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

NOV 20 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F2968 (RCB #174). Amitraz on Cattle. Amendment dated 10/23/85. (Record Number 162120).

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: John H. Onley, Ph.D., Section Head *John H. Onley*
Tolerance Petition Section 2
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

The petitioner, Nor-Am Chemical Company, has submitted an amendment dated 10/23/85 which consists of a revised label. The amendment was submitted in response to a deficiency contained in RCB's review of an amendment to PP#4F2968 for amitraz on cattle (N. Dodd, 9/6/85).

The deficiency listed in the 9/6/85 review is given below followed by the petitioner's response and RCB's conclusion.

Deficiency #1 (previously listed as Item #1 under "Other Considerations" in RCB's 9/6/85 review of the amendment dated 7/18/85 to PP#4F2968):

"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."

Petitioner's Response to Deficiency #1:

The petitioner has submitted a revised label (received by EPA on 10/25/85) which removes the statement "Repeat applications as necessary" and replaces it with "For control of lice, a second treatment 10 to 14 days later is recommended." This change is made under the heading "Ticks and Lice, Spray Dipping."

RCB's Conclusion #1:

Deficiency #1 is now resolved.

Other Considerations

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

TOX and EAB considerations permitting, RCB recommends for establishing the proposed amitraz tolerances on cattle commodities as follows:

<u>Commodity</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

Attachment 1: International Residue Limit Status sheet

cc:R.F.,Circ., Reviewer, EAB, EEB, PP#4F2968, FDA, PMSD/ISB-Eldredge
RDI:J.H.Onley:11/18/85:R.D.Schmitt:11/18/85
TS-769C:RCB:CM#2:RM810:X557-7484:N.Dodd:R.Kilby:11/18/85

CHEMICAL amitrazPETITION NO 4F2968CCPR NO. 122

N. Dodd

Codex StatusProposed U. S. Tolerances☐ No Codex Proposal
Step 6 or aboveT. Jones
9/27/75Residue (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

Crop(s)	Limit (mg/kg)
carcass meat of cattle	0.05
cattle meat byproducts	0.2
milk	0.01*

Crop(s)	Tol. (ppm)
cattle fat	0.1
cattle meat	0.05
cattle meat by-products	0.3
milk	0.03
milk fat	0.3

CANADIAN LIMIT

Residue: _____

MEXICAN TOLERANCIA

Residue: _____

Crop	Limit (ppm)
none	

Crop	Tolerancia (ppm)
none	

Notes: 1. N-(2,4-dimethylphenyl)-N'-methylformamide
* at or abt limit of determination.