MEMORANDUM

SUBJECT: REVIEW OF A FOLIAR RESIDUE DISSIPATION STUDY PROTOCOL PROPOSED TO FULFILL GUIDELINE 132-1a AND SUPPORT THE REREGERISTRATION OF CHLOROTHALONIL

FROM: Jeff Evans, Biologist
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TO: Andrew W. Ertman, PM Team 71
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THRU: Alan P. Nielsen, Section Head
Reregistration Section
Larry C. Dorsey, Acting Chief
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Please find the OREB review of ....

DP Barcode: D179406

Pesticide Chemical Code: 081901

EPA Reg. No.: 50534-138

EPA MRID No.: N/A

Review Time: 2 Days

PHED: N/A
I. INTRODUCTION:

ISK Biotech Corp. has submitted a protocol for a foliar dislodgeable residue study in response to a generic Data Call-In (DCI) for chlorothalonil issued 07/31/91. In the DCI, the following data were required to support the reregistration of chlorothalonil:

158.390 Reentry Protection
132-1a Foliar Dissipation
133-3 Dermal Exposure
133-4 Inhalation Exposure

Mixer/Loader/Applicator Exposure Monitoring
231 Estimation of Dermal Exposure at Outdoor Sites
232 Estimation of Inhalation Exposure at Outdoor Sites
233 Estimation of Dermal Exposure at Indoor Sites
234 Estimation of Inhalation Exposure at Indoor Sites

Chlorothalonil is a fungicide registered for use on field grown agricultural and ornamental crops, for use in greenhouses, and for use as a fungicide when formulated into paints. Chlorothalonil is in toxicity category I for acute inhalation and, is a Group B2 carcinogen (Q = 1.1 x 10^3). Technical chlorothalonil contains the contaminants hexachlorobenzene (HCB) at concentrations of 0.05% (500 ppm) and small amounts of pentachlorobenzonitrile (PCBN). Both substances are carcinogens with HCB being more potent having a Q of 1.7 x 10^3.

A protocol addressing mixer/loader/applicator exposure monitoring for paint applications was recently reviewed by OREB (See memorandum from J. Evans/OREB to A. Ertman/SRRD dated 06/25/92). Other estimations of mixer/loader/applicator exposure were calculated using surrogate data with subsequent worker exposures ranging from 10^{-8} to 10^{-4}. The current protocol addresses a study designed to measure the foliar residue dissipation of chlorothalonil when applied to broccoli, cucumbers, and cherries. The registrant proposes conducting these studies at Ricerca's Ohio Research Facilities. Ricerca is a subsidiary of ISK Biotech and will also be responsible for the analytical portion of the study. The cherry portion of the study was reportedly underway at the time this memorandum was being prepared.

II. DETAILED CONSIDERATIONS:

The research plots are small consisting of at least 8 rows, 100 feet long for the row crops (cucumber and broccoli) and consisting of 5 trees for the orchard crop (cherries). This study appears to meet the climatic, geographic, and correct application timing requirements suggested under Subdivision K. Although the crops will receive the maximum application rates, the row crops may not receive the maximum number of applications
for a growing season. These crops will however be treated at the
typical labeled frequency of 7 to 10 day intervals. An on-site
automated weather station will be situated in the immediate
vicinity of the research plots. However, OREB suggested that
relative humidity be included in the meteorological data
reporting.

III. CONCLUSIONS:

The protocol as submitted cannot be approved based on the
following reasons:

Only 40 leaf punch disks measuring 1.262 cm will be taken
per sample rather than 40 leaf punch disks measuring 2.54 cm
as required under Subdivision K. Therefore, the number of
leaf disks to be taken must increase commensurately to
maintain the same approximate leaf area per sample.
Furthermore, there was no specific mention of duplicate
samples being taken which are also required under
Subdivision K.

There was no detailed discussion of method validation, field
fortification, or storage stability data provided in the
protocol. These parameters were mentioned as being
discussed in a separate Ricerca document not provided with
the protocol. There was also no discussion regarding the
contaminants HCB or PCBN in the protocol.

There was no mention of dermal or inhalation exposure
studies and it is unlikely that any data regarding these
guidelines can be obtained from plots as small as those
discussed above. Please note that the Agency now requires
that foliar dissipation and soil dissipation studies be
conducted concurrently with dermal and inhalation exposure
studies, and that the dermal and inhalation exposure
studies were included in the DCI.

At best these studies may provide supplemental data only.

IV. REFERENCES:

Undated Memorandum from P. Poli, HCB Review Manager to HCB Team
Members Regarding the Hexachlorobenzene Option Paper from the
Special Review Branch.


cc: J. Evans, OREB
    W. Waldrop, SRRD (H7508W)
    Correspondence File
    Chemical File (chlorothalonil)
R117886

Chemical: Chlorothalonil

PC Code:
081901

HED File Code: 19000 Protocol/Guidance
Memo Date: 7/24/1992
File ID:
Accession #: 412-06-0009

HED Records Reference Center
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