

US EPA ARCHIVE DOCUMENT



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

8-23-94

AUG 23 1994

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Chlorothalonil. Case No. 0097. Registrant's Response to Dioxin/Furans Data Requirement. MRID No. 42779301. CBRS No. 12193. DP Barcode: D192977

FROM: Leung Cheng, Chemist *Lee Cheng*
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Attached is a review of response to S. Funk's memorandum dated 9/24/92 (CBRS No. 9952) submitted by the registrant for reregistration. This information was reviewed by Dynamac Corporation under the supervision of CBRS, HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies.

The registrant must submit an updated Confidential Statement of Formula for their technical material to incorporate the results of the dioxin/dibenzofuran analyses following confirmatory analysis for one component. See the Confidential Appendix for details.

We also defer to TOX Branch for their toxicological assessment of the levels of dibenzodioxin/furan found.

If you need additional information, please advise.

Confidential Appendix: Dynamac review of Registrant's Response to Product Chemistry Data Requirements (4 pages)

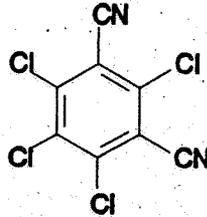
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cc(with Confidential Appendix):SF, RF, Reg Std File, Cheng, Dioxins, Kocialski (CCB), Rowland (TOX)
RDI:ARRathman:8/23/94:MSMetzger:8/23/94
7509C:CBRS:LCheng:CM#2:RM810D:8/22/94:CHLOROTHALONIL.001



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CONFIDENTIAL

CHLOROTHALONIL



Shaughnessy No. 081901; Case 0097

(CBRS No. 12193; DP Barcode D192977)

Task 4

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to an Agency Memorandum (CBRS No. 9952, D178734, dated 9/24/92, by S. Funk) concerning analytical chemistry data on polyhalogenated dibenzo-p-dioxins/dibenzofurans, Compliance Services International, an authorized representative for Veterans Ilex, Inc. has submitted a report (MRID 42779301, 5 volumes) entitled "Analysis of Technical Chlorothalonil for Residues of Halogenated Dibenzo-p-dioxins and Dibenzofurans."

CBRS No. 9952, dated 9/24/92 determined that the sample collection and analysis protocols submitted with the dioxin study are satisfactory according to the 6/87 DCI and the Guidelines for the Determination of Dibenzo-p-Dioxins and Dibenzofurans in Commercial Products (EPA-560/5-87/007). The Agency Memorandum tentatively concludes that none of the chlorinated dibenzo-p-dioxins specified in the 6/87 DCI are present at or above the EPA LOQ, and that the following chlorinated dibenzofurans are present at the accompanying maximum concentrations: [REDACTED]

[REDACTED]. CBRS No. 9952, dated 9/24/92 notes that these conclusions are not definitive and are subject to change upon the evaluation of the following additional information:

(i) Supporting raw data including chromatograms, retention times, and ion areas. All calibration, sample, blank, matrix spike, and duplicate sample chromatograms and raw data must be included to verify the concentrations reported for the samples and the results reported for the quality controls.

(ii) Information concerning the production period (time) and the fraction of annual production represented by the samples collected. The dates of production of the sampled lots and what percentage of the yearly production these represent should be included. In addition, the operating conditions of the facility during production of the sampled lots, and any unusual events such as high or low production rates, out-of-specification materials, or other abnormalities should be discussed.

CBRS No. 9952, dated 9/24/92 concludes that if the review of the raw data substantiates the results previously reported, the registrant will be required to submit a modified Confidential

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Statement of Formula (CSF) incorporating those dibenzofurans which were detected above the EPA LOQs.

CONCLUSIONS and RECOMMENDATIONS

Supplemental information concerning the production batches sampled and the raw data of the dioxin results reviewed under CBRS No. 9952 were submitted (MRID 42779301) for the Veterans Ilex chlorothalonil technical. Adequate information was supplied concerning the production period of the sampled batches and their representation of the annual production.

The review of the submitted raw data does not substantiate the results reported under CBRS No. 9952. As presented in CBRS No. 9952, [REDACTED]

[REDACTED] See Detailed Considerations for further explanation.

The registrant must submit a modified CSF which includes nominal concentrations and upper certified limits for the [REDACTED] equivalent confirmatory column prior to establishing certified limits for this impurity.

DETAILED CONSIDERATIONS

Compliance Services International, an authorized representative for Veterans Ilex, Inc. has resubmitted a dioxin study (MRID 42779301, 5 volumes) to include supplemental information requested by CBRS No. 9952, dated 9/24/92. The raw data (chromatograms, retention times, and ion areas) for all samples, instrument calibrations, and all blanks, duplicates, and matrix spike samples were submitted.

