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

FEB 26 1992

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum:

SUBJECT: PP#2E4050. Chlorothalonil. Evaluation of Request for Exemption from Tolerances for Metabolites SDS-3701 and SDS-46851 in Rotational Crops, and of Request to Delete Label 12-Month Rotational Crop Restriction. (MRID# 420901-09, CBTS #9021, Barcode #D172017).

FROM: Jerry B. Stokes, Chemist
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THRU: Debra Edwards, Acting Chief
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TO: Cynthia Giles-Parker, PM-22
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and

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This is an expedited review per the request of RD. The completion date is 2/25/92.

Background

ISK Biotech has submitted a letter dated September 24, 1991, Revised Sections B and F, and copies of residue data (previously submitted to RD to request the exemption from tolerances for chlorothalonil metabolite SDS-3701 (4-hydroxy-2,5,6-trichloroisophthalonitrile) and SDS-46851 (3-carbamyl-2,4,5-

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trichlorobenzoic acid) in rotational crops. The company had submitted data for the rotational crop studies to the Agency in July 1990 (MRID #415648-01 to 415648-46) for evaluation. The company also affirms their belief that sufficient data has now been submitted to the Agency to justify removal of the 12-month rotational crop label restriction.

Tolerances are established on numerous r.a.c's ranging from 0.05 to 15.0 ppm for chlorothalonil and its metabolite SDS-3701.

Recommendations:

1. TOX has decided that metabolites SDS-3701 and SDS-46851 do not need regulation in all registered chlorothalonil uses. TOX and EFGWB considerations permitting, we have no objection to exempting these metabolites from tolerances in rotational crops. Exemptions from the requirement of a tolerance for SDS-3701 and SDS-46851 should be established. However, to avoid a conflict with the existing tolerances for residues of chlorothalonil and its metabolite SDS-3701, only the soil metabolite SDS-46851 should be listed as exempt in a separate subsection of §180.275. An interim subsection for the metabolite SDS-3701 will also be established for rotational crops not included in §180.275 (a) on tolerances for direct use. The registrant must reevaluate his residue data base in support of the existing chlorothalonil tolerances to determine if the removal of metabolite SDS-3701 will necessitate the lowering of any tolerances. Only after these data have been submitted and reviewed by the Agency should the tolerance expressions, both for chlorothalonil and SDS-3701, be changed. At that time, CBTS recommends that the tolerance expression, which covers primary crops, be rewritten to include parent only. Metabolite SDS-3701 should then be included with SDS-46851, and the interim subsection for SDS-3701 removed.

A revised Section F must be submitted as follows:

An exemption from the requirement of a tolerance is proposed for the residues of 3-carbamyl-2,4,5-trichlorobenzoic acid in or on all raw agricultural commodities which occur from the direct application of chlorothalonil to crops in §180.275(a) and/or as inadvertent residues resulting from the soil metabolism of chlorothalonil when applied to crops in §180.275(a), and subsequent uptake by crops when used according to approved agricultural practices.

Prior to removal of metabolite SDS-3701 from the chlorothalonil tolerance expression, a revised Section F must also be submitted as follows:

An exemption from the requirement of a tolerance is proposed for the residues of 4-hydroxy-2,4,5-trichloroisophthalonitrile in or on all raw agricultural commodities, except those listed

in §180.275(a), which occur as inadvertent residues resulting from the soil metabolism of chlorothalonil when applied to crops in §180.275(a), and subsequent uptake by crops when used according to approved agricultural practices.

2. Based on the available data, residues of the parent chlorothalonil are not of concern in rotational crops (<0.1ppm). Chlorothalonil is strongly adsorbed to soils and has a low water solubility and is not taken up from the soil by plants. Rotational crop data have been previously satisfied (See memo of 4/26/84, S. Creeger, MRID#'s 00139550 and 00156477).

Therefore, since the rotational crop restriction was added previously to cover metabolites, TOX and EFGWB considerations permitting, CBTS recommends that the 12-month crop rotation restriction be removed from the label.

Note to PM: Metabolite SDS-3701 should be checked for pesticidal activity. If SDS-3701 has pesticidal activity, it may not be appropriate to exempt it from the requirement of a tolerance.

Chlorothalonil tolerances listed in §180.275 should be as follows:

- (a) remains the same
- (b) An exemption from the requirement of a tolerance is established for the residues of 3-carbamyl-2,4,5-trichlorobenzoic acid in or on all raw agricultural commodities which occur from the direct application of chlorothalonil to crops in §180.275 (a) and/or as inadvertent residues resulting from the soil metabolism of chlorothalonil when applied to crops in §180.275 (a), and subsequent uptake by crops when used according to approved agricultural practices.
- (c) An exemption from the requirement of a tolerance is established for the residues of 4-hydroxy-2,4,5-trichloroisophthalonitrile in or on all raw agricultural commodities, except those listed in §180.275 (a), which occur as inadvertent residues resulting from the soil metabolism of chlorothalonil when applied to crops in §180.275 (a), and subsequent uptake by crops when used according to approved agricultural practices.
- (d) Tolerances with regional registration presently as subsection (b) should be changed to (d).

Comments/Conclusions:

TOX stated previously that additional toxicological data for the soil metabolite SDS-46851 was needed. Apparently, the petitioner has now submitted sufficient data for both SDS-3701 and SDS-46851.

Based on the data available to the Agency, TOX has determined that both SDS-3701 and SDS-46851 are not of toxicological concern (See attached memo of 2/21/92, B. Doyle).

