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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAY 17 1993

MEMORANDUM

SUBJECT: FAP# 3H5383. Fenvalerate in Food Handling Establishments. Evaluation of analytical method and residue data.

FROM: Martha J. Bradley, Chemist
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THRU: Charles L. Trichilo, Chief
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TO: PM Team 17
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and

Toxicology Branch
Hazard Evaluation Division (TS-769)

The McLaughlin Gormley King Company has requested a food additive regulation and tolerance of 0.05 ppm on food for the insecticide fenvalerate (cyano(3-phenoxyphenyl)methyl-4-chloro-alpha(methylethyl)benzeneacetate, Pydrin) to be used in food handling establishments. Fenvalerate is to be formulated with pyrethrins, piperonyl butoxide and MGK-264 (N-octyl-bicycloheptene dicarboximide).

Pydrin tolerances have been established (40 CFR 180.379) for a number of commodities ranging from 0.02 ppm on apples to 1 ppm on soybean hulls. Several petitions are pending for other Pydrin tolerances.

Food additive tolerances of 10 ppm have been established for piperonyl butoxide (193.360 and 561.310) and N-octylbicycloheptene dicarboximide (193.320) for use with pyrethrins in food handling establishments. A tolerance of 1 ppm for pyrethrins on food and feeds has been established (193.390 and 561.340).

Conclusions

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

2. For the proposed use, we consider the parent compound, fenvalerate, to be the residue of concern.

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

4. 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 attached protocol. The maximum recommended or exaggerated application rate should be used. (We are not requesting all six of the studies recommended in the protocol.)

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

6. There are no international and foreign tolerances for food handling use.

Recommendations

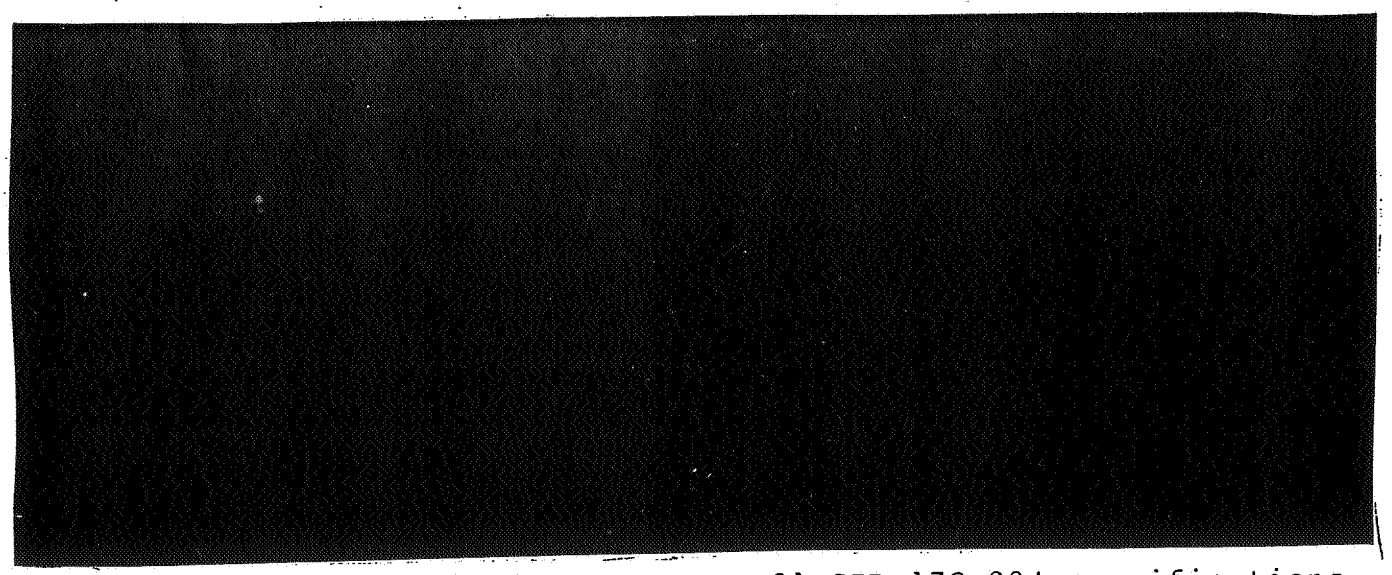
We recommend against the proposed tolerance and regulation because of Conclusions 1, 3, 4 and 5.

A typical food handling use regulation is attached for the petitioner's information.

DETAILED CONSIDERATIONS

Manufacture and Formulation

The manufacturing process for fenvalerate was submitted with PP# OF2013 and reviewed in conjunction with that petition (memo of 4/21/78, E.L. Gunderson). The technical material is ca 92% pure.



The petroleum distillate meets 21 CFR 172.884 specifications for odorless light petroleum hydrocarbon and is cleared under [illegible].

Proposed Use

Formula X-3486 is to be used as a space spray at 0.5 fl. oz./1000 cu. ft. of room space (0.007g fenvalerate/1000 cu. ft.) and formula X-3489 is to be used as a general spray at 1 gallon/1000 sq. ft. (7.5 g fenvalerate/1000 sq. ft.). Precautions are: do not apply directly to food; cover or remove all food and food processing equipment during application; do not apply space sprays while food processing is underway; after use, wash all surfaces and equipment where exposed food will be handled with potable water.

For the general treatment, food processing operations may continue while applying a wet spray with care in establishments which do not operate under USDA inspection programs.

Treatments may be repeated as necessary with a maximum of ten applications of the space spray in a given month.

