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

EXPEDITE

MAR 23 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: FAP#0H5599. Lambda-cyhalothrin in/on Imported Dried Hops. Amendment dated 1/31/92.

DP Barcode: D174321. CBTS # 9350.
No MRID #.

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

THROUGH: Debra F. Edwards, Ph.D., Acting Chief
Chemistry Branch I -- Tolerance Support
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TO: George LaRocca/John Hebert, PM 13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

and

Toxicology Branch I
Health Effects Division (H7509C)

This review is under the general expedite request for this petition by letter of Anne Lindsay, 8/29/91. The due date is 4/1/92.

The present submission from ICI Agricultural Products includes a letter dated 1/31/92 and a Confidential Statement of Formula (CSF). A multivolume submission was submitted to EPA on 1/15/92 and contains responses to our questions concerning PP#0H5599 as outlined in our memorandum of 9/19/91. That memo also addressed PP#7F3560/7H5543 and PP#1F3952/1H5607. Relevant volumes of that submission have been reviewed in this memo.

Deficiency Remaining to Be Resolved

Revised Section F needs to be submitted.

Conclusions (pertaining to this memo only)

1a. The correct Chemical Abstracts name for lambda-

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cyhalothrin is [1α(S*),3α(Z)]-(±)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate. The correct Chemical Abstracts name for the epimer of lambda-cyhalothrin is [1α(R*),3α(Z)]-(±)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate.

1b. CBTS recommends that the IUPAC names for lambda-cyhalothrin and its epimer -- rather than the Chemical Abstract names -- appear in the regulation. In our opinion, a practicing chemist can more readily relate the IUPAC name to the structure.

The IUPAC name for lambda-cyhalothrin is --

A 1:1 mixture of

(S)-α-cyano-3-phenoxybenzyl (1R)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethyl-cyclopropanecarboxylate

and

(R)-α-cyano-3-phenoxybenzyl (1S)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethyl-cyclopropanecarboxylate

The IUPAC name for the epimer of lambda-cyhalothrin is a 1:1 mixture of the (S,S) and (R,R) isomers. The full name appears in the text of this memo.

2. The Confidential Statement of Formula for Karate 2.5 EC, used only overseas, has been submitted.

3a. The nature of the residue in plants is adequately understood. The residue to be regulated is lambda-cyhalothrin and its epimer.

3b. The nature of the residue in animals is adequately understood for purposes of this petition. The residue to be regulated is lambda-cyhalothrin and its epimer. For use in/on the raw agricultural commodities (racs) of PP#7F3560/7H5543, which could result in higher residues in animal products, the issue of HO-CPA needs to be resolved (see discussion in this memo).

4. Metabolites in dried hops have been shown to be stable under frozen storage conditions for 113 days. Residue samples were held for up to six months prior to analysis. However, a 12 month storage stability study

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with 13 racs sufficiently supports the hops residue analyses.

5. ICI has estimated that >99% of lambda-cyhalothrin will concentrate in the fat of milk. Therefore, the appropriate milkfat tolerance can be obtained from the tolerance for whole milk by dividing that tolerance by 0.04, the fraction of fat in whole milk. For this petition, predicted residues in milk are lower than 0.01 ppm, the limit of quantitation. The appropriate milkfat tolerance is 0.25 ppm (reflecting 0.01 ppm in whole milk).

   For this petition only, the following tolerances should be proposed:

Dried Hops (FAT)	10.0 ppm
Fat of cattle, goats, horses, and sheep	0.02 ppm
Meat and meat byproducts of cattle, goats, horses and sheep	0.01 ppm
Milkfat (reflecting 0.01 ppm in whole milk)	0.25 ppm

Recommendation

CBTS recommends against the proposed tolerances for the reason given in Conclusion 5 (revised Section F).

Detailed Considerations

Deficiencies are listed from our 9/19/91 memo with ICI's response and CBTS' comments.

CBTS Deficiency #1 (Conclusion #1 from our 9/19/91 memo)

The registrant should obtain written confirmation from Chemical Abstracts Service that the proposed CAS name, [1α(S*),3α(Z)]-(+)-cyano-(3-phenoxyphenyl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate, is the correct Chemical Abstracts name.

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ICI Response (MRID #421723-01)

A letter is enclosed from Chemical Abstracts Service dated 11/18/91. The CA name for lambda-cyhalothrin is [1α(S*),3α(Z)]-(±)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate. The CAS Registry No. is 91465-08-6.

