (1988; MRID 40974502). Clothodim is separated from the sample using reverse-phase HPLC, and quantified by comparisons of UV absorption at 254 nm with a reference standard containing a known amount of clothodim. The samples and the standard solutions are diluted with acetonitrile prior to analysis; the mobile phase consists of acetonitrile:acetic acid:water (68.6:1.4:30). The limits of detection were not provided. The method precision and accuracy are presented in a table on the next page.

<u>Product</u>	<u>Precision</u> %	<u>Accuracy</u> % (Sample No.)	<u>Fortification</u> ppm (total)
90.5% T	±0.48	104 (5)	42-137 (150-236)
2 lb/gal EC	±0.35	101 (5)	80-100 (112-179)

Representative chromatograms of the reference standard and 90.5% T and 2 lb/gal (26.6%) EC product showed one major peak identified as clethodim (RE-45601) and a minor peak labeled as "polar form". The study authors concluded that the "polar form" of RE-45601 is that conformation of the molecule in which the oxime with associated alkoxy group is "syn" to the cyclohexane-dione ring and the "non-polar", or normal form, of the molecule is that conformation in which the oxime with associated alkoxy group is "anti" to the cyclohexane-dione ring. Additional information is needed to clarify whether or not the polar form has herbicidal activity and, if so, if it is included in the calculations for percent active ingredient.

The analytical methods (along with the validation data) for determination of clethodim, discussed above, and impurities, discussed in Confidential Appendix E satisfy the requirements of 40 CFR 158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the 90.5% T and for the 2 lb/gal (26.6%) EC. No additional data are required.

PHYSICAL AND CHEMICAL CHARACTERISTICS

Data regarding the physical and chemical characteristics of the Chevron 90.5% T (1988; MRID 40974505) and the 2 lb/gal (26.6%) EC (1988; MRID 40974502) have been submitted. These properties are presented in Table 1. The following additional data are required:

- o Data concerning oxidizing/reducing action, flammability, explosability, storage stability, viscosity, miscibility, and corrosion characteristics are required for the 90.5% T. No additional data are required concerning physical and chemical characteristics for the 2 lb/gal (26.6%) EC.

Table 1. Physical and chemical properties of clethodim purified active ingredient (PAI), technical grade of the active ingredient (TGAI), and end-use products (EUP).

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; Substrate; MRID) ¹
63-2. Color	<p>amber, Munsell Color Designation of 7.5 YR 6/12 [ASTM D1535-80] (90.5% T; TGAI; 40974505)</p> <p>amber, Munsell Color Designation of 10 YR 7/14 [ASTM D1535-80] (2 lb/gal or 26.6% EC; EUP; 40974502)</p>
63-3. Physical state	<p>viscous liquid (90.5% T; TGAI; 40974505)</p> <p>liquid emulsifiable concentrate (2 lb/gal or 26.6% EC; EUP; 40974502)</p>
63-4. Odor	<p>no characteristic odor [olfactory perception at 23 C] (90.5% T; TGAI; 40974505)</p> <p>light aromatic odor [olfactory perception at 23 C] (2 lb/gal or 26.6% EC; EUP; 40974502)</p>
63-6. Boiling point	<p>decomposes at temperatures below the boiling point (90.5% T; TGAI; 40974505)</p>
63-7. Density	<p>1.1395 g/cu. cm at 20 C [Mettler/Paar oscillating density meter, Model DMA-46] (90.5% T; TGAI; 40974505)</p> <p>0.9446 g/cu. cm at 20 C [Mettler/Paar oscillating density meter, Model DMA-46] (2 lb/gal or 26.6% EC; EUP; 40974502)</p>

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; Substrate; MRID)																		
63-8. Solubility	<table> <tr> <th>Solvent</th><th>Solubility @ 25 C (g/100 ml)</th></tr> <tr> <td></td><td>PAI</td></tr> <tr> <td>water (pH 3.73)</td><td>1.81×10^{-3}</td></tr> <tr> <td>water (pH 4.92)</td><td>7.18×10^{-3}</td></tr> <tr> <td>water (pH 5.81)</td><td>4.79×10^{-2}</td></tr> <tr> <td>water (pH 6.46)</td><td>0.174</td></tr> <tr> <td>water (pH 7.01)</td><td>0.540</td></tr> <tr> <td>water (pH 7.55)</td><td>1.24</td></tr> <tr> <td>water (pH 7.74)</td><td>1.48</td></tr> </table> <p>TGAI: >90% soluble in acetone, ethyl acetate, hexane, and DMF [HPLC at 254-nm] (90.5% T; TGAI and PAI; 40974505)</p>	Solvent	Solubility @ 25 C (g/100 ml)		PAI	water (pH 3.73)	1.81×10^{-3}	water (pH 4.92)	7.18×10^{-3}	water (pH 5.81)	4.79×10^{-2}	water (pH 6.46)	0.174	water (pH 7.01)	0.540	water (pH 7.55)	1.24	water (pH 7.74)	1.48
Solvent	Solubility @ 25 C (g/100 ml)																		
	PAI																		
water (pH 3.73)	1.81×10^{-3}																		
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water (pH 5.81)	4.79×10^{-2}																		
water (pH 6.46)	0.174																		
water (pH 7.01)	0.540																		
water (pH 7.55)	1.24																		
water (pH 7.74)	1.48																		
63-9. Vapor Pressure	<p>$<1 \times 10^{-7}$ (TORR) at 25 C [Gas Saturation Method] (90.5% T; PAI; 40974505)</p>																		
63-10. Dissociation constant	<p>$pK_a = 4.47$ [OECD Guideline 112] (90.5% T; PAI; 40974505)</p>																		
63-11. Octanol/water partition coefficient	<p>$K_{ow} = 1.5 \times 10^4$ [EPA method described in FR Vol. 50, No. 88, CFR Part 769, Section 1.550: Partition Coefficient (n-Octanol Water)] (90.5% T; PAI; 40974505)</p>																		
63-12. pH	<p>4.1 in a stirred solution or 4.2 in a standing solution [ASTM E 70-77] (90.5% T; TGAI; 40974505)</p> <p>4.9 (5% aqueous solution) [Corning pH/ion meter 150] (2 lb/gal or 26.6% EC; EUP; 40974502)</p>																		

