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

JAN 25 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil & HCB: List A Case No. 0097: Chemical No. 081901: ISK Biotech Submission of information in support of waivers: CBRS No 11686: DP Barcode D189849.

FROM: William O. Smith, Ph.D., Chemist
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THROUGH: William J. Hazel, Ph.D., Section Head
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TO: Lois Rossi/Andrew Ertman (PM-71)
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ISK Biotech Corporation has submitted information as a follow-up to a meeting held with SRRD and HED Representatives on 2/10/93. The submission consists of the following two documents that have not been assigned MRID numbers:

ISK Biotech Document No. RC-93-RPB-001-001; Scientific Rationale for Waiving Data Requirements for Chlorothalonil and Hexachlorobenzene by Technical Assessment Systems, Inc., dated November 24, 1992.

ISK Biotech Document No. RC-93-RPB-002-001; Overhead Mats and Supporting Narrative, Follow-Up to February 10, 1993 Meeting Re Requests for Waivers for HCB Studies:

- Livestock Feeding (meat/milk/poultry/egg) studies [Guideline No. 171-4(j)]
- Crop Residue Studies [Guideline No. 171-4(k)]
- Processed Food Studies [Guideline No. 171-4(l)].

The purpose of the 2/93 meeting was to discuss the registrant's request for a waiver of the HCB animal feeding study required in the June, 1991 chlorothalonil DCI and for the registrant to make

presentations supporting their position that Agency assumptions concerning anticipated residues of HCB used in dietary risk assessments are inappropriate. The registrant's submissions and points concerning these issues will be discussed below followed by CBRS comments and conclusions.

ASSUMPTIONS CONCERNING HCB RESIDUES IN CROPS:

Background:

CBRS has already recommended (W. Smith; 11/10/92; CBRS Nos. 9562 & 9806; DP Barcodes D175650 & D177592) that the requirement for HCB field trials on eight representative crops, as specified in the 7/91 chlorothalonil DCI, be placed in reserved status. However, it was noted that for purposes of risk assessment, and in the absence of adequate HCB field trial data, the Agency would continue to assume that HCB residues on food crops from the application of chlorothalonil are present at a 10-fold greater level relative to chlorothalonil residues than in the formulations applied to the crops.

This estimate was made in the draft Chlorothalonil FRSTR of 1988 by comparing available HCB and chlorothalonil residue data from controlled field trials with summer squash, cucumbers, green onions, snap beans, broccoli and celery. These were the only crops on which detectable residues of both HCB and chlorothalonil occurred and, therefore, were the only crops on which estimates of HCB residues as a percentage of chlorothalonil residues could be made. Therefore, the Agency used the 10x concentration factor for HCB on crops as an interim means of calculating anticipated residues of HCB. We required exaggerated-rate-field trials in the 7/91 DCI in order to obtain additional data regarding the degradation of HCB relative to chlorothalonil on crops.

Present Considerations:

The registrant requests that we give further consideration to their claim that anticipated residues of HCB in crops should be estimated based on its relative concentration in the chlorothalonil formulations applied to crops and assuming that residues of chlorothalonil and HCB dissipate at the same rate on these crops.

The following points were either discussed in the 2/93 meeting with the registrant, and included in the present submission, or gleaned from other residue chemistry data available to CBRS. These points provide the basis for our conclusions and recommendation concerning estimation of anticipated residues of HCB in crops resulting from application of chlorothalonil formulations.

(1) Dissipation of HCB vs. Chlorothalonil on Lima Bean Vines

The registrant pointed out that MRID 41413201 reported detectable residues of HCB and chlorothalonil at 0, 7, and 14 days after application of chlorothalonil to bean vines. The ratio of HCB to chlorothalonil on vines harvested at all post-treatment intervals was the same as the ratio in the formulation applied to the vines.