According to Chemical Abstracts Service, the CA name for the epimer of lambda-cyhalothrin is identical to that for the parent except that S* is replaced with R*. The convention "S*" signifies that the orientation about 1 chiral carbon (1α) is opposite to the orientation of the CN - C. "R*" implies the same orientation. (This information was conveyed in a telephone conversation between the reviewer and C. Smith, ICI, 3/17/92.)

CBTS Comment

This deficiency is resolved. Although the CAS names uniquely specify lambda-cyhalothrin and its epimer, CBTS recommends that the IUPAC names appear in the final regulation. To a practicing chemist, the structures are more easily derived from the IUPAC names.

The IUPAC name for lambda-cyhalothrin is --

A 1:1 mixture of

(S)-α-cyano-3-phenoxybenzyl (1R)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane-carboxylate

and

(R)-α-cyano-3-phenoxybenzyl (1S)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane-carboxylate

Similarly, the IUPAC name for the epimer of lambda-cyhalothrin is --

A 1:1 mixture of

(S)-α-cyano-3-phenoxybenzyl (1S)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane-carboxylate

and

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(R)-α-cyano-3-phenoxybenzyl (1R)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane-carboxylate

(These names are given in ICI Volume 118 [MRID # 421823-01], PP#7F3560).

We note that the IUPAC name given for lambda-cyhalothrin in MRID # 419346-01 (ICI's Volume 104), as reported in our 9/19/91 memo, was really the name for the epimer of lambda-cyhalothrin.

CBTS Deficiency #2

The use label from West Germany is for a KARATE 2.5 EC. A Confidential Statment of Formula should be submitted for this particular product.

ICI Response (No MRID #)

The Confidential Statement of Formula for Karate 2.5 EC (YF7884) has been submitted (Volume 120).

CBTS Comment

This deficiency is resolved.

CBTS Deficiency #3

The nature of the residue in plants is not adequately understood.....

CBTS Comment

In our 1/22/92 memo for PP#7F3560/7H5543, we concluded that the nature of the residue in plants was now adequately understood. The residue to be regulated is lambda-cyhalothrin, per se. However, the epimer should also be included in the tolerance expression (meeting with TB1, 10/31/91). This deficiency has been resolved.

CBTS Deficiencies #4e, 5d, 10c

These deficiencies relate to the need for an analytical method, storage stability, and residue data for the animal metabolite HO-CPA. In an internal meeting held 4/11/91, CBTS and TB1 decided that unless the registrant could show that HO-CPA was a rat metabolite, residue data on this metabolite and a validated analytical method would be needed before a final decision could be made whether or not this metabolite should appear in the tolerance expression.

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ICI Response

The primary metabolite found in rat urine following administration of cyclopropane-labeled cyhalothrin was the glucuronide conjugate of the cyclopropyl carboxylic acid moiety (25% of the dose). Minor metabolites included the free carboxylic acid and another glucuronide which was not identified, but by analogy to permethrin could be HO-CPA and its glucuronide conjugate. Copies of the cyhalothrin and permethrin rat metabolism studies are included. The acid moiety of lambda-cyhalothrin is identical to the acid moiety of tefluthrin. In ICI Report No. CTL/P1295 [ICI Report No. 45; MRID No. 40161109], it was demonstrated that the acid moiety is metabolized primarily to a cis-hydroxylated cyclopropane acid metabolite which is then excreted largely as acid hydrolyzed conjugates.

In summary, the metabolism in the rat of lambda-cyhalothrin has been shown to be similar to the metabolism of structurally similar pyrethroids. Hydroxylated cyclopropane carboxylic acid metabolites have been identified in the rat for these other pyrethroids. While a minor metabolite of lambda-cyhalothrin in the rat was not identified, the weight of evidence suggests that the unidentified lambda-cyhalothrin in the rat is HO-CPA.

CBTS Comment

There really is no direct analytical evidence that any of the minor metabolites found in the cyhalothrin rat study is HO-CPA. The statement is made in the study: "Other minor metabolites included the free carboxylic acid and another glucuronide which is unidentified but by analogy to permethrin (Gaughan 1977) could be a conjugate of a 2-trans hydroxymethyl derivative." The permethrin study (MRID No. 421723-08) is a copy of the journal article: "Permethrin Metabolism in Rats," L.C. Gaughan, T. Unai, and J.E. Casida, J. Agric. Food Chem., Vol. 25, No. 1, 1977, Pgs. 9-17. Free hydroxymethyl cyclopropane carboxylic acids were detected by TLC in both urine and feces, and the glucuronide conjugate of the cis-HO isomer was found in urine.