The Registrant has submitted residue data for parent, metabolite SDS-3701, soil metabolite SDS-46851, and impurities HCB (hexachlorobenzene) and PCBN (pentachlorobenzonitrile) in numerous rotational crops. These rotational crops included lettuce, spinach, celery, broccoli, cabbage, turnip, collard, carrot, red beet, sugar beet, potato, sweet potato, radish, onion, wheat, sorghum, oat, corn, rice, peanut, soybean, cotton, rapeseed, pea, bean, tomato, pepper, cantaloupe, cucumber, and squash. The PPI's (days between last application and planting date) ranged from 31 to 280 days. The PHI's (days between last application and harvest date) ranged from 100 to 420 days. The chlorothalonil had been applied to primary crops of peanut (3.3 to 6.1 lb a. i./A/season), potato (4.2 to 6.6 lb a. i./A/season), tomato (8.3 to 9.0 lb a. i./A/season), broccoli (5.3 lb a. i./A/season), soybean (2.2 lb a. i./A/season), and cucumber (9.0 lb a. i./A/season).

Analytical data showed that in all but several samples, residues of manufacturing impurities HCB and PCBN were non-detectable (<0.003 ppm HCB, and <0.005 ppm PCBN). PCBN residues were only detected in cabbage at 0.008 ppm (untreated control 0.010 ppm), carrot root at 0.005 ppm, and wheat straw at 0.005 ppm. HCB was detected in carrot root only at 0.006 ppm (untreated control 0.004 ppm).

Chlorothalonil was detected in turnip top (0.01 ppm), collard (0.02 ppm), carrot top (0.02 ppm), sugar beet (two samples showed 0.01 ppm and 0.05 ppm), onion (0.02 ppm), wheat straw (0.02 ppm), wheat forage (0.01 ppm), sorghum (0.03 ppm), peanut hull (0.02 ppm), cottonseed (0.03 ppm), tomato (0.02 ppm), bell pepper (0.02 ppm), cucumber (0.01 ppm), and summer squash (0.04 ppm). However, relatively few samples (15 samples with measurable residues out of more than 200 samples analyzed) showed measurable residues, but the control untreated samples in these cases showed chlorothalonil residues of 0.02-0.03 ppm. Thus, it appears that all the rotated crops presented by the registrant took up negligible levels of chlorothalonil (<0.01 ppm).

Sample analyses for residues of metabolite SDS-3701 showed residues in lettuce, spinach, turnip top, collard, carrot top, carrot root, potato, wheat straw, sorghum forage, oat straw, cottonseed, and summer squash. The levels of SDS-3701 were measured at 0.01 - 0.02 ppm except for two crops at 0.04 ppm. However, as stated above in the few samples (more than 200 samples analyzed) which showed measurable residues, the level of SDS-3701 in the control untreated samples in these cases showed SDS-3701 residues of 0.02-0.03 ppm.

The only measurable residues resulted from the chlorothalonil soil metabolite SDS-46851. Sample analyses for residues of metabolite SDS-46851 showed maximum residues in spinach (0.8 ppm), broccoli

(0.2 ppm), turnip top (0.6 ppm), carrot top (0.4 ppm), red beet top (0.3 ppm), sugar beet top (<0.1 ppm), carrot root (0.2 ppm), potato (0.7 ppm), sugar beet (0.1 ppm), turnip (0.1 ppm), red beet (0.2 ppm), radish (0.2 ppm), onion (<0.1 ppm), wheat straw (0.3 ppm), wheat forage (0.1 ppm), sorghum forage (0.3 ppm), oat straw (3.0 ppm), wheat (0.3 ppm), corn (0.1 ppm), oat (0.4 ppm), soybean (0.1 ppm), cottonseed (<0.1 ppm), fresh pea (<0.1 ppm), tomato (<0.1 ppm), cucumber (0.1 ppm), and winter squash (1.2 ppm).

The analytical methodology used to measure the residues of chlorothalonil, SDS-3701, SDS-46851, HCB, and PCBN were previously reviewed by CBTS (See memo of 2/22/91, W. T. Chin), titled "General Analytical Procedure for the Determination of Residues of Chlorothalonil (SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN on Selected Crops", and recommended that this method be included in PAM II as a letter method. Validation data for this method were presented for carrot, potato, celery, soybean, tomato, cucumber, cherry, wheat grain and many other crops in numerous storage stability studies submitted to support chlorothalonil registration (See MRID#'s 41564820- 4156446). This methodology is written such that each residue, i.e., chlorothalonil, SDS-3701, SDS-46851, HCB, and PCBN, can be analyzed individually. This method is adequate for determination of the residues of chlorothalonil, metabolites SDS-3701 and 46851, and impurities HCB and PCBN at the level of quantitation of 0.01 ppm, 0.01 ppm, 0.03 ppm, 0.003 ppm, and 0.005 ppm, respectively.

The current PAM II Method I for chlorothalonil residues includes the measurement of parent and its metabolite SDS-3701 since the tolerance expression is written for the combined residues of parent and SDS-3701 in primary crops. The PAM methodology measures parent and SDS-3071 separately, so there should be no need to develop new methodology. However, when the chlorothalonil tolerance expression is rewritten to reflect the recommendation to remove SDS-3701, the PAM enforcement methodology should also be changed to reflect the need to analyze only for parent. Therefore the registrant must rewrite the existing enforcement methodology, or provide new methodology for analysis of parent only.

NOTE: The removal of SDS-3701 from the tolerance expression may affect residue data requirements for the reregistration of chlorothalonil. This should be addressed by the petitioner.

cc: J. Stokes (CBTS); E. Zager (CBRS); C. Furlow (PIB/FOD); Chlorothalonil S.F.; R.F.; Circulation (7)
 RDI: PERRICO:2/26/92:RLORANGER:2/26/92 H7509C:CBTS:JStokes:js:Rm
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