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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Accession No. 252036

Subject: FAP#3H5383. Fenvalerate in Food Handling Establishments. Amendment of 11/15/83

From: Martha J. Bradley, Chemist
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To: T. Gardner, PM 17
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and

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McLaughlin Gormley King Company has submitted this amendment in response to our memo (M.Bradley) of 9/11/83 and discussed in a conference 11/21/83. 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.

Revised labeling for the space spray, containing 0.05% fenvalerate (F-2370), limits application to not more than every three days and for the residual spray, containing 0.2% fenvalerate (F-2371), limits application to every 14 days.

Comments/Conclusion 1.

This deficiency has been resolved.

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Deficiency 2.

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

Response 2.

Recovery of fenvalerate from butter, bread and candy fortified at 0.05 ppm is reported as 110, 78, and 94%, respectively. Previous recoveries from fortification at 0.1, 0.2, 0.3 ppm ranged from 90 to 120%.

Comments/Conclusion 2.

This deficiency has 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 labeling for the F-2371 formulation has been revised to specify the areas to be treated, such as floors, baseboards, around walls, benches and equipment with a dosage of 1 gallon/1000 sq. ft. Application while food processing is under way and application to surfaces or utensils that may come in contact with food is prohibited.

Comments/Conclusions 3.

The revised directions for use are sufficiently specific to conform to the conditions of the submitted residue study to conclude that residues are not expected to exceed the proposed tolerance of 0.05 ppm. The significant changes are that the areas to be sprayed are more clearly defined and that spraying is not permitted while food processing is in operation.

This deficiency has 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.

In the conference of November, 1983, requirements for the feed tolerance and regulation were discussed. We had determined that the existing data were inadequate for establishing such regulations for pyrethrins, piperonyl butoxide and MGK 264, with which fenvalerate is formulated. This lack of proper data is a result of the manner in which food handling establishment uses were regulated at the time tolerances for synergised pyrethrins were established. It was decided that the problem would be more properly addressed by the registration standards for synergised pyrethrins, and feed additive regulations would not be required at this time.

The need for a food additive regulation has not been addressed by the petitioner.

Comments/Conclusions 4.

On reconsideration, we see no reason to tie the regulations for food handling establishment use of fenvalerate to the regulations for synergised pyrethrins, and feel that a feed handling tolerance of 0.05 ppm and regulation are needed.

Established tolerances for milk, meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep are adequate for residue levels from the proposed use. The residue of concern is Pydrin per se in these commodities.

A low level ^{14}C-labeled poultry feeding study was discussed in memo of E. Gunderson, 4/21/78 in connection with PP#7F2013. Birds were fed 0.03 ppm Pydrin for 7 and 32 days. No detectable activity was noted in tissues or eggs with detection limits ranging from <0.001 ppm in egg yolks to <0.008 ppm in fat or skin. Higher level poultry feeding studies, (9, 29 and 86 ppm), have been submitted, however metabolism questions remain unresolved (PP#2F2657, 2/21/84, K. Arne). We conclude by extrapolation of the available data that no detectable residues in poultry and eggs would result from this use.

This deficiency has not been resolved.

Food and feed additive regulations must be submitted with wording similar to the following:

21CFR 193.... (561.97)

A food (feed) additive tolerance of 0.05 ppm is established for residues of cyano(3-phenoxyphenyl)methyl-4-chloro-alpha(methylethyl)benzeneacetate as follows:

In or on all food (feed) items (other than those already covered by a higher tolerance as a result of use on growing crops) in food handling establishments where food (feed) and food products are held, processed or prepared.

Application shall be limited to space treatment with a maximum of 0.5 fl. oz. of a 0.05% active ingredient solution per 1000 cu. ft. of space or as a contact spray applied as a coarse wet spray at a maximum of 1 gallon of a 0.2% active ingredient solution per 1000 sq. ft. of surface. Food must be removed or covered during treatment. Spray should not be applied directly to surfaces or utensils that may come into contact with food (feed). Food contact surfaces and equipment should be thoroughly cleaned before using.

To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

Recommendations

We recommend against the proposed tolerance because of Conclusion 4. The petitioner should be advised of our comments regarding the necessary food and feed additive regulations.

cc: R.F., Circu, Reviewer, FAP3H5383, TOX, EEB, EAB, FDA, Thompson
RDI:Section Head:RSQuick:Date: 3/15/84:RDSchmitt:Date: 3/15/84
TS-769:RCB:Reviewer:MJBradley:MJBradley:557-7377:CM#2:RM:810 3/8/84