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

MAR 22 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: REVIEW OF DRAFT PROTOCOL ADDRESSING GREENHOUSE APPLICATOR EXPOSURE DATA REQUIREMENTS TO SUPPORT THE REREGISTRATION OF CHLOROTHALONIL

FROM: Jeff Evans, Biologist
Reregistration Section
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

TO: Andy Ertman, PM Team 71
Reregistration Branch
Special Review and Reregistration Division (7508W)

THRU: Alan P. Nielsen, Section Head
Reregistration Section (7509C)

Larry C. Dorsey, Chief
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Please find the OREB review of ....

DP Barcode: D197141

Pesticide Chemical Code: 081901

EPA Reg. No.: N/A

EPA MRID No.: N/A

Review Time: 1 day

PHED: No

I. INTRODUCTION:

ISK Biotech has submitted a draft protocol addressing the greenhouse applicator exposure data requirements needed to support the reregistration of chlorothalonil. Issues pertaining to the draft protocol were discussed in a meeting with ISK Biotech and EPA personnel on 1/25/94. In the meeting, the registrant requested an expedited review of the draft because a trial run of the experiment is scheduled in the early spring.

II. DETAILED CONSIDERATIONS:

The exposure study is to address application of chlorothalonil using a backpack sprayer. The draft protocol briefly addresses the main components of an acceptable study with respect to Subdivision U guideline requirements. These are as follows:

Fifteen (15) replicates each of mixer/loaders and applicators. However, ISK Biotech suggested combining activities due to the small amounts of ai handled during mixing and loading and since both tasks are likely to be conducted by the same person.

The study will be conducted at a minimum of three sites. One of these sites may be in Maryland. OREB suggested the possibility of OREB staff observing the Maryland trial since travel expenses would be minimal.

Hand exposure will be measured using hand rinses; head and neck exposure will be measured using a head patches (front and back); and whole body dosimeters will be used for the remaining areas. The whole body dosimeters will consist of long-sleeved underwear tops and long underwear bottoms to be worn under typical work clothing.

Inhalation monitoring will be measured using two personal air sampling pumps (2 liters/minute). Air inside the respirator and outside the respirator will be monitored.

Field fortification will consist of duplicate samples of the respiratory filters, handwashes, long-sleeved shirts, and underwear bottoms at 2x the method limit. Additional field fortifications include 10 and 50 μg (respirator filters); 100 and 200 μg (handwash); 100 and 1000 μg (shirts and underwear bottoms).

Storage stability samples will consist of four sets of each matrix and fortification level discussed above.

III. CONCLUSIONS:

OREB recommends proceeding with the trial as presented in the draft protocol plus the following suggestions:

Include postapplication inhalation monitoring using the personal air monitoring pumps in a fixed position until two non detects samples are recorded. Worker Protection Standard (WPS) ventilation criteria can be used in lieu of conducting the postapplication inhalation monitoring.

Applicator clothing should be for WPS requirements.

Finalize the monitoring of mixer/loaders and applicators separately or combined in the final protocol.

cc: J. Evans, OREB
Correspondence File
Chemical File (081901)

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

JUN 25 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: REVIEW OF WORKER EXPOSURE STUDY PROTOCOL PROPOSED TO FULFILL GUIDELINES 231, 232, 233, AND 234 REQUIRED TO SUPPORT THE REREGISTRATION OF CHLOROTHALONIL (HED Project # 2-1744)

FROM: Jeff Evans, Biologist
Reregistration Section
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

TO: Andrew W. Ertman, PM Team 71
Special Review and Reregistration Division (H7508W)

THRU: Alan P. Nielsen, Section Head
Reregistration Section
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Larry C Dorsey, Acting Chief 6/25/92
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Please find the OREB review of ....

DP Barcode: D175474

Pesticide Chemical Code: 081901

EPA Reg. No.: N/A

EPA MRID No.: N/A

Review Time: 3 days

PHED: No

I. INTRODUCTION:

OREB has reviewed ISK Biotech's protocol for a worker exposure study (using chlorothalonil) to be performed under the requirements of Subdivision U (Guidelines § 231, 232, 233, and 234). This memorandum presents suggested revisions to the protocol and provides a discussion of the issues raised at a recent meeting with EPA, ISK Biotech, and Ricerca, Inc. representatives. As discussed in the meeting held on May 28, 1992, the submitted protocol is a working document subject to change as laboratory methodologies and logistical considerations are resolved. OREB agrees with the general approach described in the protocol. However, the revisions identified in this memorandum are strongly recommended in order that the proposed study will more effectively fulfill the Subdivision U Guideline requirements.

