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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil Reregistration: List A Case No. 0097:
Chemical No. 081901: ISK-Biotech's Submission of Banana
Field Trial Data: DP Barcode D204405: CBRS No. 13888:
MRID No. 43251601.

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THROUGH: Edward Zager, Chief *Edward Zager*
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TO: Walter Waldrop/Andrew Ertman (PM-71)
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Attached is a review of chlorothalonil residue chemistry data submitted in response to the 7/31/91 Chlorothalonil DCI. 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.

The registrant has satisfactorily responded to the requirement to modify the labels for all products registered for use on bananas targeted for import to the U.S. to specify a 2-day PHI. In lieu of the establishment of a 2-day PHI, the registrant has submitted field trial data, which support the existing use pattern (0-day PHI) and tolerances on bananas (0.5 ppm) and banana pulp (0.05 ppm).

No further data are required to support the reregistration of chlorothalonil uses on bananas.



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Attachment: Registrant's Response to Residue Chemistry Data Requirements; D204405; 9/27/94.

cc(with attachment): W. Smith (CBRS), Chlorothalonil Reg. Std. File, SF, RF, circulation.

7509C:CBRS:WOS:wos:CM#2:Rm805A:703-305-5353: 10/12/94

RDI: P. Deschamp 10/12/94, T. Edwards 10/12/94, S. Knizner 10/12/94, C. Olinger 10/12/94, M. Metzger 10/13/94, E. Zager 10/13/94.

Final Report

CHLOROTHALONIL
Shaughnessy No. 081901
Case No. 0097
(CBRS No. 13888, DP Barcode
D204405)

TASK 4
Registrant's Response to Residue
Chemistry Data Requirements

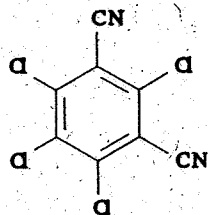
September 27, 1994

Contract No. 68-D2-0053

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

Submitted by:
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CHLOROTHALONIL



Shaughnessy No. 081901; Case 0097

(CBRS No. 13888; DP Barcode D204405)

Task 4

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

A Data Call-In Notice (DCI) dated 7/31/91 required the registrant to modify the labels for all products registered for use on bananas targeted for import to the U.S. to specify a 2-day PHI. In lieu of the establishment of a 2-day PHI, ISK Biosciences Corporation (formerly ISK Biotech Corporation) chose to support the existing use pattern (0-day PHI) and submitted field data for bananas from trials conducted in Colombia (1993; MRID 42875919), and Costa Rica, Guatemala, Honduras, and Panama (1994; MRID 43251601). Data from MRID 42875919 have been reviewed by CBRS (CBRS No. 12428, DP Barcode D194480, W. Smith, 8/5/94). Data from MRID 43251601 are reviewed in this document for adequacy in fulfilling data requirements for the reregistration of chlorothalonil.

The qualitative nature of the residues in plants is adequately understood. The residues of concern are chlorothalonil and its 4-hydroxy metabolite. Tolerances for residues in/on raw agricultural commodities are expressed in terms of the combined residues of chlorothalonil (2,4,5,6-tetrachloroisophthalonitrile) and its hydroxy metabolite, SDS-3701 (4-hydroxy-2,5,6-trichloroisophthalonitrile) [40 CFR §180.275 (a) and (b)]. An adequate GC/electron capture detection (ECD) enforcement method is available for determining residues of chlorothalonil and SDS-3701 in/on plant commodities and is listed as Method I in the Pesticide Analytical Manual (PAM), Vol. II.

Codex MRLs have been established for residues of chlorothalonil *per se* in several plant commodities. A Codex MRL (Step 8) is proposed for bananas at a level lower than the U.S. tolerance. Issues pertaining to compatibility of U.S. tolerances with Codex MRLs will be addressed at the issuance of the RED.

CONCLUSIONS

The submitted banana field trial data, in conjunction with the previously reviewed data (see CBRS No. 12428, DP Barcode D194480, W. Smith, 8/5/94), support a 0-day PHI for bananas targeted for import to the U.S., and support the established tolerances of 0.5 ppm on bananas and 0.05 ppm on banana pulp. Residues of chlorothalonil, SDS-3701, and HCB were nondetectable (<0.01 , <0.01 , <0.00025 ppm, respectively) in/on banana pulp and whole bananas harvested on the day of the last of 15 or 20 aerial applications of the 6 lb/gal FIC formulation at 1x the maximum single application rate. No additional field trial data for bananas are required.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Samples of whole bananas and banana pulp from the submitted field trials were analyzed using a GC/ECD method which is a modification of Method I in PAM Vol. II. Briefly, samples were homogenized in acetone:10 N H_2SO_4 (95:5, v:v) and vacuum filtered. The filtrate was then divided for separate determinations of chlorothalonil and HCB, and SDS-3701. For the determination of chlorothalonil and HCB, the filtrate was diluted with water and partitioned twice with petroleum ether. The combined petroleum ether extracts were evaporated to dryness and redissolved in methylene chloride:hexane (20:80, v:v). Residues were then cleaned up on a Florisil column; HCB residues were eluted with methylene chloride:hexane (20:80, v:v) and chlorothalonil residues were eluted with methylene chloride:hexane:acetonitrile (50:48.5:1.5, v:v:v). Eluants were concentrated and dissolved in toluene for GC/ECD analysis. For the determination of SDS-3701, the acidic acetone filtrate was concentrated to remove the acetone, 0.4 M $NaHCO_3$ was added, and the pH of the extract was adjusted to 4.5. The extract was then partitioned twice with petroleum ether. The aqueous phase was adjusted to pH 2 and sufficient sodium chloride was added to obtain a 30% solution. The residues were then partitioned into diethyl ether (twice), evaporated to dryness, and derivatized with diazomethane (in a solution of diethyl ether). The solvent was evaporated and the derivatized residues were dissolved in methylene chloride, cleaned up on an alumina column, concentrated, and dissolved in toluene for GC/ECD analysis.

The registrant submitted concurrent method recovery data from samples of untreated whole bananas and banana pulp fortified with chlorothalonil, SDS-3701, and HCB. The method recovery data are presented in Table 1. These data indicate that the GC/ECD method is adequate for collecting data on residues of chlorothalonil, HCB, and SDS-3701 in/on whole bananas and banana pulp.

Table 1. Concurrent method recovery of chlorothalonil, SDS-3701, and HCB from fortified untreated samples of whole bananas and banana pulp.

Commodity	Compound	Fortification levels (ppm) ^a	% Recovery
Whole banana	chlorothalonil	0.030, 0.50	83-103
	SDS-3701	0.030, 0.20	70-113
	HCB	0.0005, 0.050	86-120
Banana pulp	chlorothalonil	0.030, 0.10	83-110
	SDS-3701	0.030, 0.10 (4), 0.20 (1)	78-120
	HCB	0.0005, 0.010	84-110

^a Five samples at each fortification level, unless otherwise indicated in parentheses.

Storage Stability Data

Samples from the banana field trials were shipped to the analytical laboratory (Ricerca, Painesville, OH) and were received within 3 days of harvest. The samples were not shipped frozen, in accordance with typical shipping practices for commercial banana importation. Upon receipt by the analytical laboratory, the pulp was removed from half the samples. All the samples (whole bananas and pulp) were stored frozen until completion of analyses; analyses were completed within 2-5 months of harvest.

Previously submitted storage stability data for cherries, indicating that residues of chlorothalonil, SDS-3701, and HCB are stable in/on cherries for up to 4 years, may be translated to support the banana field trial data (see CBRS No. 12403, DP Barcode D194462, W. Smith, 8/5/94).

Magnitude of the Residue in Bananas

A tolerance of 0.5 ppm has been established for the combined residues of chlorothalonil and its metabolite SDS-3701 in/on bananas (not more than 0.05 ppm in edible pulp) [40 CFR §180.275(a)].

The 6 lb/gal FIC formulation (BRAVO 720) is registered for use on bananas targeted for import to the U.S. Applications to bananas are to be made at 0.9-1.5 lb ai/A/application in 2-5 gal/A. Applications may be repeated at 7- to 35-day intervals. A maximum number of applications or a maximum seasonal application rate is not specified. We note that the maximum application rate was incorrectly reported as 9.2 lb ai/A in a previous review (CBRS No. 12428, DP Barcode D194480, 8/5/94).

ISK Biosciences submitted data (1994; MRID 43251601) depicting residues of chlorothalonil, SDS-3701, and HCB in/on bananas harvested on the day of the last of 20 (15 in one trial) aerial applications of the 6 lb/gal FIC formulation at 1.5 lb ai/A/application with a 7- to 11-

day retreatment interval. The formulation used (Batch Number 022015GLP) contained 53.8% chlorothalonil, 0.255% PCBN, and 0.018% HCB. Five tests were conducted in Costa Rica, Guatemala, Honduras (two trials), and Panama.

One untreated and two treated samples each of whole banana and pulp were collected from each trial site and were assayed for residues using the GC/ECD method described earlier in this report. Residues were nondetectable (<0.01 ppm chlorothalonil and SDS-3701, and <0.00025 ppm HCB) in/on the untreated and the treated samples.

The submitted banana field trial data, in conjunction with the previously reviewed data (see CBRS No. 12428, DP Barcode D194480, W. Smith, 8/5/94), support a 0-day PHI for bananas targeted for import to the U.S., and support the established tolerances of 0.5 ppm on bananas and 0.05 ppm on banana pulp. Residues of chlorothalonil, SDS-3701, and HCB were nondetectable (<0.01, <0.01, <0.00025 ppm, respectively) in/on banana pulp and whole bananas harvested on the day of the last of 15 or 20 aerial applications of the 6 lb/gal EC formulation at 1x the maximum single application rate. No additional field trial data for bananas are required.

EPA MEMORANDA CITED IN THIS REVIEW

CBRS Nos.: 12393, 12403, 12420-12423, 12428-12432, 12462, 12475-12480, 12618, 13586-13590
DP Barcodes: D194461, D194462, D194480-D194488, D194685, D194690-D194693, D194695, D194696, D195417, D202280, D202282, D202285, D202288, D202290
Subject: Chlorothalonil Reregistration: List A Case No. 0097, Chemical No. 081901: ISK-Biotech's Submission of Residue Chemistry Data in Response to 7/30/91 DCI: Analytical Methods, Storage Stability, Label Amendments, Field Trial Data and Processing Study
From: W. Smith, CBRS, HED
To: W. Waldrop/A. Ertman and C. Giles-Parker/J.Stone
Dated: 8/5/94
MRID(s): 42875908-42875927

MASTER RECORD IDENTIFICATION NUMBERS

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

43251601 King, C. (1994) Determination of Residues of Tetrachloroisophthalonitrile (Chlorothalonil, SDS-2787), SDS-3701, and HCB on Bananas-1992: Lab Project Number: 5529-92-0515. Unpublished study prepared by Ricerca, Inc. 869 p.