The registrant has supplied information concerning the production period during which the lots were sampled. The production dates of the sampled lots are listed in Table 1.

Table 1. Sampling dates.

Batch Number	Production Date
910323	09/03/91
910324	09/10/91
910325	09/26/91
910326	10/03/91
910327	10/12/91
910328	10/19/91
910329	10/30/91

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Chlorothalonil

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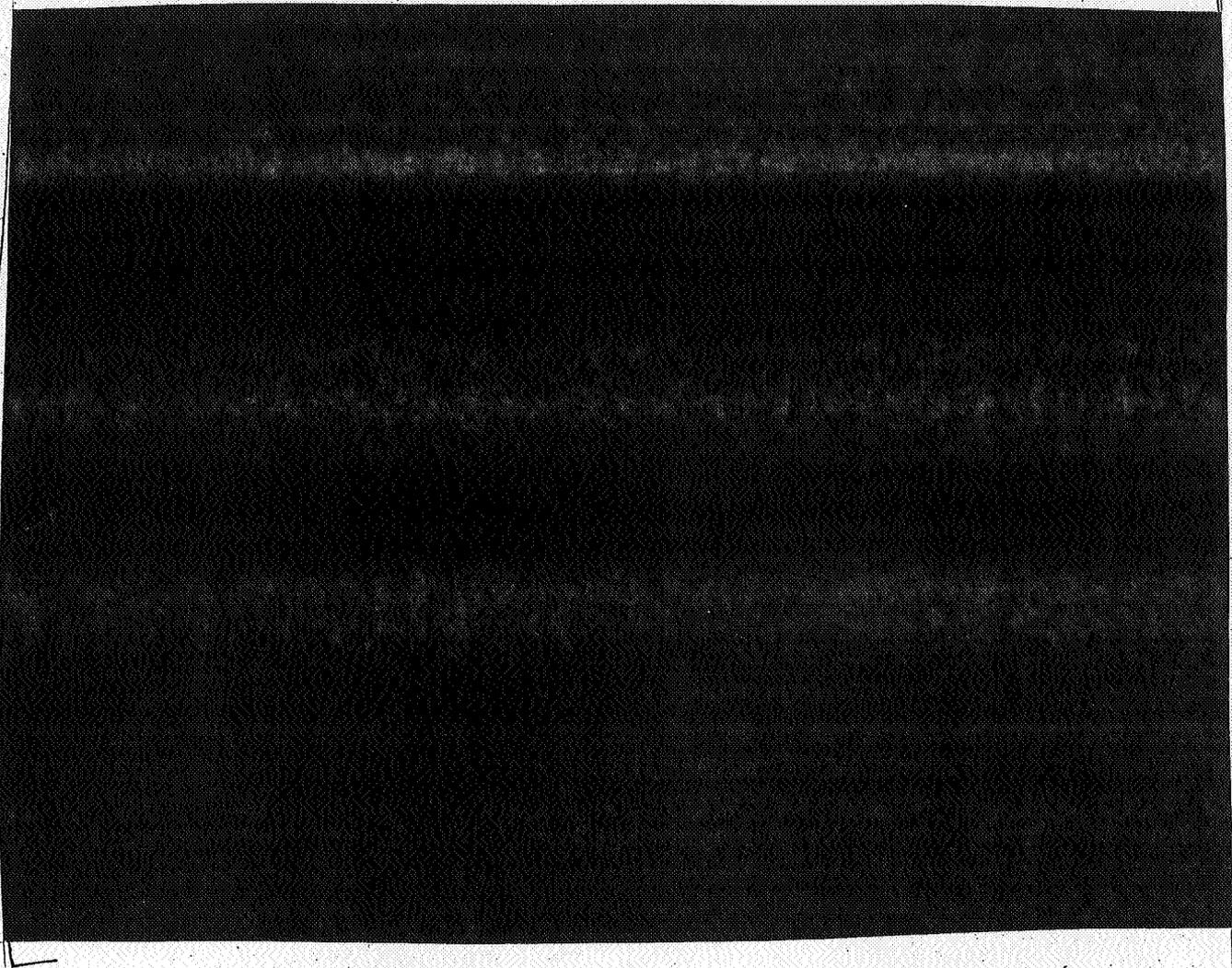
Pages _____ through _____ are not included.

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.

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MASTER RECORD IDENTIFICATION DOCUMENTS

A citation for the MRID document referred to in this review is presented below.

42779301 Jacobson, Stephen O. (1993) Analysis of Technical Chlorothalonil for Residues of Halogenated Dibenzo-p-Dioxins and Dibenzofurans. Unpublished study submitted by Compliance Services International for Veterans Ilex, Inc. 5 volumes, 1643 pp.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED