



11-23-93

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

NOV 23 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil Reregistration. List A Chemical No. 081901; Case No.0097. Veterans-Ilex: Response to Chlorothalonil DCI for their 97.5% T/MP (EPA Reg. No. 61451-2) Data Requirements (GLN Nos. 61-2, 61-3, 62-1, 63-5, 63-7, and 63-13). (MRID Nos. 426833-01 to 426833-03; CBRS No. 11584; DP BARCODE: D189159)

FROM: Freshteh Toghrol, Ph.D., Chemist *F. Toghrol*
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

THRU: William J. Hazel, Ph.D., Section Head *W. J. Hazel*
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: Lois Rossi, Chief/Walter Waldrop, PM 71
Reregistration Branch
Special Review and Reregistration Division (H7508W)

Attached is a Phase 5 review of product chemistry data submitted by Compliance Services International on behalf of Veterans-Ilex Inc. for chlorothalonil 97.5% T/MP (EPA Reg. No. 61451-2). These data were reviewed by Dynamac Corporation under the supervision of Chemistry Branch II: Reregistration Support, Health Effects Division (CBRS, HED).

This Dynamac review has undergone secondary review in CBRS and has been revised to reflect the Branch policies.



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Summary of Conclusions:

The data gaps regarding description of starting materials and manufacturing process, discussion of the formation of impurities, melting point and density (GLN Nos. 61-2, 61-3, 63-5, and 63-7) for Veterans-Ilex's chlorothalonil 97.5% T are resolved.

The data gaps regarding preliminary analysis and stability (GLN Nos. 62-1 and 63-13) for Veterans-Ilex's chlorothalonil 97.5% T are outstanding. Additionally, polychlorinated dibenzo-p-dioxins and dibenzofurans in 97% T must be determined in seven separate batches, as set forth in the 06/87 DCI.

Note to PM:

The Veterans-Ilex's chlorothalonil 97.5% T was transferred from Griffin (EPA Reg. No. 1812-268) on 12/11/90. Because the manufacturing process has not changed since, data previously accepted concerning the physical and chemical properties of the Griffin technical will satisfy the requirements for the Veterans-Ilex technical. Also, please note that preliminary analysis data indicate that the registrant's TGAI contains higher levels of HCB as a manufacturing impurity than allowed by the Agency. CBRS recommends that SRRD consider suspending use of this product until HCB levels are lowered to a level consistent with a 0.05% maximum upper limit as set forth in the 1984 Guidance Document. Also note that the HCB analytical method is not sufficiently sensitive to enforce compliance with Agency requirements.

cc: Chlorothalonil S.F., R.F., F. Toghrol, List B File, Dynamac.
RDI: W. Hazel (11/8/93): M. Metzger (11/16/93): E. Zager (11/17/93)
H7509C:CBRS:F.Toghrol:F.T.:RM:804B:CM#2:(703)305-7887:11/4/93.

Final Report

CHLOROTHALONIL
Shaughnessy No. 081901
(DP Barcode D189159;
CBRS No. 11584; Case No. 0097)

TASK 4
Registrant's Response to Product
Chemistry Data Requirements

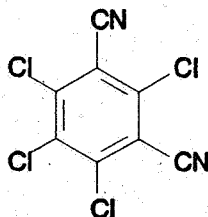
June 10, 1993

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
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2275 Research Boulevard
Rockville, MD 20850-3268

CHLOROTHALONIL



Shaughnessy No. 081901; Case 0097

(CBRS No. 11584; DP Barcode D189159)

Task 4

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to a Chlorothalonil Data Call-In (DCI) dated 7/31/91, Compliance Services International, on behalf of Veterans-Ilex, Inc., has submitted three volumes of product chemistry data (CBRS No. 11584; 1993; MRIDs 42683301-42683303) for the 97.5% technical (T; EPA Reg. No. 61451-2). The submitted data and our conclusions are discussed below.

