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

SEP 6 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F2968 (RCB #1346). Amitraz on Cattle. Amendment dated July 18, 1985. (No Accession Number).

FROM: Nancy Dodd, Chemist *Nancy Dodd*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Jay Ellenberger, Product Manager #12
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

The petitioner Nor-Am Chemical Company has submitted an amendment dated July 18, 1985 which consists of a resubmission of a cover letter dated October 3, 1984 and revised labeling. The amendment was submitted in response to deficiencies contained in Jay Ellenberger's letter dated September 10, 1984, which was based on RCB's review of PP#4F2968 for amitraz on cattle dated July 19, 1984 (Al Smith).

The deficiencies listed in the July 19, 1984 review are outlined below followed by the petitioner's responses and RCB's conclusions.

Deficiency #1:

"The chemical components of [redacted] have not been identified. These data are needed in order to determine if such components are cleared for use under §180.1001."

INFORMATION WHICH MAY REVEAL THE IDENTITY OF AN INERT INGREDIENT IS NOT INCLUDED

Petitioner's Response to Deficiency #1:

The petitioner states that he has submitted a letter and a Product Bulletin from [REDACTED] which indicate that [REDACTED] is cleared for use on animals under 40 CFR 180.1001.

RCB's Conclusion #1:

[REDACTED] has been cleared under 40 CFR 180.1001 (e). Therefore, deficiency #1 is now resolved.

Deficiency #2:

"Since replenishment data are not yet available, then deletion of the instructions for replenishment from the proposed label should be considered as noted in Conclusion 2(d) of the February 14, 1984 memo."

Petitioner's Response to Deficiency #2:

The petitioner has submitted revised labeling which deletes instructions for replenishment.

RCB Conclusion #2:

Deficiency #2 is resolved.

Deficiency #3:

"The label reference to use on swine should be deleted since this submission deals only with use on cattle."

Petitioner's Response to Deficiency #3:

The petitioner has submitted revised labeling which deletes the label reference to use on swine.

RCB's Conclusion #3:

Deficiency #3 is resolved.

Other Considerations

1. In a revised Section B submitted in the May 8, 1984 amendment to PP#4F2968, both spray and spray dipping instructions under the title "Ticks and Lice" said the following: "For control of lice, a second treatment 10 to 14 days later is recommended. RCB recommended for acceptance of the preceding instructions. Now, however,

in the present amendment of July 8, 1985, the petitioner has submitted a revised label that reinstates the phrase, "Repeat applications as necessary" under the spray dipping instructions. RCB cannot accept the reinstatement of the phrase "Repeat applications as necessary" on the proposed label. The petitioner will need to submit a revised Section B/label where the sentence "For control of lice, a second treatment 10 to 14 days later is recommended" has been placed again in the spray dipping instructions.

2. An International Residue Limit Status sheet is attached to this review. No Mexican or Canadian tolerances are established for amitraz on cattle. Codex proposals are for the sum of amitraz, calculated as N-(2,4-dimethylphenyl)-N'-methylformamidine, and N-(2,4-dimethylphenyl)-N'-methylformamidine. U.S.A. tolerances are for amitraz and its metabolites containing the 2,4-dimethylaniline moiety. Codex proposals are 0.05 mg/kg for carcass meat of cattle, 0.2 mg/kg for cattle meat by-products, and 0.01 mg/kg for milk. Numerically, only the Codex proposal for carcass meat of cattle (0.05 mg/kg) corresponds to the U.S.A. tolerance proposal of 0.05 ppm for cattle meat. The residue data submitted will not permit compatibility of the U.S. and Codex meat by-product and milk tolerances.

Recommendation

RCB recommends against the proposed use of amitraz on cattle because of reasons discussed in item 1 under Other Considerations above.

Attachment 1: International Residue Limit Status sheet

cc: R.F., Circu, Reviewer, EAB, EEB, PP# 4F2968, FDA, PMSD/ISB
RDI:J.H.Onley:8/29/85:R.D.Schmitt:8/29/85
TS-769:RCB:CM#2:RM 810:X7484:N.Dodd:Kendrick & Co.:9/3/85

INTERNATIONAL RESIDUE LIMIT STATUS

ATTACHMENT 1

CHEMICAL amitraz

PETITION NO 4F 2968
N. Dodd

CCPR NO. 122

F. Jones
9/27/75

Codex Status

Proposed U. S. Tolerances

No Codex Proposal
Step 6 or above

Residue (if Step 9): Sum of amitraz,
calculated as N-(2,4-dimethylphenyl)-N'-
methylformamide, and "contd"

Residue: amitraz, and its metabolites
containing the
2,4-dimethylaniline moiety

| <u>Crop(s)</u> | <u>Limit (mg/kg)</u> |
|------------------------|----------------------|
| carcass meat of cattle | 0.05 |
| cattle meat byproducts | 0.2 |
| milk | 0.01* |

| <u>Crop(s)</u> | <u>Tol. (ppm)</u> |
|-------------------------|-------------------|
| cattle fat | 0.1 |
| cattle meat | 0.05 |
| cattle meat by-products | 0.3 |
| milk | 0.03 |
| milk fat | 0.3 |

CANADIAN LIMIT

MEXICAN TOLERANCIA

Residue: _____

Residue: _____

Crop Limit (ppm)

Crop Tolerancia (ppm)

None

None

Notes: 4 N-(2,4-dimethylphenyl)-N'-methylformamide
* at or about limit of determination.