From a review of the tefluthrin rat metabolism study (ICI Vol. 45: PP993: Biotransformation in the Rat, 4/17/86), we conclude that conjugates of cis-3-(Z-2-chloro-3,3,3-trifluoro-prop-1-enyl)-2-hydroxymethyl-2-methylcyclopropanecarboxylic acid are the major metabolites in urine. As noted by ICI, the acid moiety of tefluthrin is identical to that of lambda-cyhalothrin. It is therefore likely, but not certain, that the hydroxymethyl cyclopropanecarboxylic acid and/or its conjugates are also rat metabolites of lambda-cyhalothrin.

ICI has conducted a residue transfer study in which lambda-

cyhalothrin was fed to beef cattle and tissue of liver and kidney analyzed for HO-CPA. Preliminary results were delivered to EPA on 2/28/92 and communicated to this reviewer on 3/4/92 by Cynthia Smith of ICI. Levels of the hydroxylated metabolite did not exceed 0.01 ppm when cows were orally dosed with 8 ppm lambda-cyhalothrin. In our 9/19/91 memo a maximum concentration in the diet of beef cattle was determined to be 7.6 ppm, based on proposed tolerances. Brewers grains -- assumed to be present at the maximum 5% of the diet -- contributed 0.05 ppm to this diet. (Although we recommended that the tolerance for dried hops should be 10 ppm, we used the maximum level for brewers grains of 1.0 ppm in estimating exposure. This point is further discussed later in this memo.) From this residue transfer study we can make a tentative conclusion -- subject to CBTS review of the study -- that any metabolite residues in cattle arising from hops will be undetectable (<0.01 ppm). The same conclusion can be reached from consideration of the residue transfer study summarized in our 9/19/91 review. In that study, tissues were not analyzed for the hydroxylated metabolite, but combined levels of lambda-cyhalothrin and the unhydroxylated cyclopropane-carboxylic acid (CPA) were estimated to be 0.05 ppm and 0.13 ppm in liver and kidney, respectively, based on the concentration of 7.6 ppm in the diet of cattle. If it is assumed that these combined levels are higher than corresponding levels of HO-CPA which may be present, we calculate that levels of the latter metabolite will be nondetected. We note that metabolism studies in both ruminants and poultry always showed HO-CPA levels lower than corresponding CPA levels, and CPA levels are also higher in the residue transfer study not yet reviewed.

We conclude that for purposes of this petition, there is no need for complete residue data on HO-CPA. Depending on our evaluation of the residue transfer study submitted 2/28/92, there may be no need to incorporate this metabolite into the tolerance expression for other racs as well. Our evaluation of the other pending petitions will not be complete before this latest study has been reviewed.

Deficiencies # 4e, 5d and 10c are resolved for this petition.

CBTS Deficiency #5b

> CPA, 3-PBAcid and 3-PBAlcohol in various racs are stable for 3 months under frozen storage. This time period is insufficient to support the residue analyses....

ICI Response

A report on storage stability of lambda-cyhalothrin and metabolites in hops has been submitted:

"Lambda Cyhalothrin: Storage Stability of the Insecticide and Its Metabolites in Frozen Dried Hops and Brewers Grains," D.M. Clarke and A. Sapiets, 11/27/90, Lab. Project ID RJ0886 -- ICI Agrochemicals, Bracknell, Berkshire, UK. (MRID # 421823-02)

Dried hops and brewers grains with lambda-cyhalothrin residues were stored at <-18°C from 3 to 8 months and reanalyzed for lambda-cyhalothrin and its epimer, PP890 (CPA) and 3-PBAcid. Results are given in the following table.

