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

JUN 20 1989

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: FAP8H5564. Petition to Amend 40 CFR 185.1300 and 186.1300 to add Esfenvalerate to the regulation and to increase application rates. Evaluation of Analytical Method and Residue Data. DEB 4568. MRID40822401.

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DEB/HED (H7509C)

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and

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The petitioner, McLaughlin Gormley King Co., proposes to amend 40 CFR 185.1300 and 40 CFR 186.1300 to add specifically (S)-cyano(3-phenoxyphenyl)methyl-(S)-4-chloro-alpha-(1-methylethyl)-benzene-acetate ["esfenvalerate"] to the current regulation of cyano(3-phenoxyphenyl)methyl-4-chloro-alpha-(1-methylethyl)benzeneacetate ["fenvalerate"]. Tolerances are currently established at 0.05 ppm for residues of fenvalerate in all food (other than those already covered by a higher tolerance as a result of use on growing crops), in food handling establishments where food and food products are held, processed or prepared, resulting from a space treatment with a maximum of 0.5 fluid ounces of a 0.05 percent active ingredient solution per 1000 cubic feet of space or as a contact spray of coarse wet spray at a maximum of 1 gallon of a 0.2 percent active ingredient solution per 1000 square feet of surface.

Esfenvalerate is the S,S isomer of fenvalerate. The product label for Evercide® Residual Insecticide Concentrate 2457 claims only the S,S-isomer of fenvalerate (see memo of 7/14/88 regards EPA Reg. No. 1021-RLAL). It should be noted that current enforcement methodology does not distinguish among fenvalerate isomers and that established tolerances cover residues of the four fenvalerate isomers (see 1/6/89 memo regards 89-TX-02).

The current regulation of fenvalerate at 40 CFR 186.1300 specify tolerances at levels between 1.0 ppm and 20 ppm in soybean hulls,

sunflower hulls, sugarcane bagasse, dried apple pomace and dried tomato pomace. There is no permitted use of fenvalerate in feed handling establishments under current 40 CFR 186.1300 or 21 CFR 561.97, although we have previously recommended establishment of such tolerances (see 5/11/84 and 3/16/84 of FAP3H5383, and 11/17/86 of FAP6H5503).

Conclusions

1. The petitioner should submit revised Section F clearly indicating by correct chemical name the chemical for which regulation is sought (i.e., § 40 CFR 185.1300(a)(3) and 186.1300(a)(3) should specify as (S)-cyano(3-phenoxyphenyl)-methyl-(S)-4-chloro-alpha-(1-methylethyl)-benzeneacetate

2. The submitted residue data do not reflect the proposed use as space spray since application rates in the submitted study were less than the maximum permitted by the proposed food additive regulation at 40 CFR 185.1300. Residue data reflecting the maximum proposed application rate are needed and should include data on a food service establishment.

3. The submitted labeling differs significantly from the accepted labeling in that surface spray is recommended for retreatment at 7 day intervals in restaurants while accepted labeling specifies 14 day retreatment. The petitioner is advised to submit revised labeling conforming to accepted labeling or submit residue data reflecting the 7 day retreatment interval.

4. The petitioner should submit revised labeling which clearly indicates retreatment intervals in food areas for space sprays and contact sprays. There are 4 different retreatment restrictions on the label:

   Repeat as necessary (Space Spray)
   Repeat every 3 days (Space Spray)
   Repeat every 7 days (Surface Spray)
   Repeat every 14 days (Surface Spray)

   Dosage and dilution rates for uses in food areas must be clearly indicated. Under "General" three dilution rates are given, yet under Surface Spray there is no mention of specific dilution to use under specific circumstance. For example, instructions to "Use a dosage of one (1) gallon of 0.025% active ingredient spray per 1000 square feet for maintenance control" are specific to dosage and dilution.

5. The label instruction allowing mixture of Evercide® Residual Insecticide Concentrate 2457 with methoprene and hydroprene must be removed or modified to clearly and specifically prohibit use of such mixtures in food handling

establishments. Neither methoprene nor hydroprene are permitted in food areas under current regulation. Pyrethrin-containing products are permitted in food handling areas but not feed handling areas, except when used in certain multiwall paper bags or cotton bags for dried feeds.

If the use of such mixtures is intended in non-food areas, such as lawn flea control, Asian cockroach control, etc., label instructions should be clear and explicit to authorize use in these areas but to prohibit use in food areas.

6. We note that we have recommended favorably for the establishment of feed additive tolerances for fenvalerate under FAP3H5383 (see 3/16/84 and 5/11/84) and more recently under FAP6H5503 (see 11/17/86). We further note that such feed additive regulations have not been promulgated. We continue to recommend establishment of tolerances for residues of fenvalerate in animal feedstuffs as a result of use in feed handling establishments, although we cannot recommend for the currently proposed feed additive regulation until other problems associated with the use of esfenvalerate are resolved. Additionally, tolerances are necessary in 40 CFR 180.379 for poultry meat and eggs to cover possible esfenvalerate residues in animal feeds from use in feed handling establishments.

7. The proposed expression of the tolerance in 185.1300(a) and 186.1300(a) should be revised to delete the phrase "...of all isomers ..." to read "....for residues of the insecticide cyano....". Additionally, in the same regulations at the newly proposed (a)(3), the phrase should read "Application of (S)-cyano(3-phenoxyphenyl)methyl-(S)-4-chloro-alpha-(1-methylethyl)-benzeneacetate...."

Recommendations

We recommend against the proposed food and feed tolerances, for the reasons cited under conclusions, above.

Proposed Use

The proposed uses of Evercide® Residual Insecticide Concentrate 2457 are not compatible nor comparable to regulations permitting use of fenvalerate in food handling establishments. The proposed label states:

> Controls Numerous Pests in and Around Structures
> Recommended For Commercial and Industrial Use
>
> For Use in and Around the Home and Food and Non-Food Areas of: Schools, Warehouses, Office Buildings, Apartment Buildings, Theatres, Hotels, Motels, Kennels, Food

Processing Plants, Food Service Establishments,Truck Trailers, Railroad Cars, and Food Manufacturing and Warehousing Establishments. Also for Use on Lawns to Kill Fleas.

The precautionary statements include:

Do not apply directly to food. Cover or remove all food and food processing equipment during application. After spraying in meat packing plants, bakeries and other food processing plants, wash with an effective cleaning compound and then rinse with potable water all equipment, benches, shelving, etc., where exposed food will be handled. In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Cover exposed food. Do not spray plants used for food or feed.

Remove pets, birds, and cover fish aquariums before spraying.

Under Directions for Use:

Do not tank mix this product with dichlorvos (DDVP)-containing products. It can be mixed with methoprene, hydroprene or pyrethrin-containing products.

[Note: There are no tolerances established for uses of methoprene or hydroprene containing products in or on food handling, processing, or service establishments under 40 CFR 185 or 186, although FAP9H3723 considers hydroprene. Pyrethrin-containing products are permitted in food processing areas and food storage areas, provided that the food is removed or covered prior to such use (185.5200). Pyrethrin-containing products are not permitted in feed handling establishments under 186.5200, although pyrethrins may be used in certain multiwall paper bags or cotton bags used for dried feeds.]

For Indoor Pests (Paraphrased)

Use either one or two fluid ounces of Evercide® Concentrate 2457 in one gallon of water or oil (odorless light petroleum hydrocarbon as in 21 CFR 172.884) to make a spray containing 0.027% or 0.05% active ingredient. For initial clean out of heavy infestations use 0.05% spray; for maintenance control or light infestations use 0.027% spray. For all applications of contact spray use at rate of one gallon per 1000 square feet of surface. For space spray applications use a maximum of ten ounces of concentrate diluted in one gallon to make a 0.25% spray.

As surface spray to kill the accessible stages of granary insects: rice weevils, confused flour beetles, rust red flour beetles, saw-toothed grain beetles, cadelles, meal moth larvae and adults, cigarette beetles, drug store beetles and granary weevils, apply as a coarse wet spray to surfaces such as floors, baseboards, around walls, benches, and pieces of equipment. Pay particular attention to cracks, crevices and similar protected locations in floors and walls. Spray around and into floor drains, non-food conveyors, and other areas where granary insects may be found. Do not apply when food processing facility is in operation or foods are exposed. Do not apply this spray to surfaces or utensils that may come into contact with food; excessive residues in food may result.

As a surface spray to kill cockroaches, silverfish, waterbugs, ants, crickets, sowbugs, spiders, and centipedes in sheltered sites, apply as coarse wetting droplets into all cracks and crevices in wood work, floors, underneath sinks, areas behind pipes and in all places where these insects shelter. Use a dosage of one gallon of spray per 1000 square feet of surface. Repeat applications as needed, but do not exceed more than one application every 7 days in restaurants and similar food service establishments or more than one application every 14 days in other types of food handling establishments.