We note that the Veterans-Ilex technical was transferred from the Griffin technical (EPA Reg. No. 1812-268) on 12/11/90. A letter authorizing Veterans-Ilex to reference Griffin data was included under CBRS No. 10018 (A. Aikens, dated 8/7/92). Because the manufacturing process has not changed since the transfer of the product from Griffin, and the technical product is similar, data previously accepted concerning the physical and chemical properties of the Griffin technical will satisfy the requirements for the Veterans-Ilex technical.

61-2. Description of Starting Materials and Manufacturing Process

Compliance Services International has submitted (1993; MRID 42683301) information concerning the suppliers and specifications of the starting materials along with a complete description of the manufacturing process for the Veterans-Ilex 97.5% T, which is presented in the Confidential Appendix. These data satisfy the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding the starting materials and the production process for the Veterans-Ilex 97.5% T (EPA Reg. No. 61451-2). No additional information is required.

61-3. Discussion of Formation of Impurities

Compliance Services International has submitted (1993; MRID 42683301) a discussion of impurities formed during the production of the Veterans-Ilex 97.5% T, which is presented in the Confidential Appendix. This information satisfies the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities for the 97.5% T (EPA Reg. No. 61451-2). No additional information is required.

62-1. Preliminary Analysis

Compliance Services International has provided (1993; MRID 42683302) preliminary analysis data for five batches of the Veterans-Ilex 97.5% T. These data are presented in the Confidential Appendix and do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis of the Veterans-Ilex 97.5% T (EPA Reg. No. 61451-2) because supporting validation data were not included for the methods used to determine the active ingredient and impurities of concern. In addition, only ca. 97% of the composition of technical chlorothalonil is accounted for in the preliminary analysis results. The registrant must identify and quantify all components present at greater than 0.1% in the 97.5% T. Additionally, polychlorinated dibenzo-p-dioxin and dibenzofurans in 97% T must be determined in seven separate batches, as set forth in the 06/87 DCI.

CBRS recommends that SRRD consider suspending use of this product until HCB levels are lowered to a level consistent with a 0.05% maximum upper limit as set forth in the 1984 Guidance Document. Note that the HCB analytical method is not sufficiently sensitive to enforce compliance with Agency requirements.

PHYSICAL AND CHEMICAL CHARACTERISTICS

Compliance Services International has submitted (1993; MRID 42683303) information concerning melting point, density, and storage stability for the Veterans-Ilex 97.5% T. These properties are presented in Table 1. We note that the registrant has submitted storage stability data (GLN No. 63-17; representing storage of the product in the commercial packaging at ambient conditions for one year) under Guideline 63-13; stability (GLN 63-13) is defined as the stability of the TGA1 at ambient and elevated temperatures and on exposure to sunlight, metal, and metal ions. The requirement regarding stability (GLN No. 63-13) is outstanding. The submitted data satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-5 and 63-7) concerning the melting point and density of the Veterans-Ilex 97.5% T (EPA Reg. No. 61451-2). The storage stability study (GLN 63-17) is in progress.

Table 1. Physical and chemical properties of the 97.5% T (EPA Reg. No. 61451-2) technical grade of the active ingredient (TGAi). Data are located in MRID 42683303.

Guidelines Reference No., 40 CFR §158.190; Name of Property		Description [Method]
63-5.	Melting point	251.5-254.1 C [OECD No. 102]
63-7.	Density, bulk density, or specific gravity	1.8324 ± 0.0155 g/cm ³ at 20 C [CIPAC Method MT3]
63-17.	Storage Stability	test in progress; the active ingredient is stable after 2 months of storage; analysis will be conducted at 6, 9 and 12 months to establish the stability of the active ingredient.