Table 1

Storage Stability of Lambda-Cyhalothrin, Epimer, and Metabolites in Frozen Dried Hops and Brewers Grains (<18°C)

	Dried Hops			Brewers Grains		
	Initial Residue (mg/kg)	Storage Period (days)	Residue After Storage (mg/kg)	Initial Residue (mg/kg)	Storage Period (days)	Residue After Storage (mg/kg)
Lambda-Cyhalothrin + Epimer	9.6*	254	10.8*	0.86 0.71	112 119	1.1 0.88
PP890	1.0	113	1.0	0.35	131	0.45
3-PBAcid	1.0	113	1.1	0.18	131	0.17

CBTS Comment

A review of 1989 residue trials report (MRID # 416146-05), indicates that dried hops samples were harvested 9/1/89 to 9/12/89 and analyzed for parent and epimer in October. Storage stability data support these analyses. However, samples were not analyzed for metabolites until 2/26/90 to 3/1/90 (these dates appeared on submitted chromatograms). The storage stability data for metabolites cover little more than one-half the actual storage period of the samples. Therefore, the storage stability data on hops do not support the residue analyses. Storage stability data for hops would be necessary for six months.

Three month storage stability data for metabolites in 13 racs were reported in our 9/19/91 memo. Stability data are now available for 12 months. The data have been submitted in PP#2F4100 (dried bulb onions and garlic) in the following report:

"Interim Report on Storage Stability of Puyrethroid Metabolites in Raw Agricultural Commodities;" C.L. Eckstein; 1/21/92; ICI Americas Inc. Western Research Center, Richmond, CA; Lab. Study No. PYRE-89-SS-01; Report No. RR 91-034B. (MRID # 422068-02)

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The report also includes data on DCVA, dichlorovinyl acid, (the cyclopropane carboxylic acid moiety of permethrin).

Thirteen racs -- apples, cabbage, corn fodder, corn forage, cotton, lettuce, peanut hulls, peanut meats, sorghum grain, soybeans, sugar beets, tobacco and tomatoes -- were fortified at -20±5°C with 0.1 ppm metabolites. A slight decline was observed in some of the racs over the 12 month period. Average recoveries for all racs at 0 Day and 12 Months are compared in Table 2.

Table 2

Average Recoveries (µg/g) for All RACS
(Fortification Level 0.1 µg/g)

Metabolite	0 Day	12 Months
PP890 (CPA)	0.099±0.009	0.084±0.016
3-PBAcid	0.10±0.009	0.089±0.011
3-PBAlcohol	0.104±0.006	0.0848±0.010
DCVA	0.099±0.006	0.0993±0.012

Greater declines were observed in certain racs. For example, recoveries from peanut meats for PP890 averaged 0.099 µg/g at 0 day and 0.066 µg/g at 12 months. This 12 month recovery was the lowest observed. The storage stability study will be continued for an additional two years. Intervals from extraction to analysis are reported on page 27 of the report. The longest interval was 29 days.

We conclude that the stability data support the metabolite analyses for hops.

CBTS Deficiency #5c

CPA, 3-PBAcid and 4'-OH-3-PBAcid are reportedly stable in cow and chicken matrices for 35-42 months under frozen storage conditions. Matrices spiked included muscle, milk, kidney, liver, egg and fat. Except for milk and egg, it is not clear whether cow or poultry tissues were fortified. The registrant should clarify this relatively minor issue.

ICI Response

Cow and poultry samples were fortified prior to storage.

CBTS Comment

This deficiency is resolved.

CBTS Deficiency #8

Based on submitted residue data, a tolerance of 10 ppm for residues of lambda-cyhalothrin, per se, in/on dried hops appears to be adequate. However, before a revised Section F is submitted proposing this tolerance, the registrant must submit validation data from the 1985 field trials (at least the 1985 trials held in Germany -- the trial in Czechoslovakia employed much lower use levels, so residue levels were much lower). If validation data are unavailable, additional field trials will be necessary. The dates of analysis should also be submitted.

ICI Response

Enclosed as ICI Volumes 126 [Report No.: M4315B Addendum, **MRID # 421723-06**] and 127 [Report No.: M4211B Addendum, **MRID # 421723-07**] are validation data for the 1985 field trials conducted in Germany and Czechoslovakia, respectively. Also enclosed as Attachment 1 is a revised Section F.

Recoveries from the German field samples averaged 97% from three spikes at levels of 1.0, 1.0 and 2.5 mg/kg. The analytical method utilized an internal standard, which probably accounts for recoveries near 100%. According to ICI's addendum, samples of hops were harvested August-September 1985 and received frozen at Jealott's Hill Research Station, UK during September, 1985. All analyses were completed between 2-17 December, 1985. Storage stability data are adequate to support these analyses. (Metabolites were not analyzed.)