As a space spray to kill houseflies, mosquitoes, gnats and small flying moths, close room and shut off all air conditioning or ventilating equipment. Use a mechanical aerosol fogger or generator which produces particles of 30 microns or less. Direct spray first into all cracks and crevices, behind all equipment, appliances, cupboards or any harborage areas, then treat as a space spray directing the spray towards the ceiling and upper corners of the room at one ounce per 1000 cubic feet of space. Do not remain in treated area. Keep area closed for at least 1/2 hour and ventilate thoroughly before reentry. Repeat as necessary.

As a space spray to kill the adult and accessible insect pests [rice weevil, yellow meal worm, cadelle, confused flour beetle, saw-toothed grain beetle, angoumeis grain moth, Mediterranean flour moth, Indian meal moth, cigarette beetle, grain mite, and cockroaches] of stored food (stored in multiwalled paper bags or in cloth bags) in warehouses, storage rooms, and similar locations. Use one ounce per 1000 cubic feet of space. Keep area closed for at least 1/2 hour. Do not remain in treated area and ventilate thoroughly before reentry. Do not repeat application more than once every three days.

Section F proposes both food and feed additive regulations. The following is the proposed amendment to existing 40 CFR 185.1300:

40 CFR 185.1300

(a) A food additive tolerance of 0.05 ppm is established for residues of all isomers of the insecticide Cyano(3-phenoxyphenyl)methyl-4-chloro-alpha-(1-methylethyl)-benzeneacetate and an isomer (S)-cyano(3-phenoxy-phenyl)-(S)-4-chloro-alpha-(1-methylethyl)benzene-acetate [sic] as follows:

[Note: the isomer should be designated as ...phenoxyphenyl)methyl-(S)-4...]

[Note: the phrase ...of all isomers... has been added in the proposed regulation.]

(1) [Note: No change.]

(2) Application of cyano(3-phenoxyphenyl)methyl-4-chloro-alpha-(1-methylethyl)benzeneacetate shall be limited to space treatment with a maximum of 0.5 oz. of a 0.05% active ingredient solution per 1000 cubic feet of space, or as a contact spray applied as a coarse wet spray at a maximum of 1 gallon of a 1.0% active ingredient solution per 1000 square feet of surface or as a pressurized spot/crack and crevice spray at a 1.0% solution. 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. Food contact surfaces and equipment should be thoroughly cleaned with an effective cleaning compound and rinsed with potable water before using.

(3) Application of (S)-cyano(3-phenoxyphenyl)-(S)-4-chloro-alpha-(1-methylethyl)benzeneacetate (sic) shall be limited to space treatment with a maximum of 1.0 fluid ounce of a 0.25% active ingredient solution per 1000 cubic feet of space or as a contact spray applied as a coarse wet spray at a maximum of 1 gallon of a 0.25% active ingredient solution per 1000 square feet of surface, or as a pressurized spot/crack and crevice spray of a 0.25% solution.
[Note: Remainder of paragraph (3) is the same as the last three sentences of paragraph (2)].

The petitioner proposes amendment to 40 CFR 185.1300 (sic; should be 186.1300) for use in feed handling establishments by substituting "feed and feed products" for "food and food products". The dosage rates and other instructions are as above.

We note that the use of fenvalerate in feed handling establishments is not authorized by regulation at 40 CFR 186.1300.

As can be seen in the attached table, the proposed amendment is not only adding the use of esfenvalerate in food handling establishments, the amendment and the associated label use directions add pressurized spot/crack and crevice uses and increase the application rates (fenvalerate as contact spray is increased 5X, from 0.2% to 1%) for fenvalerate and esfenvalerate.

In addition, it is noted that the label directions indicate repeat application as a surface spray every 7 days to control cockroaches, silverfish, etc., in restaurants and similar food service establishments or 14 days in other types of food handling establishments. For the space spray to kill houseflies, mosquitoes, etc., directions indicate "Repeat as necessary", while for stored food insect pest (weevils, beetles, etc.) the retreatment interval is 3 days. The petitioner must resolve the conflict between "Repeat as necessary" and repeat application every three days. The petitioner must resolve the question whether the 7 or 14 day retreatment interval specified for the surface spray for cockroaches, silverfish, etc. also applies to surface spray for granary insects. The placement of the retreatment interval information is such that we are not able to conclude which restriction applies to which use; the petitioner must resolve this.

Food Additive Regulation

Site	Current Regulation Fenvalerate	Proposed Regulation Fenvalerate	Esfenvalerate
Space Spray	0.05% x 0.5 oz.	0.05% x 0.5 oz	0.25% x 1.0 oz
Contact Spray	0.2% x 1 gal.	1% x 1 gal.	0.25% x 1 gal.
Spot/Crack/ Crevice Spray	Not Authorized	1% solution	0.25% solution

Feed Additive Regulation

Space Spray	Not Authorized	0.05% x 0.5 oz	0.25% x 1.0 oz
Contact Spray	Not Authorized	1% x 1 oz	0.25% x 1.0 oz
Spot/Crack/ Crevice Spray	Not Authorized	1% solution	0.25% solution

Residue Data: MRID40822401

The petitioner submits a residue study title "Residue Study of Esfenvalerate In a Simulated Food or Feed Storage Situation" by Vernon J. Meinen and John T. Bergman. Two types of typical stored food samples, rice and peanuts, were exposed to space spray application of esfenvalerate at proposed application rates. Two food storage rooms at the facilities of McLaughlin Gormley King Company were used; one room was 6000 cubic feet and the other room was 2640 cubic feet. The large room was treated with 0.5 oz. of 0.25% active ingredient per 1000 cubic feet. The smaller room was treated with 2 oz. of 0.25% active ingredient per 1000 cubic feet. The petitioner describes these application rates as "1X" and "4X"; however, these application rates are 0.5X and 2X the label dosage rate of 1 oz. of 0.25% active ingredient per 1000 cubic feet. It is calculated, then, that the currently proposed use of esfenvalerate is at 10 times the application rate of fenvalerate currently authorized under 40 CFR 185.1300.

The food commodities tested were peanuts and rice. Shelled raw peanuts were placed in cloth bags stapled closed. Rice (not specified whether whole rice, hulled rice, or polished rice) was also stored in stapled cloth bags. Bags were placed one deep on pallets, 10 bags of each commodity in each room. The rooms were treated with the solution described above, as dispensed from a Thiocol Micro-Jet ULV Model 7401 Electric Sprayer directed over the pallets into the middle of the room. The preparation of the spray formulation is not described; it is not known whether one batch of formulation was made prior to the start of the test (i.e., the spray solution is homogeneous) or whether a new spray solution prepared every third day (i.e., the spray solution is not homogeneous over the duration of the study). The petitioner should clarify the preparation of the spray solutions. The room was closed for 30 minutes, whereupon the doors opened and rooms ventilated ("exhaust started") for an unspecified period of time. The exhaust was not described, whether built-in ventilation system, portable fan, window exhaust fan, etc., nor the amount of air exhausted. At some unspecified time (whether during or after "exhaust") a sample of each commodity was taken and placed in plastic bag and frozen for later analysis. This sequence of events was repeated at 3 or 4 day intervals until the commodities had received a total of 10 treatments.

Analytical procedures are provided in the submission. Peanuts were extracted with acetonitrile and partitioned into petroleum ether, followed by Florisil column cleanup and silica cleanup ("Maxi-Clean Cartridges"). Samples were quantitated by electron capture GLC.

Recovery of esfenvalerate in rice and peanuts are reported:

Commodity	Fortification Levels	% Recovery
Rice	0.05 - 0.4 ppm	74 - 83%
Peanuts	0.05 - 0.3 ppm	73 - 102%

The petitioner reports that the "practical limit of sensitivity" is 0.05 ppm, however, residue levels of 0.02 are reported as significant values and levels between 0.01 and 0.02 ppm are reported as trace.

Residues of esfenvalerate in rice contained in cloth bags were all less than 0.02 ppm from 10 treatments at the 0.5 X application rate. Residues of esfenvalerate in rice were less than 0.02 ppm until the 10th application, which showed 0.044 ppm, from the 2X treatment rate (the petitioners claimed 4X rate).

Residues of esfenvalerate in peanuts in cloth bags and receiving 10 treatments at the 0.5X rate (the petitioners claimed 1X rate), were 0.01 - 0.02 ppm after 5 - 10 applications. At the 2X rate (the petitioners 4X rate), residues of esfenvalerate were <0.02 ppm after 6 applications and 0.032 - 0.027 after 8 - 10 applications.

