

US EPA ARCHIVE DOCUMENT

CONFIDENTIAL

12-2-94



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

DEC 2 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM (CONFIDENTIAL)

Subject: Chlorothalonil (Chemical 081901, List A, Case 0097).
Determination of Polychlorinated Dioxins and
Dibenzofurans. DP Barcode D207699, CBRS No. 14466,
MRID 43363301.

From: Stephen Funk, Ph.D., Chemist *J. R. Funk*
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

Through: Andrew Rathman, Section Head *ARR*
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

To: Walter Waldrop, CRM 71\Andrew Ertman
Reregistration Section 2
Accelerated Reregistration Branch
Special Review and Reregistration Division (7508W)

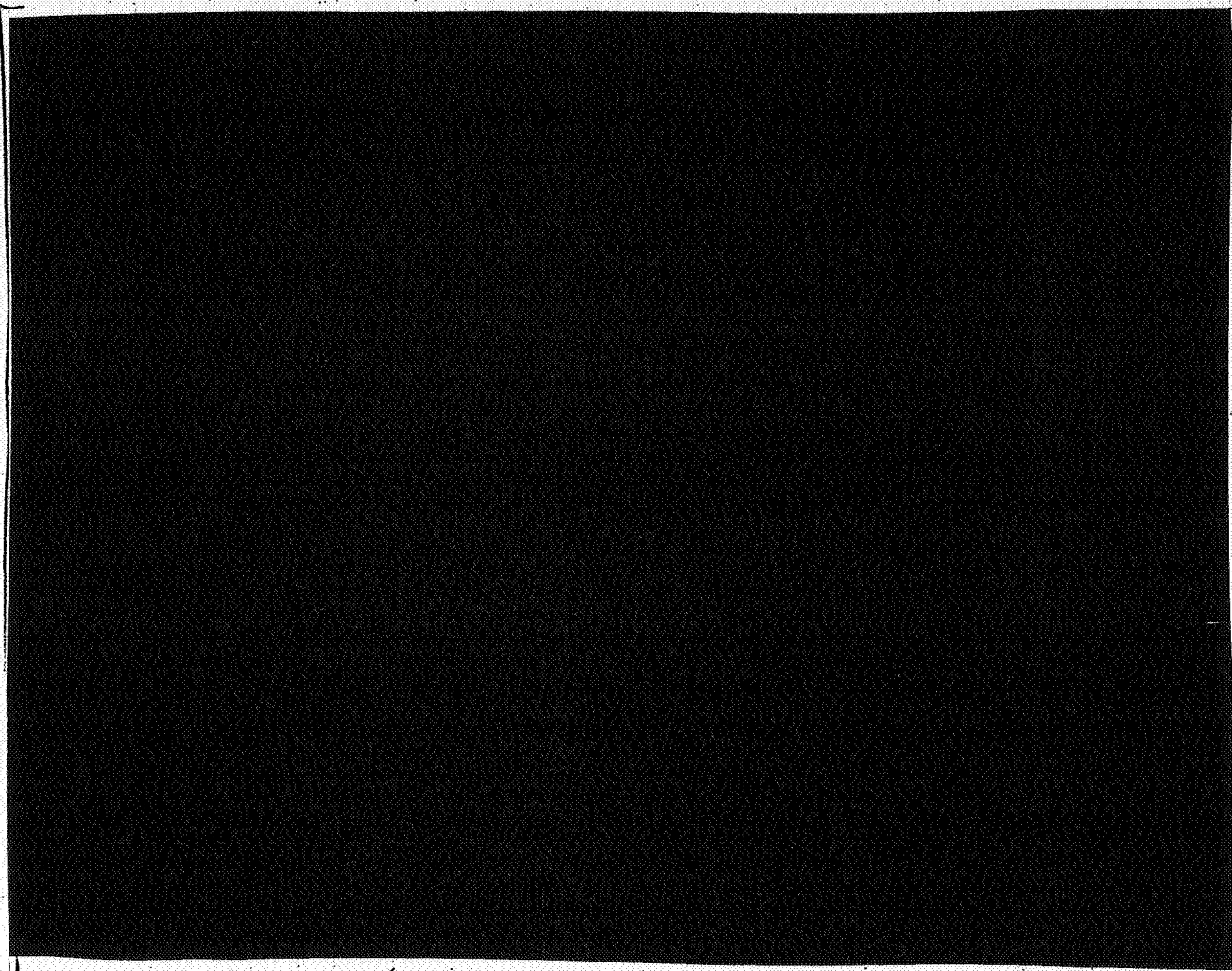
In response to a 6/87 DCI for product chemistry data on polyhalogenated dibenzo-p-dioxins/dibenzofurans in chlorothalonil, ISK Biotech Corporation previously submitted a report (W. Smith, CBRS No. 13029, DP Barcode D197984, MRID 43052701, 08/15/94) entitled "Batch Assays of Technical Chlorothalonil (EPA Reg. No. 50534-7) for Polyhalogenated Dibenzop-Dioxins/Dibenzofurans; Chlorothalonil Unit I Samples." It was concluded that no 2,3,7,8-substituted tetra- through heptachlorinated dibenzo-p-dioxins or dibenzofurans are present in technical chlorothalonil produced at Unit I at levels equal to or greater than the EPA-required Limits of Quantitation (LOQs), as defined in the 6/87 DCI. It was noted that a matrix spike was not included as part of the method validation as required by the *Guidelines for the Determination of Halogenated Dibenzop-Dioxins and Dibenzofurans in Commercial Products (EPA-560/5-87/007)* and by the 06/87 DCI. Because all other supporting validation data



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

were found to be adequate, it was concluded that the absence of the matrix spike did not compromise the study. The registrant was encouraged to include a matrix spike as part of the supporting validation data for chlorothalonil produced at the Unit II facility.

The Agency required (CBRS No. 9853, D177726, 6/3/92, S. Funk) that chlorothalonil technical samples manufactured at both of ISK Biotech Corporations's manufacturing facilities (Chlorothalonil Unit I and Chlorothalonil Unit II, formerly Daconil I and Daconil II) be analyzed for polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDDs and PCDFs). The registrant now reports upon the analysis of technical chlorothalonil at Unit II in a document (CBRS No. 14466, DP Barcode D207699, MRID 43363301) entitled "Batch Assays of Technical Chlorothalonil (EPA Reg. No. 50534-7) for Polyhalogenated Dibenzop-Dioxins/Dibenzofurans; Final Report - Chlorothalonil Unit II Samples." The registrant claims data confidentiality for the current submission.



INFO NOT INCLUDED -
CLAIMED CONFIDENTIAL

Chlorothalonil

Page _____ is not included in this copy.

Pages 3 through 14 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.

REGISTRANT - STAMPED "CONFIDENTIAL"

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.
