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

Lead

OCT 12 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Chlorothalonil: Chemical 081901: Case 0097:
Product Chemistry Data: Veterans Ilex, Inc.: DP
Barcodes D202277 & D205005: CBRS Nos. 13592 &
13953: MRID Nos. 43196101 & 43264801.

From: William Smith, Chemist *William D. Smith*
Chemistry Pilot Review Team
Chemistry Branch II-Reregistration Support (CBRS)
Health Effects Division (HED) 7509C

Through: Edward Zager, Chief *EZ*
Chemistry Branch II - Reregistration Support
Health Effects Division

To: Walter Waldrop/Andrew Ertman
Reregistration Branch
Special Review and Reregistration Division 7508W

Attached is a review of chlorothalonil product chemistry data submitted by Compliance Services International on behalf of Veterans Ilex, Inc. This information was reviewed by Dynamac Corporation under supervision of CBRS, HED. The data assessment has undergone secondary review in the Branch and has been revised to reflect Branch policies.

We have included a product chemistry data summary, which contains the present status of reregistration data requirements for the registrant's TGAI (EPA Reg. No. 61451-2). Also, please note that confidential business information has been discussed in a separate attachment.



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Attachment 1: Registrant's Response to Product Chemistry Data Requirements: D202277 & D205005: 09/13/94.

Attachment 2: Confidential Appendix to D202277 & D205005.

cc (with attachments): W. Smith, Reregistration Standard File, SF, Dynamac Corp.

cc (without attachment 1): RF, Circ.

7509C:CB-II:WOS:wos:Rm805A:CM#2:X5353: 10/05/94

RDI: B. Cropp-Kohlligian 10/05/94, P. Deschamp 10/05/94, T. Edwards 10/05/94, C. Olinger 10/05/94, M. Metzger 10/06/94, E. Zager 10/06/94.

DYNAMAC
CORPORATION
Environmental Services

Final Report

CHLOROTHALONIL
Shaughnessy No. 081901
Case No. 0097
(CBRS Nos. 13592 & 13953,
DP Barcodes D202277 & D205005)

TASK 4
Registrant's Response to Product
Chemistry Data Requirements

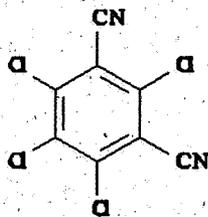
September 13, 1994

Contract No. 68-D2-0053

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

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

CHLOROTHALONIL



Shaughnessy No. 081901; Case 0097

(CBRS No. 13592; DP Barcode D202277)

(CBRS No. 13953; DP Barcode D205005)

Task 4

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to reregistration data requirements, Compliance Services International, on behalf of Veterans Ilex, Inc. has submitted two volumes of product chemistry data and a Confidential Statement of Formula (MRID 43196101, MRID 43264801 and CSF dated 6/7/94).

Information submitted in MRID 43196101 (CBRS No. 13592) outlines changes which have been incorporated into the manufacturing process to reduce HCB levels to below the 0.05% maximum upper certified limit set by the Chlorothalonil Guidance Document dated 9/84. Results of a non-GLP analysis of chlorothalonil produced by the current manufacturing process were also reported. Five batches of the 98% T/TGAI produced in 1993 were analyzed for the active ingredient and HCB by Veterans Chemical Company (parent company of Veterans Ilex) using a newly developed HPLC method for the determination of HCB. These data indicated that HCB levels were within the allowable limits; however, the HPLC method used had not been validated. The registrant has submitted an amended report, which includes re-analysis of the 1993 batches for the active ingredient and impurities of concern, including HCB, using GC/FID methods. Results from the re-analysis of the 1993 samples produced by the current process (MRID 43264801; CBRS No. 13953) are evaluated in this document.

Our conclusions concerning the adequacy of these data are provided below for each guideline number addressed in the submissions.

GLN 61-1 (product identity) and GLN 62-2 (certified limits)

Compliance Services International has submitted an updated CSF dated 6/7/94 based on preliminary analysis of batches produced in 1993 (see GLN 62-1). These data are presented in the Confidential Appendix and do not satisfy the requirements of 40 CFR §158.155 and §158.175 (Guideline Reference Nos. 61-1 and 62-2) regarding product identity and certified limits of the Veterans Ilex 98% T (EPA Reg. No. 61451-2) because the registrant must confirm that the "other unidentified impurities" are present individually at less than 0.1%; otherwise, the registrant will be required to identify these impurities and provide nominal concentrations and upper certified limits. In addition,

[REDACTED] (see reviews of these data in CBRS No. 9952, D178734, 9/24/92, S. Funk and CBRS No. 12193, D192977, 8/23/94, L. Cheng). Nominal concentrations and upper certified limits must be provided only for dioxins and dibenzofurans detected at levels above the Agency-specified LOQs. Additional data are required for GLNs 61-1 and 62-2.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

GLN 61-2 (starting materials and manufacturing process)

The registrant has outlined (1994; MRID 43196101) changes that have been incorporated into the manufacturing process to reduce the HCB levels to below the 0.05% maximum upper certified limit set by the Chlorothalonil Guidance Document. These modifications to the manufacturing process are discussed in the Confidential Appendix and satisfy the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding starting materials and the manufacturing process for the Veterans Ilex 98% T (EPA Reg. No. 61451-2). No additional data are required for GLN 61-2.

GLN 62-1 (preliminary analysis)

Compliance Services International has submitted (1994; MRID 43264801) data reflecting preliminary analysis of five batches of the 98% T manufactured in 1993 by the current manufacturing process. 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 98% T (EPA Reg. No. 61451-2) because no validation data were submitted in support of the analytical methods used for the determination of the active ingredient and its related impurities. We note that these methods may be suitable for enforcement purposes (GLN 62-3) if complete validation data are submitted. Additional data are required for GLN 62-1.

AGENCY MEMORANDA

CBRS No(s): 9952
DP Barcode(s): D178734
Subject: Chlorothalonil: Determination of Chlorinated Dibenzo-p-Dioxins and Dibenzofurans..
From: S. Funk
To: L. Rossi/A. Ertman
Dated: 9/24/92
MRID(s): 42321601

CBRS No(s): 12193
DP Barcode(s): D192977
Subject: Chlorothalonil. Case No. 0097. Registrant's Response to Dioxin/Furans Data Requirement.
From: L. Cheng
To: Andrew Ertman
Dated: 8/23/94
MRID(s): 42779301

MASTER RECORD IDENTIFICATION NUMBERS

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

43196101 Jacobson, S. (1994) Supplemental Report: Determination of the Chemical Characteristics of Chlorothalonil Technical: Product Chemistry - Preliminary Analysis. Report No. VTNS-9202-62. Unpublished study prepared by Compliance Services International for Veterans Ilex, Inc. 70 p.

43264801 Jacobson, S. (1994) Amended Supplemental Report: Determination of the Chemical Characteristics of Chlorothalonil Technical: Product Chemistry - Preliminary Analysis. Report No. VTNS-9202-62. Unpublished study prepared by Compliance Services International for Veterans Ilex, Inc. 77 p.

Case No. 0097
Chemical No. 081901

Case Name: Chlorothalonil
Registrant: Veterans Ilex, Inc.
Product(s): 98% T (EPA Reg. No. 61451-2)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Requirement Fulfilled? ^a	MRID Number
61-1	Product Identity and Disclosure of Ingredients	N ^b	CSF dated 6/7/94
61-2	Starting Materials and Manufacturing Process	Y	43196101
61-3	Discussion of Formation of Impurities	Y	
62-1	Preliminary Analysis	N ^c	43264801
62-2	Certification of Ingredient Limits	N ^b	CSF dated 6/7/94
62-3	Analytical Methods to Verify the Certified Limits	N ^d	
63-2	Color	Y	
63-3	Physical State	Y	
63-4	Odor	Y	
63-5	Melting Point	Y	
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	
63-8	Solubility	Y	
63-9	Vapor Pressure	Y	
63-10	Dissociation Constant	Y	
63-11	Octanol/Water Partition Coefficient	Y	
63-12	pH	Y	
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	
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	N	

^a Y = Yes; N = No; N/A = Not Applicable. Data were submitted in response to CBRS No. 11584, D189159, dated 11/23/93, by F. Toghrol. Data requirements followed by an MRID citation reflect conclusions determined in this document (CBRS No. 13592; D202277, and CBRS No. 13953; D205005).

^b The registrant must confirm that the "other unidentified impurities" are present individually at less than 0.1%; otherwise, the registrant will be required to identify these impurities and provide nominal concentrations and upper certified limits. In addition, [REDACTED]

[REDACTED] (CBRS No. 9952, D178734, 9/24/92, S. Funk and CBRS No. 12193, D192977, 8/23/94, L. Cheng). Nominal concentrations and upper certified limits must be provided only for dioxins and dibenzofurans detected at levels above the Agency-specified LOQs.

^c Validation data must be submitted in support of the analytical methods used for the determination of the active ingredient and its related impurities.

^d Methods submitted under preliminary analysis (GLN 62-1) may be suitable for enforcement purposes if complete validation data are submitted.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED