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

SEP 11 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: FAP#3H5383. Fenvalerate in Food Handling Establishments. Amendment of 6/22/83

From: Martha J. Bradley, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Martha J. Bradley

Thru: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

To: T. Gardner, PM 17
Registration Division

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

McLaughlin Gormley King Company has submitted this amendment in response to our deficiency memo (M.Bradley) of 5/17/83. The deficiencies are repeated below in their original order along with the response and our comments and conclusions.

Deficiency 1.

The minimum interval between treatments should be given rather than "repeat treatments as needed".

Response 1.

The petitioner states that a minimum interval between treatments will be given on the labels based on the efficacy data.

Comments/Conclusion 1.

No revised labels or Section B were submitted. This deficiency has not been resolved.

Deficiency 2.

Validation data are needed for fortification levels in the range of 0.02 to 0.1 ppm for fenvalerate.

Response 2.

Validation data will be generated for the 0.02 to 0.1 ppm range using butter, bread and candy. The recovery level used will be 0.05 ppm which is the requested tolerance.

Comments/Conclusion 2.

Fortification at 0.02 ppm should also be validated.

This deficiency has not been resolved.

Deficiency 3.

The residue data are not adequate to determine an appropriate tolerance. Additional residue data are needed for the X-3489 formulation for general use. We recommend a "worst case" study be conducted in a delicatessen, grocery or bakery in accordance with the (food handling establishment) protocol. The maximum recommended or exaggerated application rate should be used. (We are not requesting all six of the studies recommended in the protocol.)

Response 3.

The application rate for the submitted X-3489 formulation study was slightly less than the maximum recommended rate.

Comments/Conclusions 3.

Although the general treatment was conducted at near the maximum rate, residues were much less than those resulting from the less concentrated space spray treatment. This is contrary to the expected higher residues from the more general treatment with a more concentrated fenvalerate formulation. The general, more concentrated fenvalerate formulation is also to be used while food processing operations are underway. Therefore, we feel that a more valid study should be conducted with the concentrated fenvalerate formulation as a general treatment under actual conditions of use.

This deficiency has not been resolved.

Deficiency 4.

An animal feed tolerance and regulation are needed (21 CFR 561). The food and feed regulations must specify the maximum conditions of use.

Response 4.

An animal feed tolerance will also be requested and submitted as outlined in 21 CFR 561.

Comments/Conclusions 4.

This deficiency has not been resolved.

Recommendations

We recommend against the proposed tolerance and regulation as none of the four deficiencies have been resolved by this amendment.

cc: R.F., Circu, Reviewer, FAP3H5383, TOX
RDI:Section Head:RSQuick:Date:10/3/83:RDSchmitt:Date:10/3/83
TS-769:RCB:Reviewer:MJBradley:MJBradley:LDT:557-7377:CM#2:RM:810