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

JUN 7 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#5E3246 [RCB #1034]. Endothall on Hops. Evaluation of Analytical Methodology and Residue Data (Accession Number 073511).

FROM: Michael P. Firestone, Ph.D., Chemist
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: John H. Onley, Ph.D., Section Head
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Hoyt L. Jamerson, Minor Use Officer
Process Coordinator Branch
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Interregional Research Project Number 4 Associate Coordinator, Dr. M. E. Burt, and National Director, Dr. R. H. Kupelian, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of Oregon and Washington, request the establishment of a tolerance for residues of the pesticide endothall (7-oxa-bicyclo [2.2.1] heptane-2,3-dicarboxylic acid) from use of its mono-N, N-dimethylalkylamine salt wherein the alkyl group is the same as the fatty acid of coconut oil in or on the raw agricultural commodity hops at 0.1 ppm.

Endothall tolerances currently established under 40 CFR 180.293 include cottonseed and potatoes at 0.1 ppm and rice and rice straw at 0.05 ppm. An interim tolerance is established for endothall residues in sugarbeets at 0.2 ppm under 40 CFR 180.319.

A letter of authorization has been submitted from J. T. Waddington of Pennwalt Corporation to H. L. Jamerson of EPA, dated April 9, 1985, for the use of all Pennwalt data on endothall (EPA Chemical No. 38901) in support of this petition.

Endothall has not yet been the subject of a Registration Standard.

Conclusions

1. Since data submitted with PP#1F1105/FAP#2H5016 reportedly show no detectable residue of N-nitrosamines (see R. Hummel memo of 7/12/79), RCB does not expect a nitrosamine residue problem.

2. The nature of the residue in plants and animals is considered adequately understood. The residues of concern consist of endothall, parent compound only.

3. Adequate analytical methods are available for enforcement purposes with regard to the proposed use on hops.

4. Based on data reportedly demonstrating no detectable residues (<0.1 ppm) in/on mature green or mature dried hops treated at the maximum proposed use (i.e., twice at 1.0 lb ai/A), RCB considers the proposed endothall 0.1 ppm tolerance for hops adequately supported.

5. RCB has no reasonable expectation of secondary endothall residues occurring in meat, fat, milk, poultry and eggs as a result of the proposed use on hops.

6. Since Codex, Canada and Mexico have no tolerances/limits established for residues of endothall in/on hops, there are no compatibility problems.

Recommendation

TOX and EAB considerations permitting, RCB recommends for the proposed tolerance covering residues of endothall in/on hops at 0.1 ppm.

Detailed Considerations

Manufacature and Formulation

A discussion of the manufacaturing process and a list of the impurities found in technical endothall has been presented in Chemistry Branch's review of PP#4G1510 (see J. Shaughnessy memo of 7/25/74 and A. Smith memo of 8/13/74). Technical endothall is reportedly approximately 91% pure. Chemistry Branch has previously concluded that the impurities are not likely to present a residue problem.

The formulation proposed for use on hops is Pennwalt's DES-I-CATE™ (EPA Reg. No. 4581-206), a water soluble liquid concentrate containing 0.52 lb ai/gal (as the dimethylcocamine salt). The 7-oxabicycol[2.2.1]heptane-2,3-dicarboxylic acid equivalent is 5.5%. All inerts are cleaned under 40 CFR 180.1001.

Alkyl groups in the mono (N, N-dimethylalkylamine) salt are derived from coconut oil. Data submitted with PP#1F1105/FAP#2H5016 reportedly show no detectable residue of N-nitrosamines (see R. Hummel memo of 7/12/79). Thus, RCB does not expect a nitrosamine residue problem resulting from the proposed use of endothall on hops.

Proposed Use

For hops sucker suppression in the Spring, apply endothall to basal growth of hops up to 2 times. Make first treatment when main hops shoots are 2 to 3 feet high. Repeat 7 to 14 days later when hops suckers are 1 to 2 feet long. Do not apply within 85 days of harvest. Apply by ground equipment only. The proposed treatment rate is 0.5 to 1.0 lb ai/A/application.

Nature of the Residue

The metabolism of endothall in plants has been extensively discussed in conjunction with review of PP#1F1105 (see A. Smith memo of 11/4/71).

In plants, endothall is absorbed, translocated, and rapidly catabolized. Extensive degradation results in reincorporation of constituent atoms into various natural plant components. For the purposes of this petition for endothall use on hops, the residues of concern consist of parent compound only.

The metabolism of radiolabelled endothall in goats was also reviewed by RCB in conjunction with PP#1F1105/FAP#2H5016 (see R. Hummel memo of 7/12/79). The results indicate that endothall is catabolized and reincorporated into natural constituents such as carbohydrates, proteins and fatty acids. The nature of the residue in large ruminants is considered adequately understood. As with plants, the residues of concern in animals consist of parent compound only.