While these residue levels of esfenvalerate do not exceed the established 0.05 ppm food additive tolerance for residues of fenvalerate, these residue levels do not reflect the proposed use; these residue levels reflect 0.5X and 2X the maximum proposed application rate.

The petitioner contends there are 2 reasons for the residue levels in rice and peanuts:

(1) Esfenvalerate is used at one-fourth the rate of fenvalerate.

(2) The commodity samples are larger, presenting a lower surface-to-volume relationship.

We note that esfenvalerate is used in space spray at concentrations 10 times as great as currently authorized for fenvalerate, when used as space spray. The petitioner is comparing proposed esfenvalerate applications to previously rejected fenvalerate application rates for space sprays. The application rate for esfenvalerate in contact spray is one-fourth the rate for the proposed contact spray; in reality, the authorized rate for fenvalerate is 0.2% active ingredient and thus the proposed 0.25% esfenvalerate exceeds the authorized rate. In the absence of residue data reflecting the higher 0.25% esfenvalerate rate, we are unable to conclude that the established 0.05 ppm tolerance will not be exceeded by the contact spray application. Residue data reflecting proposed use

are required and should include data on a food service establishment.

We note that previously reviewed fenvalerate residue data (FAP6H5503) showed fenvalerate residues exceeding the established 0.05 ppm tolerance from 5-8 applications of space spray at application rates less than the rates proposed herein for esfenvalerate.

We note that animal metabolism and animal feeding studies have been previously reviewed and appropriate tolerances established in raw agricultural commodities such as meat and milk but not in poultry meat or eggs. In the absence of tolerances for residues in poultry or eggs, we recommend against the establishment of feed additive tolerances under 40 CFR 186.1300.

Conclusions

1. The petitioner should submit revised Section F clearly indicating by correct chemical name the chemical for which regulation is sought [i.e., §40 CFR 185.1300(a)(3) and 186.1300(a)(3) should specify as (S)-cyano(3-phenoxyphenyl)-methyl-(S)-4-chloro-alpha-(1-methylethyl)-benzeneacetate]

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   Dosage and dilution rates for uses in food areas must be clearly indicated. Under "General" three dilution rates are given, yet under Surface Spray there is no mention of

specific dilution to use under specific circumstance. For example, instructions to "Use a dosage of one (1) gallon of 0.025% active ingredient spray per 1000 square feet for maintenance control" are specific to dosage and dilution.

5. The label instruction allowing mixture of Evercide® Residual Insecticide Concentrate 2457 with methoprene and hydroprene must be removed or modified to clearly and specifically prohibit use of such mixtures in food handling establishments. Neither methoprene nor hydroprene are permitted in food areas under current regulation. Pyrethrin-containing products are permitted in food handling areas but not feed handling areas, except when used in certain multiwall paper bags or cotton bags for dried feeds.

   If the use of such mixtures is intended in non-food areas, such as lawn flea control, Asian cockroach control, etc., label instructions should be clear and explicit to authorize use in these areas but to prohibit use in food areas.

6. We note that we have recommended favorably for the establishment of <u>feed</u> additive tolerances under FAP3H5383 (see 3/16/84 and 5/11/84) and more recently under FAP6H5503 (see 11/17/86). We further note that such feed additive regulations have not been promulgated. We continue to recommend establishment of tolerances for residues of fenvalerate in animal feedstuffs as a result of use in feed handling establishments, although we cannot recommend for the currently proposed feed additive regulation until other problems associated with the use of esfenvalerate are resolved. Additionally, tolerances are necessary in 40 CFR 180.379 for poultry meat and eggs to cover possible esfenvalerate residues in animal feeds from use in feed handling establishments.

7. The proposed expression of the tolerance in 185.1300(a) and 186.1300(a) should be revised to delete the phrase "...of all isomers ..." to read "....for residues of the insecticide cyano....". Additionally, in the same regulations at the newly proposed (a)(3), the phrase should read "Application of (S)-cyano(3-phenoxyphenyl)methyl-(S)-4-chloro-alpha-(1-methylethyl)-benzeneacetate...."

cc:PM15, Cook, FAP8H5564,RF,Circ(7),ISB/PMSD (Eldredge)
H7509C:DEB:RCook:mb:x77484:Rm810:6/1/89:edited:rcook:6/19/89
RDI:R.Quick:6/9/89:R.Loranger:6/14/89