(Continued.)

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Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; Substrate; MRID)
63-13. Stability	The half life, when exposed to sunlight at an average temperature of 23.9 C is 16.3 hours. The half lives at 20 C, 38 C, and 50 C are 8.4, 1.2, and 0.7 months respectively. Metals in contact with the product do not contribute to decomposition. [ORC NB Ref. 9377-27] (90.5% T; TGAI; 40974505)
63-14. Oxidizing or reducing action	not an oxidizing or reducing agent (2 lb/gal or 26.6% EC; EUP; 40974502)
63-15. Flammability	flashpoint (close cup) is 110 C ✓ [Setaflash Closed Cup Flash Point Apparatus] (2 lb/gal or 26.6% EC; EUP; 40974502)
63-16. Explodability	not a potential explosive (2 lb/gal or 26.6% EC; EUP; 40974502)
63-17. Storage Stability	<1% and <3% degradation in glass containers and aluminum containers respectively after one year of storage at 21 C. [ORC NB Ref. 9377-27, SX-Book No. XV] (2 lb/gal or 26.6% EC; EUP; 40974502)
63-18. Viscosity	10.0 cps at 20 C [Brookfield Model DVII Viscosity Meter] (2 lb/gal or 26.6% EC; EUP; 40974502)
63-19. Miscibility	not diluted with petroleum solvents (2 lb/gal or 26.6% EC; EUP; 40974502)
63-20. Corrosiveness	not corrosive to glass or aluminum containers [ORC NB Ref. 9377-27, SX-Book No. XV] (2 lb/gal or 26.6% EC; EUP; 40974502)
63-21. Dielectric Breakdown Voltage	not used around electrical equipment (2 lb/gal or 26.6% EC; EUP; 40974502)

T = technical; EC = emulsifiable concentrate.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE CLETHODIUM 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</u>				
<u>Product Composition</u>				
61-2. Beginning Materials & Production Process	TGAI	R	X	40974501
61-3. Formation of Impurities	TGAI	R	X ³	40974501
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis	TGAI	CR	X	40974503
<u>Physical and Chemical Characteristics⁴</u>				
63-2. Color	TGAI	R	X	40974505
63-3. Physical State	TGAI	R	X	40974505
63-4. Odor	TGAI	R	X	40974505
63-5. Melting Point	TGAI	NA ⁵	X	
63-6. Boiling Point	TGAI	R	X	40974505
63-7. Density	TGAI	R	X	40974505
63-8. Solubility	TGAI or PAI	R	X	40974505
63-9. Vapor pressure	TGAI or PAI	R	X	40974505
63-10. Dissociation Constant	TGAI or PAI	R	X	40974505
63-11. Octanol/Water Partition Coefficient	PAI	CR	X	40974505
63-12. pH	TGAI	CR	X	40974505
63-13. Stability	TGAI	R	X	40974505
<u>Other Requirements:</u>				
64-1. Submittal of Samples	TGAI or PAI	CR	X ⁶	

1. Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Clethodum Manufacturing-Use Product".

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TABLE A. (Continued).