The study is designed to address the application of interior and exterior paints containing the fungicide/algicide chlorothalonil. The study is to take place in Madeira, California and is to be conducted by Pan-Agricultural Laboratories, Inc. on behalf of ISK. Biotech. Ricerca, Inc. a subsidiary of ISK Biotech, is presently developing the methods for the analytical phase and will be responsible for the analytical portion of the study. The proposed study is expected to consist of three trials, 1) an indoor application of interior latex paint (10 replicates), 2) an exterior application of latex paint (10 replicates), and 3) an exterior application of a solvent based paint (10 replicates). The paints are to be applied by either air powered sprayers or airless sprayers (air powered sprayers can produce more mists).

II. DETAILED CONSIDERATIONS:

Number of Sites and Replicates:

The proposed number of sites (one) and number of replicates (10) do not strictly adhere to Subdivision U Guideline requirements which require 3 different sites and a total of 15 replicates. However, there are a total of 30 replicates in the proposed study. Considering the apparent lack of geographic significance of painting houses, as compared to applying pesticides in diverse agricultural conditions, there appear to be enough replicates in this proposed study. However, OREB recommends that more individuals be used for the replicates than proposed in the protocol (2 persons per trial). This will incorporate more diverse working habits into the study and provide a better range of potential exposures. As discussed in the meeting, the registrant may eliminate the outdoor latex paint trial providing 5 replicates are added to each remaining trial (interior latex and exterior solvent base).

Quality Assurance/Quality Control Considerations:

As previously stated, the method validation for this study has not been completed. This portion of the protocol must be submitted when the methods are finalized. As we discussed in the meeting, Subdivision U guidance for field fortifications is as follows:

> Each matrix must be fortified at 3 levels (for example 1X, 10X and 100X of the detection limit; higher levels may be needed if high exposure to hands is expected);
>
> The number of field fortifications should include one set of field fortifications (3 levels) per matrix per replicate. This is particularly important if the registrant anticipates sample result measurements at or near non-detectible limits.

In addition, provide one field blank per worker per matrix. It is OREB's understanding that the registrant will use the formulated paints for the field fortifications rather than the technical grade chemical as proposed in the protocol.

Regarding the use of storage stability data from other studies submitted to support other data requirements. The registrant contends that they have submitted several storage stability studies which show the compound is stable after freezing. Since the storage stability studies submitted by the registrant to the Chemistry Branch have not been reviewed, these data must be generated for this study. In addition, it is suggested that storage stability data be generated for this study considering the possible complications of a paint/chlorothalonil matrix.

Clothing Worn by the Applicators and Dosimeter Considerations:

When selecting whole body dosimeters try to select the dosimeters from the same lot. The dosimeters should be laundered and preextracted with a solvent to remove any additives and plasticizers which may cause interference during analysis. Obtaining dosimeters from the same lots is recommended since not all cotton products are the same. Cotton gloves (pallbearer type or winter, glove liners) should also be obtained from the same lot and washed as discussed above. Latex gloves may be worn beneath the cotton gloves. Shoes do not need to be monitored.

Typical work clothing may include:

> long sleeve shirts and long pants;
> coveralls (do not use tyvek);
> hats;
> goggles;
> dust mask or half-face respirators (with appropriate paint mist cartridge).

There is however, no standard for painter work clothing. In addition, painters may use ear plugs if air powered sprayers are used.

III. CONCLUSIONS:

In order for the protocol to be approved, the registrant must submit a revised protocol including the following:

provide appropriate QA/QC information regarding method validation, field recovery, and storage stability;

provide more details pertaining to the handling of the dosimeters such as preparation, and prevention of contamination during removal;

address postapplication/reentry for the indoor applications. For example, air conduct monitoring of the breathing zone at sufficient intervals to establish a decline curve ending with two non-detectable samples;

Obtain paints from the same production lots and analyze to verify the concentration of chlorothalonil in the paint.

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

13544

R117956

Chemical:	**Chlorothalonil**
	PC Code:
	081901
HED File Code:	**12000 Exposure Reviews**
Memo Date:	**3/22/1994**
File ID:	
Accession #:	**412-06-0009**

HED Records Reference Center
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