One fortification was done from the Czechoslovakia field samples (from one field trial). At a fortification level of 0.1 mg/kg, the recovery was 93%. Samples were harvested in August, 1985 and received fresh at Jealott's Hill Research Station, UK during October, 1985. All analyses were completed between 26 March-2 April, 1986. However, the samples apparently remained unfrozen for about three months, and there are no storage stability data to support these analyses. As we implied in our 9/19/91 memo, the data from this field trial are not especially useful for tolerance setting purposes because the application rate of lambda-cyhalothrin was much lower than the application rates in the German studies.

ICI has submitted a revised Section F in which a tolerance of 10 ppm is proposed for lambda-cyhalothrin in/on dried hops (**MRID # 421823-01**).

CBTS Comment

The data from the field trials held in Germany are acceptable. This deficiency is resolved. However, see our comment below concerning inclusion of the epimer of lambda-cyhalothrin in the tolerance expression.

CBTS Deficiency #10a

Based on results from ruminant and poultry feeding studies, ICI should submit a revised Section F in which the following tolerances for lambda-cyhalothrin are proposed:

Milk, meat and mbyp of cattle, goats, hogs, horses and sheep	0.2 ppm
Fat of cattle, goats, hogs, horses and sheep	4.0 ppm
Meat, fat, mbyp and eggs of poultry	0.01 ppm

CBTS Deficiency #10b

Because lambda-cyhalothrin -- as other pyrethroids -- concentrates in fat, data are necessary to show concentration of residues in the fat of milk. This can be done by analyzing milk fat from samples of the original feeding study or by spiking milk with lambda-cyhalothrin and analyzing the milk fat. Based on the concentration factor, an appropriate tolerance for lambda-cyhalothrin in milk fat should be proposed.

ICI's Response to Deficiencies 10a and 10b

A tolerance of 0.2 ppm is proposed for the meat and mbyp of cattle, goats, hogs, horses and sheep. A tolerance of 3 ppm is proposed for the fat of cattle, goats, hogs, horses and sheep. A tolerance of 0.01 ppm is proposed for the meat, fat, mbyp and eggs of poultry. A tolerance of 3 ppm is proposed for milk, fat (reflecting 0.1 ppm in whole milk).

ICI proposes to use maximum measured residue values instead of tolerance values for proposed worst case diets and tolerances. The tolerance of 3 ppm for milkfat was determined assuming that 100% of lambda-cyhalothrin concentrates in milkfat. Experimental determination was not considered necessary because tefluthrin residues in both whole milk and milk fat were measured in the tefluthrin residue transfer study in the cow (MRID #40141328), and results demonstrated that ≥99% of tefluthrin residues concentrate in the milk fat. The octanol/water partition

coefficients of tefluthrin and lambda-cyhalothrin are similar -- 6.5 and 7.0 at 20°C, respectively. The proposed tolerance was determined by dividing 0.1 ppm by 0.03. The 0.1 ppm was obtained using a maximum measured residue values in the diet of dairy cattle instead of tolerances.

CBTS Comment

Tolerances for animal products are set assuming that pesticide residues in the components of the animal's diet are present at the tolerance levels. We agree that these tolerances exaggerate chronic exposure to the pesticide, but they are useful for purposes of enforcement. If it becomes necessary to estimate exposure more accurately -- e.g., if the reference dose is exceeded when tolerances are used in a DRES calculation -- CB routinely uses anticipated residues to obtain a more accurate estimate. In determination of the anticipated residue in an animal tissue, the average residue for a given rac is used instead of the tolerance.

The tolerance of 4.0 ppm for residues of lambda-cyhalothrin in fat of cattle, goats, hogs, horses and sheep includes a contribution due to dermal use of the pesticide on cattle. In our 9/19/91 memo, we noted that if cattle were excluded, the proper tolerance would be 3.0 ppm. ICI may wish to propose a tolerance of 4.0 ppm for lambda-cyhalothrin in/on the fat of cattle and 3.0 ppm for the pesticide in/on the fat of goats, hogs, horses and sheep. Otherwise, as recommended in our previous memo, the tolerance should be 4.0 ppm for lambda-cyhalothrin in the fat of all these animals.

