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

FEB 06 1981

MEMORANDUM

Subject: Request for Conditional Registration of the New Chemical, Safrotin(TM) for Control of Cockroaches

To: Douglas D. Campt
Director
Registration Division (TS-767)

This memo is being transmitted for concurrence on the conclusion that use of the subject pesticide meets the criteria specified in Section 3(c)(7)(C) of the FIFRA, as amended and is thus eligible for conditional registration.

Background:

On November 1, 1978, Sandoz, Inc. applied for registration of a new chemical, Safrotin(TM) for control of cockroaches in non-food areas of food handling establishments and in or on buildings including homes, apartment buildings, stores and warehouses for use as a general, spot, or crack and crevice treatment.

The label was revised on March 30, 1979 to include ants, crickets, firebrats, silver fish, earwigs, fleas, carpet beetles, long-bodied spiders, and cellar spiders.

On August 14, 1979, Sandoz was informed of the results of the toxicology review. The only outstanding tox data identified at that time by Toxicology Branch, HED was the need to either validate or repeat the neurotoxicity study which was an IBT study.

The neurotoxicity study was repeated by Sandoz and submitted to the Agency for review on April 10, 1980. Upon review of the study, Tox Branch concluded that the chemical was not a delayed neurotoxic agent, but also concluded that the following data gaps existed.

1. Reproduction - one species [Sect. 163.83.4(a)(1)]

2. Chronic/Oncogenic - one species [Sect. 163.83.1(a)(1)]

124

In addition, because of the residual effect of the proposed new insecticide, residue data on food items from the proposed home use or the proposed use in food handling establishments were requested.

Though these studies were cited as data gaps, Toxicology Branch recommended for a conditional registration in view of the fact that review of the available tox data revealed no potential adverse effects to humans. Refer to attached memo from Douglas Campt to Edwin Johnson regarding the various types of tox data reviewed by the Toxicology Branch and their findings.

Since that memo, interim reports for both the reproduction and chronic/oncogenicity studies have been submitted and reviewed by Toxicology Branch. Results of that review are as follows:

1. Reproduction - Summarized results up to FIIIA generation - From the data presented, there are no consistent, dose-related significant effects at dosages up to 20.0 ppm.

2. Chronic/Oncogenic - Information obtained from 12 and 18 month interim necropsies -no significant compound - induced proliferative changes have been observed.

Sandoz has since revised their proposed label to restrict application in household kitchens to crack and crevice and spot treatments only.

Also, residue analysis from two food handling establishments have been submitted in support of the applicant's recent petition for temporary food additive tolerance to cover residues resulting from the pending experimental use in food areas of food handling establishments.

Discussion:

In toxicology's initial review of the subject application (review dated July 2, 1979), no data gaps other than the neurotox study were identified. The data gaps cited above under Background were not identified until their review of April 29, 1980, which did not provide sufficient time for generation of the requested long-term data.

The requested studies, however, are currently in progress and interim reports on both the reproduction and chronic/oncogenic studies have since been submitted and reviewed by Toxicology Branch. Results, as cited above, indicate that there were no significant effects attributed to the pesticide.

The proposed labeling has been subsequently revised to restrict application in household kitchens to crack and crevice and spot treatments only, thus reducing the possible contamination of foodstuffs. Use in food handling establishments is restricted to non-food areas only.

In addition, residue analysis from two food handling establishments treated with the chemical have been submitted in support of a temporary food additive tolerance. This petition satisfies the request for residue data as verified per phone conversation of December 3, 1980 with the toxicologist who reviewed the subject application. Review of this petition has been completed by HED, and copies of the reviews are attached.

The establishment of a tolerance or the exemption from the requirement of a tolerance would not be needed for the subject proposed uses which include use in household kitchens, the non-food areas of food handling establishments and in areas of stores and warehouses where feed or foodstuffs are not stored or displayed. The requirement for such a tolerance, as set forth in the Federal Register Notice of August 10, 1973 and the EPA PR notice 74-6, covers the use of residual insecticides in food handling establishments. A food handling establishment is defined in the Federal Register Notice as an area or place other than a private residence in which food is held, processed, prepared and/or served.

The applicant has proposed a restricted use classification for the product, thereby virtually eliminating exposure of homeowners and the general population to the concentrated product as offered for sale. The directions for use of the 50% product state that it is to be diluted to a 0.5-1.0% concentration.

Use against the various listed pests is limited to spot or crack and crevice treatment except for use against fleas where it is recommended that infested rugs, floor coverings and upholstered furniture be treated. The product may not be applied as a space spray.

Because of its residual effect, it is anticipated that use of this chemical will result in a decrease in the number of repeat applications cited in communications received from various pest control operators as being necessary with the pesticides currently registered for use against fleas. The proposed label does not, however, include any restrictions regarding repeat applications. As per conversation with the efficacy reviewer, TSS, such label restrictions would not be practical for flea control.

Several letters received from pest control operators, agricultural extension entomologists and State Universities, indicate that there is a need for another chemical to control fleas.

The information contained in these letters has been reviewed by Efficacy, TSS and the following comments were received.

Though there are no data available to show that the current registered products for flea control are no longer effective, there have been reports of control failures in certain areas, some of which are probably due to insect resistance.

The data submitted for the use of Safrotin against fleas have demonstrated that the chemical is a highly effective insecticide for fleas. Since use against fleas is deemed to be a public health use as defined by 40 CFR 162.18-2(d)(3), use of the subject product would thus be considered to be in the public interest.

Review of the available toxicology data on the chemical has revealed no potential adverse effects to humans and the Toxicology Branch, HED has recommended for a conditional registration of the proposed use.

Conclusion

The proposed use of the new chemical Safrotin™ for control of specified pests including roaches and fleas in non-food areas of food handling establishments and in or on buildings, stores and warehouses is eligible for conditional registration under Section 3(c)(7)(C) of the Act, as amended. Conditions of registration must include submittal of the following data requested by the Toxicology Branch, HED within a specified period of time.

1. Reproduction - one species [Sect. 163.83.4(a)(1)]

2. Chronic/Oncogenic - one species [Sect. 163.83.1(a)(1)]

We recommend that the proposed use of Safrotin for control of specified pests as described above be conditionally registered subject to the conditions cited above.

We also plan to write to the basic manufacturers of currently registered products to question the ineffectiveness of their products as was done in the Section 18 program. We will proceed with this plan unless you recommend against such a plan.

Herbert S. Harrison
Insecticide-Rodenticide Branch
Registration Division (TS-767)

CONCUR:
DO NOT CONCUR:
DATE: 2/5/81

Attachment

122