



PC 106201 R.F.

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

JAN 12 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: PP# 4E4349 - AMITRAZ (MITAC®) ON HOPS.
EVALUATION OF THE NOVEMBER 28, 1994, AMENDMENT.
(No MRID #[CBTS # 14886]{DP Barcode # D210571})

From: Francis D. Griffith, Jr., Chemist
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

To: Dennis H. Edwards, Jr., PM-19
Insecticide-Rodenticide Branch
Registration Division (7505C)

and

Albin Kocialski, Ph.D.
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Thru: Richard A. Loranger, Ph.D., Acting Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

BACKGROUND

AgrEvo, a company of Hoechst and Nor-Am, submitted this amendment consisting of a cover letter dated November 28, 1994, signed by J.J. Vukich and a revised Section F (a new numerical tolerance at 60 ppm). This amendment was submitted in response to a deficiency outlined and summarized in our November 8, 1994, by F. Griffith, Jr. The deficiency is repeated in the body of this review as it appeared in our November 8, 1994, review followed by the petitioners responses, then CBTS comments. Our conclusion and recommendation follow.

There is a co-pending petition, 2F4110, for direct dermal application of amitraz on hogs currently in reject status. Deficiencies remaining (see memorandum dated Sept. 21, 1994, by F. Griffith) include revised labeling/directions for use, and revised tolerances.

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES

- NONE -



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

CONCLUSIONS

1. CBTS Conclusions on Magnitude of the Residue - Crop Field Trials and Proposed Tolerance

a. The petitioner has presented an adequate amount of varietal, multi-year, and geographically representative crop field trial data. CBTS reiterates that those field trials for which we have data on the %DM in dried hops are the primary data we use to determine the appropriate import tolerance. None of the data are discarded because we lack the %DM in hops.

b. CBTS concludes the magnitude of the amitraz residue data on dried imported hops supports the revised 60 ppm tolerance. Deficiency 7c is resolved.

2. CBTS Conclusions on Harmonization of Tolerances

Since there are no Canadian, Mexican, or Codex MRLs for amitraz on dried hops, compatibility should not be a problem.

RECOMMENDATIONS

Tox considerations permitting CBTS recommends for the proposed revised import tolerance for residues of amitraz (N'-[2,4-dimethylphenyl]-N-[[[(2,4-dimethylphenyl)imino]methyl]-N-methylmethanimidamide) and its metabolites N-(2,4-dimethylphenyl)-N-methyl formamide and N-(2,4-dimethylphenyl)-N-methylmethanimidamide (both calculated as the parent compound) in or on dried hops at 60 ppm.

The regulation in 40 CFR §180.287 should bear the notation that there are no USA registrations for the uses of amitraz on hops as of (the date of the regulation).

DETAILED CONSIDERATIONS

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS AND PROPOSED TOLERANCE

DEFICIENCY

7c. CBTS concludes that the magnitude of the amitraz residue data on dried imported hops supports a 60 ppm tolerance. The petitioner needs to present a revised Section F proposing a total amitraz tolerance on dried hops at 60 ppm.

PETITIONER'S RESPONSE

In the November 28, 1994, the petitioner submitted a revised Section F proposing a revised numerical total amitraz tolerance on dried hops at 60 ppm. The tolerance expression was not changed.

CBTS COMMENTS

CBTS reiterates that the petitioner has presented an adequate amount of varietal, multi-year, and geographically representative crop field trial data. CBTS reiterates that those field trials for which we have data on the %DM in dried hops are the primary data we use to determine the appropriate import tolerance. None of the data are discarded because we lack the %DM in hops.

CBTS concludes the magnitude of the amitraz residue data on dried imported hops supports the revised 60 ppm tolerance. Deficiency 7c is resolved.

HARMONIZATION OF TOLERANCES

An INTERNATIONAL RESIDUE LIMIT (IRL) status sheet is attached to this review. There are no Canadian, Mexican, or Codex tolerances for amitraz on dried hops; thus, compatibility is not a problem.

Since this is an import tolerance proposed for dried hops from Germany, the United Kingdom, and other countries, CBTS notes that only in Germany is there an amitraz tolerance on hops at 0.2 ppm. The present German amitraz on hops tolerance is more than an order of magnitude less than the proposed USA tolerance. German use has been revised and will necessitate a higher tolerance. The new proposed 60 ppm tolerance on dried hops covers residues resulting from the current German use.

ATTACHMENT: INTERNATIONAL RESIDUE LIMIT STATUS SHEET

cc:Circu., R.F., PP#4E4349, Reviewer(FDG), AmitrazReg.Std.File, FDA.
7509C:CBTS:Reviewer(FDG):CM#2:Rm804Q:305-5826:FDG:1/9/95:edit:fdg:1/12/95.
RDI:SecHd:RSQuick:1/11/95:ActBrSrSci:MTFlood:1/11/95.

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INTERNATIONAL RESIDUE LIMIT STATUS

J. Mew
1/10/95

CHEMICAL Amitraz (Mitac[®])

CODEX NO. 122

CODEX STATUS:

☒ No Codex Proposal
Step 6 or above (on hops)

Residue(if Step 8): Sum of amitraz
and N-(2,4-dimethylphenyl)-N'-methylformanilide
calculated as N-(2,4-dimethylphenyl)-N'-methyl
formanilide

Crop(s)

Limit
(mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 4E 4349

RCB Reviewer F. D. Griffith, Jr 9 Jan 95

Residue: For 40 CFR § 180.287

Amitraz* and its 2,4-dimethylaniline
metabolites

Crop(s)

Limit
(mg/kg)

Dried Hops

60

CANADIAN LIMITS:

☒ No Canadian limit

Residue: _____

Crop(s)

Limit
(mg/kg)

MEXICAN LIMITS:

☒ No Mexican limit

Residue: _____

Crop(s)

Limit
(mg/kg)

NOTES:

* N-[2,4-dimethylphenyl]-N-[[[2,4-dimethylphenyl]imino]
methyl]-N-methylmethanimidamide