



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

NOV 26 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#2E4113: Chlorothalonil (Bravo® 720) in or on Filberts.
Evaluation of Analytical Method and Residue Data (MRID
#422729-01, CBTS #9825, D #177602).

FROM: W. T. Chin, Ph.D., Chemist *W. T. Chin*
Tolerance Petition Section III
Chemistry Branch Tolerance Support I
Health Effects Division (H7509C)

THRU: P. V. Errico, Section Head *P. V. Errico for*
Tolerance Petition Section III
Chemistry Branch Tolerance Support I
Health Effects Division (H7509C)

TO: Hoyt L. Jamerson, PM #43
Minor Use Office
Registration Division (H7505C)

and

Toxicology Branch
Health Effects Division (H7509C)

The petitioner, IR-4, on behalf of the Agricultural Experiment Station of Oregon requests the establishment of a tolerance for the residues of the fungicide chlorothalonil, 2,4,5,6-tetrachlorophthalonitrile (SDS-2787) and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile (SDS-3701) in or on the raw agricultural commodity filberts at 0.1 ppm in Oregon only. A letter written by R. P. Burton (ISK-Biotech, 3/24/92) is submitted to authorize the use of registrant's data to support this tolerance request.

Tolerances are established for residues of chlorothalonil and its metabolite, SDS-3701, in/on various raw agricultural commodities ranging from 0.05 to 15 ppm under 40 CFR 180.275.

Chlorothalonil is a list A chemical. A registration standard for chlorothalonil has been issued in Oct. 1984 (Acc #258778). The Chemistry Chapters of the FRSTR were completed 3/11/88.



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CONCLUSIONS

- 1a. The nature of chlorothalonil in filberts is adequately understood. The parent compound and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile (SDS-3701), are of regulatory concern.
- 1b. The impurity hexachlorobenzene (HCB) is not included in the tolerance expression, but can occur as a residue in chlorothalonil treated commodities. The HCB residue levels are included in dietary risk considerations.
2. The proposed application rate, 3 lbs ai/100-200 gallons of water per acre is not clear. The petitioner is requested to revise Section B proposing exact gallons of water to be applied per acre.
3. There are no feed items associated with the proposed use on filberts. Therefore, there is no concern with secondary residues in milk, meat, poultry and eggs.
4. Adequate enforcement methods are available in PAM II for residues of chlorothalonil and SDS-3701. The protocol I of the FDA multiresidue methods is adequate to determine the HCB and PCBN impurities present in technical chlorothalonil.
- 5a. None of the metabolites (SDS-3701 and SDS-46851) and the manufacturing impurities (HCB or PCBN) were detected on the treated filberts at harvest. For the purposes of risk assessment, we recommend use of 0.0005 ppm for HCB.
- 5b. The residue data generated from the proposed formulation BRAVO® 720 are considered adequate to support the proposed 0.1 ppm tolerance of chlorothalonil and its metabolite, SDS-3701, on/on filberts in Oregon.
6. There are no Canadian, Mexican and Codex tolerances for chlorothalonil and its metabolite established in/on filberts. Therefore, there are no compatibility problems involved in this petition.

RECOMMENDATION

Pending the revision of Section B specified in Conclusion 2 and TOX considerations permitting, CBTS recommends for the establishment of a 0.1 ppm tolerance for the residues of chlorothalonil and its metabolite, SDS-3701, in or on the raw agricultural commodity filberts in Oregon.

DETAILED CONSIDERATIONS

Manufacture and Formulation

The manufacturing process of technical chlorothalonil and a discussion of its impurities, including HCB (hexachlorobenzene) and PCBN (pentachlorobenzonitrile), have been previously reported in detail in connection with PP#4E1502 (see R. Schmitt's 11/27/74 memo).

The proposed formulation of chlorothalonil is Bravo® 720 (EPA Reg. #50534-188 which is a liquid concentrate containing 6.0 lb ai/gal (54.0% ai and 46.0% inerts)).

Proposed Use

For control of Eastern filbert blight on filberts in Oregon, 4 pints of Bravo® 720 per acre (3 lbs ai/A) is proposed. Applications begin at leaf bud break and repeat at 2 to 4 week intervals. Do not make more than 3 applications per season. Do not apply within 120 days before harvest. Do not combine Bravo® 720 in the spray tank with oils, other pesticides, surfactants or fertilizers. Do not apply within one week of application of an oil-based pesticides. Do not apply this product through any type of irrigation equipment. Do not feed treated plant parts to livestock. Ground application is preferable to aerial application.

The proposed amount of water per acre specified in the submitted label is confusing. Field trials were based on 4.5 lbs ai/100-200 gallons of water per acre. The petitioner is requested to revise Section B proposing exact gallons of water to be applied per acre.

Nature of Residues

The nature of chlorothalonil in plants is adequately understood. A detailed discussion on metabolism of chlorothalonil in plants was reported in connection with PP#7F3471 (see J. Stokes' 5/30/90 memo). CBTS has previously concluded that the water soluble soil metabolite (SDS-46851, 3-carboxy-2,5,6-tri-chlorobenzamide) could be present in infinitesimal amounts and should not be of regulatory concern (see FR p.24552, 6/10/92). CBTS has also determined that inadvertent residues of SDS-3701 in rotational crops resulting from direct application of chlorothalonil to primary crops listed in 40 CFR 180.275(a) would be below background levels (<0.01 ppm). A tolerance or exemption from a tolerance is not required for residues of SDS-3701 in rotational crops.

