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

APR 8 1992

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Leon Sawyer, Chemist
Pesticides and Industrial Chemicals
Branch, HFF-426
Division of Contaminants Chemistry
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Mr. Sawyer:

Enclosed is the following Multiresidue Test Information for the updating of PAM I:

| | |
|---|---|
| Title: | Analysis of 3-(4'-Hydroxy) Phenoxy Benzoic Acid by Multi-Residue Methods in FDA Pesticide Analytical Manual Volume I<br><br>D.F. Gillard, author<br>Lab Project I.D. HAS Study No. A030.007E<br>October 10, 1991<br>37 pages |
| Chemical: | 3-(4'-Hydroxy)phenoxybenzoic acid ($C_{13}H_{12}O_2$)* |
| Type: | Insecticide |
| Sponsor: | ICI Americas Inc. |
| Protocols: | A-E |
| Performing Laboratory | Huntingdon Analytical Services<br>Middleport, New York 14105 |
| PP#: | 7F3560 |
| MRID #: | 421723-02 |
| 40 CFR Ref: | §180.438 |

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| | |
|---|---|
| Title: | Analysis of 3-Phenoxybenzyl Alcohol (3-PBA) by Multi-Residue Methods in FDA Pesticide Analytical Manual Volume I |

D.F. Gillard, author
Lab Project I.D. HAS Study No. A030.007B
September 16, 1991
30 pages

| | |
|---|---|
| Chemical: | 3-Phenoxybenzyl alcohol ($C_{13}H_{13}O_2$)* |
| Type: | Insecticide |
| Sponsor: | ICI Americas Inc. |
| Protocols: | A-E |
| Performing Laboratory | Huntingdon Analytical Services<br>Middleport, New York 14105 |
| PP#: | 7F3560 |
| MRID #: | 421723-03 |
| 40 CFR Ref: | §180.438 |

* 3-(4'-Hydroxy)phenoxybenzoic acid and 3-phenoxybenzyl alcohol are metabolites of lambda-cyhalothrin and other pyrethroids. They are not listed in §180.438.

If, upon examination, you consider the data submitted by the sponsor of these chemicals to be deficient in any respect, please notify us as to the additional data/information you require.

Sincerely,

Michael T Flood

Michael T. Flood, Ph.D.
Chemistry Brancy I
Health Effects Division
(H7509C)

Attachments:

"Analysis of 3-(4'-Hydroxy) Phenoxy Benzoic Acid by Multi-Residue Methods in FDA Pesticide Analytical Manual Volume I" Lab Project ID HAS A030.007E, EPA MRID # 421723-02

"Analysis of 3-Phenoxybenzyl Alcohol (3-PBA) by Multi-Residue Methods in FDA Pesticide Analytical Manual Volume I" Lab Project ID HAS A030.007B, EPA MRID # 421723-03

cc (with attachments): Harvey Hundley (H7503W)

cc (without attachments): Mike Flood, M.J. Bradley, RF, Circu., PP#7F3560/7H5543, SF, PIB/FOD, E. Haeberer.

RDI:Branch Senior Scientist:R.A.Loranger:4/8/92.
H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(mtf):4/8/92.

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NOV 23 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

**MEMORANDUM**

SUBJECT: Lambda-Cyhalothrin. ICI Americas, Inc.'s Anticipated Residue Calculations. Proposed Strategy for Analysis of Metabolites in Future Residue Studies.

DP Barcode: D178118. CBTS # 9882.
MRID # 422884-01.

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
Health Effects Division (H7509C)

TO: G. LaRocca/A. Heyward, PM 15
Insecticide-Rodenticide Branch
Registration Division (H7505C)

**Background**

ICI has submitted residue data on numerous crops, including field and sweet corn, wheat, sorghum, soybeans, peanuts, sunflowers, broccoli, cabbage, tomatoes, hops, onions and lettuce. These crops and relevant processed commodities were analyzed for lambda-cyhalothrin, its epimer (an isomer pair that is always present at low concentrations), and three metabolites: PP890, 3-PBAcid and 3-PBAlcohol. Our most recent memo is dated 11/19/92.

In the present submission, ICI has assembled all the collected residue data in one volume and calculated averages for each crop. Such information should be quite useful in determining anticipated residues. However, present policy is to first conduct a DRES analysis using tolerances. If the reference dose is exceeded, exposure is then calculated with anticipated residues, and the submitted information can be used at that time.

ICI has also submitted a proposal for conducting residue analyses based on patterns observed in previous analyses. The company notes the following:

1. Maximum metabolite residues (PP890, 3-PBAcid and PBAlcohol) are always low and/or substantially less than the maximum regulated residues (lambda-cyhalothrin plus its epimer).

2. With one exception, metabolite residues are always below the limit of determination (<0.01 ppm) when the combined regulated residues are ≤0.04 ppm. In one field trial with wheat, residues of lambda-cyhalothrin and epimer were <0.01 but the level of PP890 was 0.02 ppm.

3. Average metabolite residues are always low (≤25%) relative to the combined residues of lambda-cyhalothrin and epimer.

The company therefore proposes the following program for future analyses:

1. All samples will be analyzed for lambda-cyhalothrin and epimer.

2. For commodities with maximum combined residues of parent and epimer ≥0.05, metabolite analyses will be conducted on samples from each trial having the three highest combined parent and epimer residues. [We assume that this means that from all the field trials on one RAC, metabolite analyses will be carried out on samples from three trials.]

3. For commodities with maximum combined parent and epimer residues ≤0.04 ppm, no metabolite analyses will be conducted.

For <u>processed commodities</u>, ICI notes that:

1. With the exceptions of grain dust [not really a processed commodity] and tomato pomace, all residues of parent, epimer and metabolites are low.

2. With the exception of crude corn oil, peanut soapstock and soybean soapstock, PP890 and combined 3-PBAcid and 3-PBAlcohol residues are always ≤ to the lambda-cyhalothrin residues.

ICI therefore proposes that:

1. All samples would be analyzed for parent and epimer.

2. Metabolites would be analyzed in soapstock samples and in commodities with maximum combined parent and epimer levels of ≥0.05 ppm; otherwise no metabolite analyses

would be carried out.

CBTS Comment

CB I and TB I have agreed that, at present, only the parent and epimer need appear in tolerance expressions for lambda-cyhalothrin. This conclusion was based on probable toxicities of the metabolites as well as low concentrations. The residue data summary for the raw agricultural commodities does indicate that when concentrations of parent lambda-cyhalothrin are low, metabolite concentrations are lower. We therefore agree with ICI's proposal to analyze for metabolites only when parent + epimer concentration exceeds 0.05 ppm.

On the other hand we recommend that metabolite analyses be continued for processed commodities, at least for human food items. Data from seven completed processing studies do indicate that even when parent is present at low levels, metabolites -- usually PP890 -- may be also present at low but quantifiable levels. For example, in tomato juice, parent + epimer concentration was 0.02 ppm, PP890 concentration was 0.02 ppm and PBAcid + PBAlcohol concentration was 0.01 ppm. Should the tolerance expression for lambda-cyhalothrin be reassessed, such analytical data would be useful. Such reassessment might occur, for example, if data from new field trials show significant concentrations of metabolites and a general DRES analysis becomes necessary.

cc: SF, RF, Circu., Mike Flood, E. Haeberer, PP#7F3560, PP#2F4109, PP#2F4414.

H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(mtf):11/20/92.
RDI:SectionHead:ETHaeberer:11/20/92:BranchSeniorScientist:RALoranger: 11/20/92.