The petitioner should be informed that the minimum interval between treatments should be given rather than "repeat treatments are needed".

Nature of the Residue

Metabolism studies on cotton, apples, lettuce and tomatoes have been reviewed earlier. These studies indicate that fenvalerate is not readily translocated and that degradation is slow. The majority of the residues is the parent compound, although a photodegrate has been observed on a variety of raw agricultural commodities and could comprise up to 10% of the total residue.

A cattle metabolism study showed that highest residues occur in the fat and consists primarily of the parent compound.

For food handling establishment use, we would expect the residue of concern to be the parent compound, with contamination of food to result from volatilization and spray drift.

Analytical Method

The analytical method is essentially the same as the FDA PAM I method for extraction and partitioning of residues from non-fatty and fatty foods. The residues are separated and eluted from non-activated florisil with ethyl acetate/petroleum ether. The fenvalerate and pyrethrin eluates are concentrated and determined by EC-GLC. The piperonyl butoxide and MGK-264 eluates are brominated, cleaned-up on a second Florisil column and determined by EG-GLC. The petitioner claims the method has a practical sensitivity of 0.1 ppm, however, residues are reported at 0.02 ppm and controls as low as 0.002 ppm.

Recoveries for fenvalerate ranged from 90 to 120% in all samples except lemon pie where recoveries were 63 to 93%. Pyrethrin recoveries were satisfactory for all commodities (67-97%), while MGK-264 and piperonly butoxide recoveries were 80-120% for meat, pie, and potatoes but were low (43-80%) for bread, butter and candy. All fortifications were at 0.1, 0.2 and 0.3 ppm.

A method trial for allethrin (FAP# OH5265) using this method on butter and bread was successful at fortification levels of 0.5 and 1 ppm.

Except for the extraction and eluting solvents, the method is similar to the method for fenvalerate which has undergone a successful method trial in cottonseed, meat and milk (PP# 7F2013).

We conclude that adequate methodology is available for enforcement. However, the petitioner's method appears to be more sensitive than stated (0.1 ppm) and in view of the requested tolerance (0.05 ppm) and low levels reported in the residue study (0.02 ppm), recovery data are needed for the 0.02 to 0.1 ppm levels.

Residue Data

Three studies were conducted; one using the X-3489 formulation and two using the X-3486 formulation at 1X and 4X.

The X-3489 formulation for general use was sprayed, in a 112 sq. ft. room, on the floor 12 inches from the wall and 8 inches up the wall. The total dosage is not given. A table in the middle of the room held potatoes, butter, lunch meat, apples, sugar and bread. The food was in its original commercial packaging covered with two thicknesses of Kraft paper or completely exposed. The room was sealed for 4 hours before sampling. No residues of fenvalerate or pyrethrins were detected, and only traces (<0.02 ppm) of apparent pireronyl butoxide or MGK-264 were found on the uncovered meat and bread and covered butter.

The X-3486 space spray formulation was applied in a room containing 8,640 cu. ft. of space at 0.5 fl. oz. or 2 fl. oz./1000 cu. ft. The same kinds of food were exposed as in the above study. Residues of fenvalerate on uncovered food ranged from 0.02 to 0.19 ppm from the 1X treatment and 0.08 to 1 ppm from the 4X treatment. No fenvalerate residues were found in the covered food.

Residues of pyrethrins, piperonyl butoxide and MGK-264 were well below their established tolerances.

The residue data, especially for the use of the general treatment spray X-3489 containing 0.2% fenvalerate, are not sufficient to determine an appropriate tolerance level. Additional residue data are needed for the general treatment use. A protocol, giving general requirements and definitions for food handling uses is attached for the petitioner's information. We are not requesting the six studies called for in the protocol, but only for a "worst case" study such as could occur in a delicatessen, grocery or bakery. The study should use the maximum recommended rate or an exaggerated rate.

Other Considerations

Animal feed items may also be processed or stored in food handling establishments. Therefore, an animal feed tolerance and regulation are also needed. The regulations must specify the permitted uses (space spray, general treatment) and the maximum percent of fenvalerate for each use. A copy of a typical food handling establishment regulation is attached for the petitioner's information.

Attachments (2)

cc: R.F.
Circu
Reviewer
FDA
TOX

EEB
EAB
PP# No.
Robert E. Thompson (Res. Triangle Park, NC)
RDI:Section Head:RSQ:Date-5/2/83:RDS:Date-5/2/83:DCR-17931
TS-769:RCB-19:Reviewer-M.Bradley:efs:Rm-810:CM-2:x77324:5/10/83

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Fenvalerate

PETITION NO. FAP 3H5383

CCPR NO. 119

Codex Status

/ X / No Codex Proposal Step 6 or above

Residue (if Step 9):

Parent[1]/

Crop(s) Limit (mg/kg)

None (limited to food handling establishments)[2]/

CANADIAN LIMIT

Residue:

Crop Limit (ppm)

None (on processed foods)

Proposed U.S. Tolerances

Fenvalerate

Residue:

Crop(s) Tol. (ppm)

All food (food handling establishment use) 0.05

MEXICAN TOLERANCIA

Residue:

Crop Tolerancia (ppm)

None

NOTES: 1/ Step 5 with recommendation for Step 6.

2/ There are numerous temporary Codex tolerances on r.a.c.'s as well as several processed products e.g., cottonseed oil 0.1 ppm; milk products 0.2 ppm (fat basis); wheat flour (white) 0.2 ppm; wheat flour (whole) 2 ppm; wheat bran 5 ppm. The temporary limits for processed wheat products accommodate residues possible from pre- or post-harvest treatment.