



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

NOV 26 1985

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: PP#5G3185/45639-EUP-ET (RCB #121, #122) (Acc. #259626).
Amitraz (Mitac®) in or on Cottonseed. Amendment of 10/7/85.

FROM: W. T. Chin, Ph. D., Chemist *W. T. Chin*
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

TO: Jay S. Ellenberger PM #12
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

BACKGROUND

The petitioner, NOR-AM Chemical Company, has proposed a temporary tolerance for the residues of the miticide amitraz (N'-[2,4-dimethylphenyl]-N-[[[(2,4-dimethylphenyl)imino]methyl]-N-methylmethanimidamide) and its metabolites containing 2,4-dimethylaniline moiety (calculated as the parent compound) in or on cottonseed at 0.2 ppm (PP#5G3158, 11/21/84). This temporary tolerance is proposed to cover residues resulting from a proposed experimental program which involves 225 lbs a.i. limited to 200 acres in California and 100 acres in Arizona. The experimental program was planned to start on April 1, 1985 and end on September 30, 1985.

RCB recommended against establishing this temporary tolerance because of the deficiencies specified in the Conclusion Nos. 3a, 4a, 4b, 5a and 5b of RCB's (C. Deyrup) 2/27/85 review.

PRESENT CONSIDERATION

In response to the deficiencies identified above in RCB's 2/27/85 review, the petitioner submits this amendment (consisting of 2 letters dated on 9/24/85 and 10/14/85 and a volume of chromatograms). This submission also includes a revised Section G-6 proposing an EUP program between 1/1/86 and 1/1/87. The deficiencies outlined in RCB's 2/27/85 review of PP#5G3185 are restated below and are followed by the petitioner's responses and RCB's comments/conclusions.

Deficiency No. 3a

"No limit of determination for amitraz was given. No chromatograms of check samples or fortified samples were submitted so that RCB is unable to evaluate the methodology or estimate the limit of determination. The petitioner will need to submit representative chromatograms of check and fortified samples of all cotton commodities analyzed for RCB's evaluation."

The petitioner's response to deficiency No. 3a

The petitioner submits a volume of chromatograms which includes examples of amitraz treated cottonseed, processed cottonseed fractions, untreated samples and recoveries from fortified samples. The reported limit of determination for amitraz/metabolites residues is 0.01 ppm. Recoveries from fortified samples are shown in Table 1 below.

Table 1. Recoveries of Amitraz from Fortified Control Cottonseed Fractions

Sample Fraction	Fortification Level (ppm)	Recovery (%)
Cottonseed	0.10	100 and 111
	0.32	97 and 97
Cottonseed meal	0.10	100 abd 130
	0.32	109 and 112
Hulls	0.10	90 and 100
	0.32	103 and 106
Soap stock	0.10	90 and 100
	0.32	100 and 106
Refined oil	0.05	80 and 86
	0.10	84 and 86
Crude oil	0.05	98 and 104
	0.10	85 and 97

RCB's comments/conclusions on the petitioner's response to deficiency No. 3a

RCB concludes that the recovery data submitted are adequate and that deficiency No. 3a is resolved.

Deficiency No. 4a

"Samples were stored at 0°F for periods of 9 months to 2 years and 9 months before analysis. The petitioner will need to furnish storage stability data for residues of amitraz on cotton or another appropriate commodity to cover this period. Although the amitraz Registration Standard has cited a need for storage stability studies of metabolites BTS-27919, BTS-24868 and BTS-28037, for the purpose of this temporary tolerance, storage stability studies on amitraz per se will suffice."

The petitioner's response to deficiency No. 4a

No information is submitted. The petitioner indicates that this deficiency will be dealt with when NOR-AM Chemical Company applies for a permanent tolerance.

RCB's comments/conclusions on the petitioner's response to deficiency 4a

Since the EUP involves only 300 acres and the petitioner is very much aware that storage stability data must be generated before there can be any consideration given to the establishment of a permanent tolerance for amitraz in or on cotton-seed, RCB will forego the need for storage stability data on amitraz for this proposed EUP. RCB will consider deficiency No. 4a to be resolved this time.

Deficiency No. 4b

"RCB is unable to validate the residue data until the petitioner has submitted representative chromatograms of field samples for our evaluation. Representative chromatograms of the fractions from the processing study should also be submitted."