(2) Dissipation of HCB vs. Chlorothalonil on Corn Fodder

In a study submitted separately, and currently under review in the Branch (MRID 42944402; DP Barcode D195757), significant residues of chlorothalonil and HCB were detected on corn fodder samples harvested 45 days after the last of multiple applications of BRAVO 720 or BRAVO 825. The ratio of HCB/chlorothalonil in crop residues was highly correlated with the ratio in the BRAVO formulations.

(3) Dissipation of HCB vs. Chlorothalonil on grass seed, screenings and straw.

In a study submitted separately, and currently under review in the Branch (MRID 42875926; DP Barcode D194487), significant residues of chlorothalonil and HCB were detected on samples of grass straw, screenings and seed harvested 37 days after the last of multiple applications of BRAVO 720. The ratio of HCB/chlorothalonil in crop residues was highly correlated with the ratio in the BRAVO formulation.

(4) Storage Stability Studies

The registrant cited eight storage stability studies submitted to the Agency (MRIDs 41564820 through 41564827) as supportive of their claim that HCB does not concentrate in treated crops. However, as discussed in a previous memorandum (W. Smith; 11/10/92; DP Barcodes D175650 & D177592), we have concluded that these studies are not acceptable for the purpose of comparing the relative dissipation of HCB and chlorothalonil from crops. The primary reason for this conclusion is that the samples analyzed for these studies were harvested on the same day as the last spraying of the crop; therefore, the residue composition would be expected to reflect the same ratio of active ingredient and contaminants as found in the spray formulation. In the meeting of 2/93 the registrant disagreed with our conclusion and contended that due to the nature of the applications to these

crops (multiple applications at exaggerated rates) there was ample opportunity for HCB to show any trend to concentrate. They provided storage stability on other crops and stated that, at least in some cases, one might assume that half of the residues detected on the samples would be due to the last application. We note that if one accepts this assumption, then the storage stability data that the registrant provided for almond hulls, peanuts, wheat, cherries, tomatoes and soybeans support their contention that HCB is present in the chlorothalonil residue on these crops at approximately the same ratio as existed in the formulation applied to the crops. Carrot storage stability data was an exception and indicated a 10x concentration of HCB relative to chlorothalonil; however, the registrant supplied analysis of another carrot sample harvested from the same area for processing that indicated no concentration of HCB relative to chlorothalonil.

(5) Volatility of HCB vs. Chlorothalonil

The registrant has noted that the vapor pressures of HCB and chlorothalonil are 1.089×10^{-5} (20 C) and 5.72×10^{-7} (25 C). Thus, HCB is more volatile than chlorothalonil and may be expected to dissipate more rapidly from weathering.

(6) Dissipation of ^{14}C labeled residues in Metabolism Studies

(a) In response to discussions in the meeting of 2/93, the registrant provided the information, based on a celery metabolism study (MRIDs 425540-01 & -02), that the half-life for chlorothalonil residues on celery is about one week to 10 days. It is suggested that this is a typical rate of dissipation of chlorothalonil from foliage applications to crops.

(b) The registrant has submitted a study of the metabolism of ^{14}C-HCB in onions in support of reregistration of Dacthal (MRID 42298302). We note that HCB dissipates from the onion tops at a rate that is comparable to that reported for chlorothalonil dissipation from celery.

CBRS Comments and Conclusion:

Data summarized in points 1, 2 and 3 show that residues of HCB and chlorothalonil dissipate from three RACs at approximately the same rate. The data provided in these studies are of the type

requested in the 7/91 DCI and, even though they do not represent RACS eaten by humans, are acceptable support of the registrant's contention that HCB residues on crops are directly correlated with the level of chlorothalonil residues. In all three cases residues of HCB and chlorothalonil were present on crops at levels significantly higher than the detection limits of the analytical methods. Points 4, 5 and 6 do not conclusively support the registrant's claims when considered individually because they do not represent direct comparisons of HCB and chlorothalonil residues on edible crops that have been harvested according to established agricultural practices; however, taken as a whole, the weight of the evidence from points 1 through 6 is in favor of a revision of our assumptions in calculating anticipated residues of HCB on crops resulting from uses of chlorothalonil.