2. Test substance: MP = manufacturing-use product; PAI = purified active ingredient; TEP = typical end-use product; TGA1 = technical grade of the active ingredient.
3. Discussions of the following are required: the possible degradation of the ingredients in the product after its production but prior to its use, postproduction reactions between the ingredients in the product, possible migration of components of packaging materials into the pesticide, and possible carryover of contaminants from use of production equipment previously used to produce other products or substances.
4. 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 (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, pH, and stability). There are additional data requirements listed in Table B pertaining to physicochemical characteristics of the technical product which is also a manufacturing-use product.
5. Data on melting point are not required since the technical product is a liquid at room temperature.
6. If samples are required, the Agency will request them.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE CLETHODIM MANUFACTURING-USE PRODUCT.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</u>				
<u>Product Composition</u>				
61-1. Product Composition	MP	R	X ³	40974501
61-2. Beginning Materials & Production/Formulation Process	MP	R	X	40974501
61-3. Formation of Impurities	MP	R	X ⁴	40974501
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis	MP	CR		
62-2. Certified Limits	MP	R	X ⁵	40974503
62-3. Enforcement Method	MP	R	X	40974501
				40974503
<u>Physical and Chemical Characteristics⁶</u>				
63-2. Color	MP	R	X ⁷	40974505
63-3. Physical State	MP	R	X ⁸	40974505
63-4. Odor	MP	R	X ⁹	40974505
63-7. Density	MP	R	X ¹⁰	40974505
63-12. pH	MP	CR	X ¹¹	40974505
62-14. Oxidizing/Reducing Action	MP	CR	X ¹²	40974505
62-15. Flammability	MP	CR	X ¹³	
63-16. Explosibility	MP	CR		
63-17. Storage Stability	MP	R		
63-18. Viscosity	MP	CR		
63-19. Miscibility	MP	CR		
63-20. Corrosion Characteristics	MP	R		

(Continued, footnotes follow)

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TABLE B. (Continued).

Data Requirement	Test Substance	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes] [No]	Reference (MRID No.)
<u>Other Requirements:</u>				
64-1. Submittal of Samples	MP	CR	X ¹⁴	
<p>1. Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Clethodim Technical Grade of the Active Ingredient" for manufacturing-use product which consists only of the TGA1.</p> <p>2. Test substance: MP = manufacturing-use product; PAI = purified active ingredient; TEP = typical end-use product; TGA1 = technical grade of the active ingredient.</p> <p>3. Each impurity determined to be present at ≥0.1% by weight of the 90.5% technical must be individually listed on the Confidential Statement of Formula (CSF), and a nominal concentration must be provided for each of the impurities listed. For any impurity determined to be of toxicological concern, a nominal concentration and an upper certified limit are required, regardless of the amount present. In accordance with §158.175, an explanation as to how the certified limits for the active ingredient were determined is needed. A corrected CSF must be submitted on EPA Form 8570-4 (Rev. 2-85).</p> <p>4. Discussions of the following are required: the possible degradation of the ingredients in the product after its production but prior to its use, postproduction reactions between the ingredients in the product, possible migration of components of packaging materials into the pesticide, and possible carryover of contaminants from use of production equipment previously used to produce other products or substances.</p> <p>5. An acceptable explanation must be provided as to how the certified limits for the active ingredient were determined. If an acceptable explanation cannot be provided, more precise limits will be required. If new limits are required, a corrected CSF will need to be submitted on EPA Form 8570-4 (Rev. 2-85).</p> <p>6. 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 (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explosibility, storage stability, viscosity, miscibility, and corrosion characteristics). Additional data requirements regarding physicochemical properties of manufacturing-use product which contains only the technical grade of the active ingredient are listed in Table A, "Generic Data Requirements for the Clethodim Technical Grade of the Active Ingredient."</p>				

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TABLE B. (Continued).

7. Data or statements concerning the oxidizing/reducing action must be submitted.
8. Data or statements concerning flammability must be submitted.
9. Data or statements concerning explosibility must be submitted.
10. Data concerning storage stability must be submitted.
11. Data concerning viscosity must be submitted.
12. Data on miscibility must be submitted.
13. Data on storage stability are required.
14. If samples are required, the Agency will request them.

TABLE C. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE CLETHODIUM END-USE PRODUCT (2 LB/GAL OR 26.6% EC).

Data Requirement	Test Substance ¹	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	TEP	R	X	40974502
61-2. Beginning Materials & Production/Formulation Process	TEP	R	X	40974502
61-3. Formation of Impurities	TEP	R	X ²	40974502
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis	TEP	CR	X	40974502
62-2. Certified Limits	TEP	R	X	40974502
62-3. Enforcement Method	TEP	R	X	40974502
<u>Physical and Chemical Characteristics³</u>				
63-2. Color	TEP	R	X	40974502
63-3. Physical State	TEP	R	X	40974502
63-4. Odor	TEP	R	X	40974502
63-7. Density	TEP	R	X	40974502
63-12. pH	TEP	R	X	40974502
62-14. Oxidizing/Reducing Action	TEP	R	X	40974502
62-15. Flammability	TEP	CR	X	40974502
63-16. Explodability	TEP	R	X	40974502
63-17. Storage Stability	TEP	R	X	40974502
63-18. Viscosity	TEP	CR	X	40974502
63-19. Miscibility	TEP	CR	X	40974502
63-20. Corrosion Characteristics	TEP	CR	X	40974502
63-21. Dielectric Breakdown Voltage	TEP	CR	X	40974502

(Continued, footnotes follow)

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TABLE C. (Continued).

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

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

2. Discussions of the following are required: the possible migration of components of packaging materials into the pesticide and possible carryover of contaminants from use of production equipment previously used to produce other products or substances.

3. 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 end-use product (color, physical state, odor, specific gravity or density, pH, oxidizing or reducing action, flammability, explosibility, storage stability, viscosity, miscibility, corrosion characteristics, and dielectric breakdown voltage).

4. If samples are required, the Agency will request them.

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