The petitioner's response to deficiency No. 4b

Adequate chromatograms are submitted as discussed in The petitioner's response to deficiency No. 3a above. The residue data submitted in PP#5G3158 (11/21/84) are tabulated in Tables 2 and 3 below.

Table 2. Amitraz Residues in Treated Cottonseed

Application rate (lb a.i./A)	HFI	Amitraz (ppm) (uncorrected for controls)
0.5	100	0.08 - 0.12
<u>0.5 + 0.5</u>	<u>75</u>	<u>0.07 - 0.11</u>
1.0	97	0.08
1.0	118	0.05
1.0	119	0.07
1.0	141	0.03
1.0 + 1.0	97	0.05
1.0 + 1.0	119	0.10

Table 3. Amitraz Residue in Processed Cottonseed

Fraction	Application rate (lb a.i./A)	Amitraz (ppm) (Uncorrected for controls)
Cottonseed	1.0	0.03 - 0.08
	1.0 + 1.0	0.05 - 0.10
Hulls	1.0	0.02 - 0.09
	1.0 + 1.0	0.08 - 0.10
Meal	1.0	0.04 - 0.08
	1.0 + 1.0	0.07 - 0.08
Refined oil	1.0	<0.01 - 0.01
	1.0 + 1.0	0.01
Crude oil	1.0	<0.01 - 0.02
	1.0 + 1.0	0.02
Soap stock	1.0	0.01 - 0.03
	1.0 + 1.0	0.02 - 0.03

RCB's comments/conclusions on the petitioner's response to deficiency No. 4b

Since RCB has concluded that deficiencies Nos. 3a and 4a are resolved, deficiency No. 4b is also considered to be resolved for the proposed use of amitraz in or on cottonseed. RCB concludes, therefore, that the proposed temporary tolerance of 0.2 ppm for amitraz in or on cottonseed is adequate.

Deficiency No. 5a

"Except for the temporary tolerance (0.1 ppm) for the meat, fat and meat byproducts of hogs, there are only zero tolerances established for amitraz/metabolites residues in the meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep. The petitioner will need to propose finite temporary tolerances for secondary residues of amitraz/metabolites in these commodities. It may be necessary to extend the temporary tolerances on hog commodities for this EUP. Because of the low dietary burden of amitraz/metabolites imposed upon livestock by this EUP, RCB recommends that the petitioner proposes temporary tolerance levels at the level of the limit of determination of amitraz/metabolites in meat commodities (ca. 0.01 ppm, PP#2F2705, memo of K. F. Kissler, 3/11/83)."

The petitioner's response to deficiency No. 5a

The petitioner submits a revised Section F in which the following temporary tolerances are proposed:

Cottonseed.....	0.20 ppm
Hogs (meat, fat and meat byproducts).....	0.01 ppm
Poultry (meat, fat and meat byproducts).....	0.01 ppm
Eggs.....	0.01 ppm

RCB's comments/conclusions on the petitioner's response to deficiency No. 5a

RCB reiterates deficiency No. 5a above. In brief, the petitioner needs to propose temporary amitraz tolerances for all animal commodities (not just hogs, poultry and eggs) at 0.01 ppm in a revised Section F. Therefore, deficiency No. 5a is still outstanding.

Deficiency No. 5b

"No poultry metabolism studies and feeding studies have been submitted. However, because of the low dietary burden of amitraz/metabolites imposed upon poultry by this proposed use, RCB at this time will not require poultry feeding and metabolism studies. However, RCB believes that the petitioner will need to propose temporary tolerances for poultry meat, fat, meat byproducts, and eggs. Because of the low dietary burden of amitraz/metabolites imposed upon poultry from the proposed use, RCB also recommends that these proposed tolerances should reflect the limit of determination for the residues of amitraz/metabolites in meat commodities (ca. 0.01 ppm, PP#2F2705, memo of K. F. Kissler, 3/11/83)."

The petitioner's response to deficiency No. 5b

The petitioner submits a revised Section F including the proposed temporary tolerances for poultry commodities and eggs as shown in The petitioner's response to deficiency No. 5a above.

RCB's comments/conclusions on the petitioner's response to deficiency No. 5b

RCB concludes that deficiency No. 5b is resolved.

RECOMMENDATION

RCB continues to recommend against establishing the temporary tolerance for amitraz in or on cottonseed at 0.20 ppm until deficiency No. 5a above is resolved.

cc: R.F., Circu., W.T.Chin, EAB, PP#5G3185, EEB, PMSD-ISB
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