Analytical Methodology

The method used to quantitate residues of endothall in hops is essentially the same as that used successfully in the second method trial on potatoes (see K. Zee memo of 4/2/73 re: PP#1F1057).

In brief, residues are extracted from chopped samples using acidified acetone. After filtration, residues of endothall are adsorbed on activated charcoal, recovered by boiling with acetic acid and converted to the N-chloroethylimide derivative by reaction with 2-chloroethylamine. The imide is partitioned into chloroform and cleaned up with activated charcoal and Attaclay. After transfer to methanol, residue quantitation is performed by GLC (10% OV17 on Chrom W-HP, 100/120 mesh) using a nitrogen specific detector.

All controls were reportedly <0.1 ppm. Recoveries from mature cones fortified with endothall at 0.2 ppm were 60 and 65% and from dried mature cones fortified at 0.1, 0.2, and 0.5 ppm were 69, 85 and 62%, respectively, (average of 5 samples = 68%).

The methodology for determination of endothall in hops is considered adequate for regulatory purposes.

A method trial was successfully completed in conjunction with PP#1F1105 for Pennwalt's "Analytical Method for Residues of Endothall in Various Crops and other Materials" (revised May 1975) on milk, beef liver and fish (see G. Makhijani memo of 3/17/78). In RCB's 7/12/79 review of PP#1F1105 (R. Hummel), it was concluded that this method is adequate for enforcement purposes with regard to residues of endothall in animal commodities.

Residue Data

Storage stability data generated on fortified rice, sugar cane, and potatoes reportedly demonstrate that endothall residues are stable for at least one year in frozen plant samples. Since treated hops samples analyzed in conjunction with this petition were stored under frozen conditions for one year or less, RCB will not question the stability of endothall residues in these samples.

Residue field trials were conducted in the states of OR and WA. The geographical representation is considered adequate since these two states accounted for about 91% of the total U.S. production of hops during the 1981 growing season (Agricultural Statistics 1983, published by U.S.D.A.). In the case of the WA field trial, mature cones were dried at 140°F for 12 hours prior to frozen storage. The mature cones harvested in OR were not dried prior to frozen storage.

The residue data are presented below (note: the maximum proposed use allows up to 2 applications at a rate of 1.0 lb ai/A, with an 85-day PHI):

Location	Sample	Application Rate (lb ai/A)	Number of Treatments	PHI (days)	Residue (ppm)
OR	green cones	2.0	1	104	<0.1
		1.0	1	104	<0.1
		1.0	2	97	<0.1
		2.0	1	98	<0.1
		1.0	2	84	<0.1
		0.5	2	97	<0.1
WA	dried cones	2.0	1	94	<0.1
		1.0	2	85	<0.1

The residue data adequately support the proposed tolerance of 0.1 ppm for hops. The residue data generated on dried hops (<0.1 ppm as a result of endothall treatment at the maximum proposed use) adequately demonstrate the lack of a need for a food additive tolerance proposal for dried hops.

Residue in Meat, Fat, Milk, Poultry and Eggs

Spent hops is the only animal feed involved with this petition. Considering the lack of detectable residues in hops (green or dried) resulting from the maximum proposed use of endothall, and the fact that spent hops can only account for a maximum 5% of the cattle or sheep diet, RCB has no reasonable expectation of finite secondary residues occurring in the meat, fat and milk of cattle, goats, hogs, horses and swine.

No poultry feed item is involved with the proposed endothall use on hops. Thus, there is no reasonable expectation of secondary residues occurring in poultry and eggs as a result of the proposed use.

Other Considerations

An International Residue Limit Status sheet is attached. Since Codex, Canada and Mexico have no established limits/tolerances covering endothall residues in hops, there are no compatibility problems.

cc:R.F., Circu, Reviewer, TOX, EAB, EEB, PP#5E3246, PMSD/ISB
FDA, Robert Thompson
RDI:JHOnley:5/29/85:RDSchmitt:5/30/85
TS-769:RCB:CM#810:X7484:MFirestone:wh:6/3/85

1. Lee 5/24/95

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: Endothall PETITION NO.: 5E3246

CCPR NO.: REVIEWER: Michael P. Firestone

Codex Status

☒ No Codex Proposal Step 6 or above

Residue (if Step 9):

Crop(s)	Limit (mg/kg)

Proposed U.S. Tolerances

Residue: endothall (7-oxa-bicyclo [2.2.1] heptane-2,3-dicarboxylic acid

Crop(s)	Tol. (ppm)
hops	0.1 ppm

CANADIAN LIMIT

Residue:

Crop(s)	Limit (ppm)
None (on hops)	

MEXICAN TOLERANCIA

Residue:

Crop(s)	Tolerancia (ppm)
none	

Notes: