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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 3 1995

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#5E04558, Evaluation of Analytical Method and Residue Data. Chlorothalonil on Almonds and Almond Hulls. Chemical# 081901, DP Barcode: D218170, CBTS#: 15713, MRID#: 437352-01. Amended Labels for Chlorothalonil. ID#'s: 050534-00008, 050534-00188, 050534-00201, 050534-00204, and 050534-00205. DP Barcodes: D218151, D218152, D218184, D218186, D218196, D218198, D218201, D2188203, D218210, and D218215. CBTS#'s: 15708, 15709, 15710, 15711, 15712, 16053, 16054, 16055, 16056, and 16057.

FROM: William D. Cutchin, Chemist
Tolerance Petition Section I
Health Effects Division (7509C)

THROUGH: Francis B. Suhre, Acting Section Head
Tolerance Petition Section I
Health Effects Division (7509C)

TO: Cynthia Giles-Parker, PM 22
Fungicide-Herbicide Branch
Registration Division (7505W)

and

Karen Whitby, Section Head
Risk Coordination and Analysis Branch
Health Effects Division (7509C)

ISK Biosciences Corp. requests the establishment of a tolerance for the combined residues of the fungicide chlorothalonil (2,4,5,6-tetrachloroisophthalonitrile) and its hydroxy metabolite, SDS-3701 (4-hydroxy-2,5,6-trichloroisophthalonitrile) on almonds and almond hulls at 0.05 ppm and 1.0 ppm respectively. Tolerances for the combined residues of chlorothalonil and its hydroxy metabolite have been established on numerous commodities ranging from cocoa beans at 0.05 ppm to celery at 15 ppm (40 CFR §180.275). Residue data for the manufacturing impurity hexachlorobenzene were also submitted.

The petitioner has submitted amended labels for Bravo Ultrex™ (EPA Reg. No. 50534-201), Bravo® 500 (EPA Reg. No. 50534-8), Bravo® Zn (EPA Reg. No. 50534-204), Bravo® 720 (EPA Reg. No. 50534-188), and Bravo® W-75 WSB (EPA Reg. No. 50534-205).

The Product and Residue Chemistry Chapters for the Chlorothalonil Reregistration Eligibility Decision Document (RED) were completed, 6/13/95.

The name of the registrant has changed from SDS Biotech to Fermenta Plant Protection to ISK Biotech Corp. to ISK Biosciences Corp. without change in company number.

Conclusions

1. Product chemistry data requirements for chlorothalonil have not been fully satisfied. Additional confirmatory data are required (RED, 6/13/95). This data gap does not adversely affect the review of PP#5E04558.

2. The proposed use directions in Section B of PP#5E04558 are adequate.

3. The metabolism of chlorothalonil in plants has been adequately understood. The residues of concern in plants are chlorothalonil *per se* and its 4-hydroxy metabolite (RED, 6/13/95).

4. The metabolism of chlorothalonil in animals is adequately understood. The residues of concern in animals are chlorothalonil *per se* and its 4-hydroxy metabolite (RED, 6/13/95).

5. The analytical method used for data collection in connection with PP#5E04558 is similar to methods used for previous magnitude of the residue studies. In addition, a confirmatory procedure (GC/ECD) is available (Method I, PAM II).

6. Chlorothalonil is recovered (>80%) by published multiresidue methods. The hydroxy metabolite is also recovered by multiresidue methods.

7. There are sufficient residue data presented in petition PP#5E04558 to support the proposed tolerance. Combined residues of chlorothalonil and its hydroxy metabolite are not expected to exceed the proposed tolerance of 0.05 ppm on almonds and 1.0 ppm on almond hulls.

8. The storage stability data in EPA files are sufficient to support the accuracy of the residue findings for almonds and almond hulls.

9. Since residues of chlorothalonil and its 4-hydroxy metabolite in or on almond hulls do not constitute a significant increase over the current chlorothalonil dietary burden to ruminants, CBTS has no objection to establishment of a chlorothalonil tolerance at 1.0 ppm in or on almond hulls at this time.

10. Rotational crop guidelines are not necessary for this crop. No further information is necessary for this proposed use.

11. There are no Codex, Mexican, or Canadian MRLs for chlorothalonil and its hydroxy metabolite on almonds or almond hulls. Establishment of a chlorothalonil tolerance on almonds at 0.05 ppm and almond hulls at 1.0 ppm will create no compatibility problems.

Recommendations

Toxicological considerations permitting, CBTS recommends in favor of establishing a tolerance for the combined residues of chlorothalonil and its hydroxy metabolite on almonds at 0.05 ppm and almond hulls at 1.0 ppm. A DRES run should be initiated at this time.

Detailed Considerations

Manufacture and Formulation

No product chemistry data was submitted with this petition. The product chemistry data requirements have been satisfied with the exception of the dioxin analysis for the ISK Biosciences chlorothalonil technicals (EPA Reg. Nos. 50534-7, 50534-24, 50534-117, and 50534-200). Some product-specific data are incomplete for the manufacturing-use products of chlorothalonil (RED). However, although these data requirements are outstanding, it is not a deficiency for this petition. No further product chemistry data are necessary for this proposed use.

Proposed Use

The proposed use directions, Section B, are adequate. The various Bravo® products are to be applied at up to 3.12 lb ai/A. Application volumes are from 20 gal/A using aircraft up to 300 gal/A using ground equipment. The products may be applied up to six times in a year at important stages of the plant cycle from leaf fall through shuck split with a preharvest interval (PHI) of 150 days. No further information is required for this proposed use.

Nature of the Residue - Plants

No plant metabolism data were submitted with this petition. The qualitative nature of the residues in plants is adequately understood. Metabolism studies have been conducted with carrots, celery, lettuce, snap beans, and tomatoes (RED). The residues of concern are chlorothalonil *per se* and its 4-hydroxy metabolite. No further data are required for this proposed use.

Nature of the Residue - Animals

No animal metabolism data were submitted with this petition. The qualitative nature of the residue in animals is adequately understood. The residues of concern are chlorothalonil *per se* and its 4-hydroxy metabolite (RED). No further data are required for this proposed use.

Analytical Methods - Enforcement

The method used for data collection has been used in other residue studies and is similar to Method I in Pam II with modifications. The method will be submitted for publication in PAM II pending Agency validation (RED). Residues of chlorothalonil, its hydroxy metabolite, and manufacturing impurity hexachlorobenzene (HCB) were extracted from almond hulls and nutmeats and selectively partitioned into an organic solvent. The residues of chlorothalonil and HCB were separated by column chromatography prior to subsequent quantitation by GC-ECD. The residues of the hydroxy metabolite were derivatized and cleaned-up by column chromatography prior to quantitation.

Concurrent method validations were performed on almond nutmeats and hulls fortified with chlorothalonil at 0.01-1.0 ppm, the hydroxy metabolite at 0.01-0.5 ppm, and HCB at 0.00025-0.03 ppm. The average recoveries of chlorothalonil, the hydroxy metabolite, and HCB on the nutmeats were reported as 89%, 89%, and 80% respectively. The average recoveries of chlorothalonil, the hydroxy metabolite, and HCB on the hulls were reported as 83%, 89%, and 94% respectively.

Because the performing laboratory, Ricerca, Inc., used a single standard method for calibration of the GC, the method limits of quantitation (LOQ) and the limits of detection (LOD) were the same numerical values. The LOQ and LOD were 0.01 ppm for both chlorothalonil and the hydroxy metabolite and 0.00025 ppm for HCB. The performing laboratory has supplied sample chromatograms and calculations.

Analytical Methods - Multiresidue

The PESTDATA database dated 1/94 indicates that chlorothalonil is completely recovered (>80%) using multiresidue methods in PAM I. The database also indicates that the 4-hydroxy metabolite is

recovered (no quantitative information given) using Sections 302 and 303 but is not recovered using Section 304 (RED). No further data are required for this proposed use.

Magnitude of the Residue

The residue data submitted with this petition are sufficient to establish the requested tolerance. Four magnitude of residue studies were performed in the following California locations: Ripon, Madera, Fresno, and Huson. The studies in Ripon and Fresno consisted of a control and two treated plots. The other two studies consisted of a control plot and a single treated plot. All applications were conducted using a tractor mounted airblast sprayer. The treated plots in Madera and Huson and the first plots in Ripon and Fresno were treated at 100 gal/A. The second plots in Ripon and Fresno were treated at 20 gal/A, the recommended minimum volume. Chlorothalonil was applied six times at 3.12 lb ai/A (maximum seasonal rate 18.8 lb ai/A) to both treated plots in Ripon and the treated plot in Huson. Chlorothalonil was applied five times at 3.12 lb ai/A (15.6 lb ai/A) to the remaining treated plots. PHIs ranged from 148 to 170 days.

Residues of chlorothalonil found on almond nutmeats ranged from no detect (ND) to 0.04 ppm. All almond nutmeat samples were ND for both the hydroxy metabolite and HCB. The residues of chlorothalonil found on almond hulls ranged from 0.2 to 1.07 ppm with an average of 0.35 ppm. The 1.07 ppm residue was from a sample which was handled by hand after processing in an attempt to remove excess 'trash' on the final product. Residues of the hydroxy metabolite on almond hulls were found to be from ND to 0.04 ppm. HCB residues on almond hulls ranged from ND to 0.00037 ppm. Sample chromatograms and calculations were submitted.

Geographic Representation

The geographic diversity of the studies submitted with this petition are adequate to represent the U.S. almond growing regions, i.e. California. The four residue studies were conducted in California. This represents 100% of the almond growing regions in the U.S. No further data are required for this proposed use.

Storage Stability

No storage stability data were submitted with this petition. Residues of the 4-hydroxy metabolite and HCB are stable during frozen storage for up to 4 years in/on carrots, celery, cherries, cucumbers, peanuts, potatoes, soybeans, tomatoes, and wheat grain. Residues of chlorothalonil are stable under the same conditions in the above commodities except for an apparent decline of approximately 9% per year in peanuts. There are

sufficient storage stability data available to support this minor use. No further storage stability data are required for this proposed use.

Meat, Milk, Poultry, and Eggs

Table II (revised 9/15/95) identifies almond hulls as a feed item, which may potentially account for up to 10% of the diets of beef and diary cattle. However, since residues of chlorothalonil and its 4-hydroxy metabolite in or on almond hulls do not constitute a significant increase over the current chlorothalonil dietary burden to ruminants, CBTS has no objection to establishment of a chlorothalonil tolerance at 1.0 ppm in or on almond hulls at this time.

Please note that there are at present no chlorothalonil tolerances on animal commodities. Data reviewed in poultry and ruminant metabolism studies indicate that tolerances are not needed at this time for poultry and eggs but may be needed for meat and milk. In order to assess the need for these tolerances, a ruminant feeding study was called-in by the Chlorothalonil RED (6/13/95).

Other Considerations

There are no Codex, Canadian, or Mexican maximum residue limits for the combined residues of chlorothalonil and its hydroxy metabolite on almonds or almond hulls. Establishment of a chlorothalonil tolerance on almonds at 0.05 ppm and almond hulls at 1.0 ppm will create no compatibility problems.

Rotational Crops

Rotational crop guidelines are not necessary for this crop. No further information is necessary.

Attachment: International Residue Limit Status Sheet.

cc: RF, PP#5E04558, circ., Cutchin, SAB (B. Doyle)
7509C: CBTS, Reviewer(WDC), CM#2, Rm 804P, 305-7990, WDC: 10/3/95
R/I: Act. Sec. Head: F. Suhre, 9/25/95;
Br. Sr. Sci.: R. Loranger, 9/28/95;
Br. Chief: M. Metzger, 9/28/95

Attachment: Page___ of___

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Chlorothalonil

CODEX NO. 81

CODEX STATUS:

[X] No Codex Proposal Step 6 or Above

Residue (if Step 8): _____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 5F4558

DEB Reviewer Cutchin

Residue: Chlorothalonil + hydroxy metabolite

Crop(s)	Limit (mg/kg)
almonds	0.05
almond Hulls	1.0

CANADIAN LIMITS:

[X] No Canadian Limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

[X] No Mexican Limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES

Form Revised 1989

9/13/95 WC