For the purpose of this minor crop petition for filberts only, we conclude that the nature of the residue is adequately understood. The residues of toxicological concern are chlorothalonil and its 4-hydroxy metabolite (SDS-3701), but the infinitesimal amounts of HCB and PCBN impurities determined are not included.

Chlorothalonil and its 4-hydroxy metabolites are included in the tolerance expression for residues resulting from the use of chlorothalonil, but residue levels of HCB are considered separately. Currently, CB estimates residue levels of HCB at 0.5% of the chlorothalonil tolerance level for individual commodities. This value is utilized to estimate dietary risk associated with HCB, but additional data on HCB level has been requested for reregistration of chlorothalonil (see our memo of 4/11/89, D.F. Edwards, Ph. D., DEB No. 4892). HCB residue data has not been requested for all commodities for which chlorothalonil is registered.

Analytical Methodology

The method entitled General Analytical Procedure for the Determination of Residues of Chlorothalonil (SDS-2787), SDS-3701, SDS-46851, HCB and PCBN on Selected Crops was used for generating the residue data submitted in this petition. Briefly: Residues of the above-mentioned 5 compounds in filbert samples were extracted with a mixture composed of 380 ml acetone and 20 ml 10N sulfuric acid and then selectively partitioned into an organic solvent. the residues of chlorothalonil, HCB and PCBN were separated by column chromatography before subsequent quantitation by GC equipped with an electron capture detector. The residue of SDS-3701 was derivatized to its ether and the residue of SDS-46851 was derivatized to its methyl ester. The derivatives were separated by column chromatography and determined by GC with an electron capture detector. The limits of detection of this procedure are as follows: 0.01 ppm for chlorothalonil and SDS-3701, 0.03 ppm for SDS-46851, 0.003 ppm for HCB and 0.005 ppm for PCBN. The recoveries of the five compounds of interest from the fortified samples ranged from 70% to 120%. Adequate examples of calculation and chromatograms are provided.

The protocol I of the FDA multiresidue methods is adequate to determine the HCB and PCBN impurities present in chlorothalonil technical.

CBTS concludes that this method is adequate and appears to be better than the enforcement method published in PAM II (method I). This method, therefore, can be sent to FDA as a lettered method for inclusion in PAM II.

Storage Stability Study

A report entitled Residues of SDS-2787, SDS-3701, SDS-46851, HCB and PCBN in Cherries from A Stability Study (Field Incurred)- 1988-One Year Interim Report (MRID #415832-1) indicated that these compounds are generally stable over the time period evaluated. CBTS has concluded that this storage stability study is adequate to support the current petition.

Residue Data

Two field trials were conducted in Oregon. The first trial was conducted in 1989 with only one application at the rate of 3 qts Bravo® 720 per acre (1.5X = 4.5 lbs ai/100-200 gal/A) and a PHI of 45 days. The second trial was conducted in 1990 with four applications of the same rate and a PHI of 119 days. Nut meats and shells were separated and frozen before analysis for the parent compound and its metabolites. Residue data submitted are summarized in Table 1.

Table 1. Residues of Chlorothalonil in/on Filberts

Year	No. of appli.	Rate (lb ai /acre)	PHI (day)	Residues Determined (ppm)				
				SDS-2787	HCB	PCBN	SDS-46851	SDS-3701
1989	-	0	-	<0.01	<0.003	<0.005	<0.03	<0.01
	-	0	-	<0.01	<0.003	<0.005	<0.03	<0.01
	1	4.5*	45	<0.01	<0.003	<0.005	<0.03	<0.01
	1	4.5*	45	<0.01	<0.003	<0.005	<0.03	<0.01
1990	-	0	-	<0.01	<0.003	<0.005	<0.03	<0.01
	-	0	-	<0.01	<0.003	<0.005	<0.03	<0.01
	4	4.5*	119	<0.01	<0.003	<0.005	<0.03	<0.01
	4	4.5*	119	<0.01	<0.003	<0.005	<0.03	<0.01

* 4.5 lb ai/A = 1.5X.

Filberts is a minor crop which is primarily grown in Oregon. The residue data shown in Table 1 indicate that, at 1.5X rate, the

combined residues of chlorothalonil and its metabolite, SDS-3701, did not exceed 0.1 ppm, either with one application and a PHI of 45 days or four applications at a PHI of 119 days. Based on these data, CBTS will expect similar results for the proposed 3 applications at the rate of 3 lb ai/A and a PHI of 120 days. Therefore, CBTS concludes that these data are adequate to support the request of 0.1 ppm tolerance for the residues of chlorothalonil and its metabolite, SDS-3701, in/on filberts grown in Oregon only. For the purposes of dietary assessment, we recommend use of 0.0005 ppm for HCB (0.5% x 0.1 ppm chlorothalonil tolerance).

Milk, Meat, Poultry and Eggs

There are no feed items associated with the proposed use on filberts. Therefore, there is no concern with secondary residues in meat, poultry, milk and eggs.

Other Considerations

There are no Canadian, Mexican and Codex tolerances for chlorothalonil and its metabolites established in/on filberts. Therefore, there are no compatibility problems involved in this petition.

cc: Circu, RF, PP#2E4113, W.T.Chin, K.Kariya (SAB/HED)
RDI: J. Garbus(11/9/92), R.Loranger(11/20/92)
H7509C: CBTS: CM#2, RM812, (703)305-5352, W.T.Chin,wc(11/23/92)