CBTS recommended that a tolerance of 0.2 ppm be proposed for residues of lambda-cyhalothrin in milk. This was based on a predicted maximum residue level of 0.14 ppm using a diet in which components contained the pesticide at its tolerance levels. We agree that it is not necessary to analytically determine levels of lambda-cyhalothrin in milkfat. The assumption that all the pesticide will be in the milkfat is valid based on the known chemistry, the chemical similarity to tefluthrin and the octanol/water coefficient. In the absence of data, its is currently branch practice to use 0.04 instead of 0.03. The proper milkfat tolerance should be 5.0 ppm [0.2 ppm/0.04] (reflecting 0.2 ppm lambda-cyhalothrin in whole milk).

For this petition only, the following tolerances for residues of lambda-cyhalothrin in cattle (and goats, horses and sheep) are appropriate:

Fat	0.02 ppm
Meat and Meat	

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Byproducts	0.01 ppm
Milkfat (reflecting 0.01 ppm in whole milk)	0.25 ppm

These tolerances have been calculated under the assumption that spent hops constitute 5% of the diet of dairy and beef cattle. Dermal exposure is not included. We note that "spent hops" fed to animals not only include hops remaining after the brewing process but also hops which have been extracted to give hops extract, which is used in some beers. Pesticide levels in hops which have been extracted are not necessarily similar to levels in hops which have been spent in brewing. Presently, hops can be extracted with carbon dioxide or dichloromethane. Since lambda-cyhalothrin is organosoluble, most of the pesticide residue should appear in the hops extract, so extracted hops should contain even lower lambda-cyhalothrin residues than hops which have been directly used in brewing. Residues in these latter "spent hops" could therefore be used as a worse case. We consider the concentration in spent hops to more accurately reflect lambda-cyhalothrin residues in hops fed to animals than residue concentrations in dried hops.

If dermal use of lambda-cyhalothrin is also included, the appropriate tolerances for fat, meat and meat by-products are those determined from dermal use (PP#9F3770).

Inclusion of R157836 in Tolerance Expression

R157836, the "epimer" of lambda-cyhalothrin, is a mixture of the following enantiomers: (1) (S)-α-cyano-3-phenoxybenzyl (1S)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethyl-cyclopropanecarboxylate and (2) (R)-α-cyano-3-phenoxybenzyl (1R)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethyl-cyclopropanecarboxylate. Lambda-cyhalothrin and R157836 differ only in the arrangement of the C-CN bond. If in the parent the arrangement of groups around the C-CN bond is R, then the arrangement of the groups around the carbon atoms at the 1- and 3- positions in the cyclopropane ring is S [RSS]. If in the parent the arrangement of groups around the C-CN bond is S, then the arrangement of the groups around the carbon atoms at the 1- and 3- positions in the cyclopropane ring is R [SRR]. The situation is reversed for the epimer, i.e., the pair of isomers can be denoted RRR and SSS.

The epimer is an impurity in technical PP321 but has been found in treated racs at levels typically 10% of corresponding lambda-cyhalothrin levels. It is apparently a photodegradation product of lambda-cyhalothrin. Analyses for epimer in animal matrices have not been reported (vide infra).

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The analytical methods for lambda-cyhalothrin in plant matrices (ICI Method 81) and animal matrices (ICI Method 86) have

undergone successful EPA method validation. Method 81 has been used to quantitate the epimer in plant matrices, and Method 86 would probably work for animal matrices. A capillary GC column is necessary to resolve parent and epimer. EPA has not validated either method using the epimer, but due to the chemical similarity of the two species, additional validation would be pointless. Similarly, multiresidue testing data for epimer would be identical to the data obtained for lambda-cyhalothrin, so a multiresidue testing requirement for epimer would also be pointless. The animal residue transfer data reviewed by CB up to this time were obtained using packed column GC, which would not resolve parent and epimer. (This information was conveyed to this reviewer in a 3/12/92 telephone conversation with Cynthia Smith of ICI.) Therefore, the animal data reviewed up to this time are for the combined residues of parent and epimer.

For this and subsequent petitions, CBTS recommends that tolerances be established for the combined residues of lambda-cyhalothrin and its epimer. The numerical tolerances to be proposed in this petition -- 10 ppm for dried hops and the tolerances for cattle products listed above -- remain unchanged.

cc: SF, RF, Circu., C.Furlow(PIB/FOD), MikeFlood, E.Haeberer, PP#7F3560/7H5543, PP#1F3952/1H5607, FAP#0H5599.

H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(mtf):3/24/92.
RDI:SectionHead:ETHaeberer:3/23/92:BranchSeniorScientist:RALoranger: 3/23/92.

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