AGENCY MEMORANDUM

CBRS No.: 10018
 Subject: Chlorothalonil (081901) Reregistration. Guideline 63-12.
 From: A. Aikens
 To: W. Waldrop/A. Ertman
 Dated: 8/7/92
 MRID(s): none

MASTER RECORD IDENTIFICATION NUMBERS

Citations for the MRID documents referred to in this review are presented below.

42683301 Jacobson, Stephen O. (1993) Determination of the Chemical Characteristics of Chlorothalonil Technical: Product Chemistry - Discussion of Impurities. Unpublished compilation prepared by Compliance Services International. 35 p.

42683302 Jacobson, Stephen O. (1993) Determination of the Chemical Characteristics of Chlorothalonil Technical: Product Chemistry - Preliminary Analysis. Unpublished study prepared by Compliance Services International. 55 p.

42683303 Jacobson, Stephen O. (1993) Determination of the Chemical Characteristics of Chlorothalonil Technical: Product Chemistry - Physical Properties. Unpublished study prepared by Compliance Services International. 65 p.

Case No. 0097
Chemical No. 081901

Case Name: Chlorothalonil
Registrant: Veterans-Ilex, Inc.
Product(s): 97.5% T (EPA Reg. No. 61451-2)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? *	MRID Number
61-1	Product Identity and Disclosure of Ingredients	N	
61-2	Starting Materials and Manufacturing Process	Y	42683301
61-3	Discussion of Formation of Impurities	Y	42683301
62-1	Preliminary Analysis	N ^b	42683302
62-2	Certification of Ingredient Limits	N	
62-3	Analytical Methods to Verify the Certified Limits	N	
63-2	Color	Y ^c	
63-3	Physical State	Y ^c	
63-4	Odor	Y ^c	
63-5	Melting Point	Y	42683303
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	42683303
63-8	Solubility	Y ^c	
63-9	Vapor Pressure	Y ^c	
63-10	Dissociation Constant	Y ^c	
63-11	Octanol/Water Partition Coefficient	Y ^c	
63-12	pH	Y ^d	
63-13	Stability	N	
63-14	Oxidizing or Reducing Action	N	
63-15	Flammability	N/A	
63-16	Explosibility	N	
63-17	Storage Stability	N ^e	42683303
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	N	

* Y = Yes; N = No; N/A = Not Applicable. Data were submitted in response to the Chlorothalonil Data Call-In (DCI) dated 7/31/91. Data requirements followed by MRID citations reflect conclusions determined in this document (CBRS No. 11584).

^b Supporting statements of validation are required for the methods used to determine the active ingredient and impurities of concern. In addition, only ca. 97% of the composition of technical chlorothalonil is accounted for in the preliminary analysis results. The registrant must identify and quantify all components present at greater than 0.1% or of toxicological concern in the 97.5% T. Additionally, polychlorinated dibenzo-p-dioxin and dibenzofurans in 97% T must be determined in seven separate batches, as set forth in the 06/87 DCI. CBRS recommends that SRRD consider

suspending use of this product until HCB levels are lowered to a level consistent with a 0.05% maximum upper limit as set forth in the 1984 Guidance Document. Also note that the HCB analytical method is not sufficiently sensitive to enforce compliance with Agency requirements.

^c Because the manufacturing process has not changed since the transfer of the product from Griffin, and the technical product is similar, data previously accepted concerning the physical and chemical properties of the Griffin TGA/PAI will satisfy the requirements for the Veterans-Ilex technical.

^d CBRS No. 10018, dated 8/7/92, by A. Aikens.

^e The storage stability study is in progress.

CONFIDENTIAL

CHLOROTHALONIL (VETERANS-ILEX; CBRN NO. 11584)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDIX

4 Page(s)

Confidential Appendix to the Scientific Review of a Registration Standard Follow up Report for the pesticide chlorothalonil by the Chemistry Branch II Reregistration Support [Confidential FIFRA Trade Secret/CBI].

Chlorothalonil

Page ____ is not included in this copy.

Pages 10 through 13 are not included.

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 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.