CBRS Recommendation Concerning Anticipated Residues of HCB on Crops:

For purposes of estimation of the dietary risk of HCB resulting from its presence as a contaminant in formulations of chlorothalonil, and in those cases where residues on crops are below the limit of detection of the analytical method, residues of HCB should be estimated to be present in the same ratio relative to chlorothalonil as was present in the formulation applied to the crop. In other words, it should be assumed that residues of HCB and chlorothalonil dissipate from crops at approximately the same rate.

WAIVER REQUEST FOR HCB ANIMAL FEEDING STUDY:

Background:

The registrant has sought a waiver of requirements for HCB ruminant and poultry feeding studies, which were required in the 7/91 chlorothalonil DCI. We have previously denied this request (W. Smith memorandum dated 11/10/92; DP Barcodes D175650 and D177592) based primarily on the CBRS conclusion that adequate data were not available in published HCB feeding studies to accurately determine the extent of bioaccumulation of HCB in animal tissues.

Present Considerations:

The registrant has submitted two risk assessments conducted by Technical Assessment Systems, Inc. (TAS), which conclude that there is no significant dietary risk due to transfer of HCB residues to meat, milk, poultry and eggs. At this point we neither agree nor disagree with all of the registrant's assumptions presented in these risk assessments; however, we will take them into consideration as we conduct further chlorothalonil dietary risk assessments.

The basic contention of the registrant's risk assessment is that residues of HCB bioaccumulate only in animal fat and that the level of accumulation will not exceed a plateau of ca. 10x the feeding level under continuous feeding regimes. We rejected this assumption in our memorandum of 11/10/92 because the published studies that the registrant submitted did not include raw data that represented the level of feeding that would normally be required to satisfy the requirements for GDLN 171-4(j).

We have recently become aware of HCB feeding studies in the Agency files that were submitted in support of registration of another chemical (PCNB) containing HCB as a contaminant. We find that these feeding studies are adequate to determine the level of bioaccumulation of HCB in meat, milk, poultry and eggs. These studies are in general agreement with the registrant's conclusions, drawn from published HCB feeding studies, concerning accumulation of HCB in animal commodities.

A cattle feeding study was discussed in 9F0754 (E. Gunderson, 2/18/70) and in 1F1083 (D. Reed, 2/23/72). Lactating cows were fed 10, 1 and 0.1 ppm PCNB containing 1.8% HCB (corresponding to 0.18 ppm, 0.018 ppm and 0.0018 ppm HCB feeding levels) for 12-15 weeks. In the poultry feeding study (1F1083; R. Cook, 9/3/82) chickens were fed six levels of technical PCNB for four months resulting in HCB feeding levels of 0.00075 ppm, 0.015 ppm, 0.075 ppm, 0.23 ppm, 1.13 ppm and 4.5 ppm. In both ruminant and poultry studies HCB accumulated in fat matrices only. Residues reached a plateau in fat at a level usually less than 10x the level in the feed. Residues in eggs concentrated in the yolk and reached a plateau of less than 5x the feeding level. Residues in milk were confined to the milk fat.

CBRS Conclusions Concerning HCB Animal Feeding Studies:

We conclude that there would be no value added to our risk assessment and tolerance reassessment associated with reregistration of chlorothalonil to require further HCB feeding studies. Therefore, we recommend that the HCB feeding studies required in the 7/91 chlorothalonil DCI be waived. We recommend that the Agency estimate the dietary risk due to transfer of HCB to animal commodities based on the bioaccumulation patterns provided by the registrant and as confirmed in the PCNB studies summarized above.

Note to PM The PCNB/HCB feeding studies referred to above were submitted by Olin (Mathieson) Corporation. The residue data were reported in MRIDs 00001711 (milk cows) and 00109653 (poultry).

cc: W. Smith, Chlorothalonil Reg. Std. File, SF, RF, circulation.

H7509C:CB-II:WOS:wos:Rm805A:CM#2:X5353:11/02/93
RDI: WHazel(12/02/93) MMetzger(12/13/93) EZager(01/12/94)