Memorandum

Date: 8 February 1983

Subject: EPA Reg. No. 11273-22
Caswell #706A

From: B. T. Backus
IRB/TSS

To: Mr. William Miller
Product Manager 16

Registrant: Sandoz, Inc.
480 Camino Del Rio South
San Diego, CA 92108

Active Ingredient:
Propetamphos [(E)-1-methylethyl 3-[[(ethylamino) methoxyphosphinothioyl]oxy]-2-butenoate.....50%
Inert Ingredients:.....50%

Background:

The registrant is proposing label revisions. Those relevant to safety considerations include a claim as a "general treatment" to infested rugs, upholstered furniture etc. with a proposed statement that: "where general treatments are permitted, keep all persons and pets out of of treated area until spray mixture has dried." An inhalation LC_{50} study has been received.

Comments and Recommendations:

1. The inhalation LC_{50} study received 12-20-82 is acceptable. On the basis of this study, the product is in toxicity category III by the inhalation exposure route (LC_{50} between 0.5 and 5 mg/L for 4-hr exposure in terms of actual product concentration).

2. Before we can accept any labeling revisions relating to the use of this product on rugs, floor coverings, upholstered furniture and the like, we should have data as to potential human exposure to Propetamphos as a result of this use.

3. We should have the results of a study in which samples of various types of carpeting, as well as linoleum, are sprayed at 1X and either 3X or 5X recommended application rates, with wipes being made at 1 hr, 4 hrs, 24 hrs and 48 hrs after spraying being analyzed for residues of this active. The report should specify types of carpeting, "plushness" and/or pile types, and the area of surface wiped (the same area would not be subsequently wiped again).

4. There should be similar wipe Propetamphos analyses from upholstered furniture sprayed at 1X and either the 3X or 5X

3 passes

recommended application rates. Reporting should give a fairly good description as to type of upholstering material present.

5. There should be wipe Propetamphos from other surfaces (walls, unsprayed furniture) in the same room which were not directly sprayed with this product. Positions where these samples were taken from relative to sprayed areas within the room should be specified.

6. Some precautionary labeling and/or use direction revisions may be necessary after the data indicated above have been received and reviewed.

Review:

The following study was conducted on material identified as Safrotin at Bio/Dynamics, Inc. The study was received at EPA 12-22-82, and is in Acc. 249484.

1. Acute Inhalation LC_{50} - Rat. Title: An Acute Inhalation Toxicity Study of Safrotin in the Rat. Project No. 79-7286; dated July 31, 1979.

Procedure: Groups of 5M, 5F SD rats were exposed for 4 hours to nominal concentrations of 2.28, 3.17, 4.48, 8.56, 16.0 and 25.2 mg/L. The corresponding measured concentrations were 0.44, 0.62, 0.86, 1.6, 2.6, and 4.03 mg/L. Gas chromatography measurements indicated concentrations of the active ingredient ranged from 16 to 20% (average: 18%) of the nominal value. Aerodynamic mass median diameters were measured by Casella Cascade Impactor 8 times during each exposure; exposure means ranged from 1.6 to 2.1 um; geometric standard deviations were generally in the range of 2-3 um. Following exposure, subjects were observed for 14 days, except in the case of the rats exposed to a nominal concentration of 3.17 mg/L, which were observed for 28 days.

Results:

Nominal Concentration mg/L	Measured Concentration mg/L	Mortalities/Animals Exposed M	F
2.28	0.44	0/5	2/5
3.17	0.62	1/5	2/5
4.48	0.86	4/5	5/5
8.56	1.6	5/5	5/5
16.0	2.6	5/5	5/5
25.2	4.03	5/5	5/5

Deaths occurred by day 3. At higher concentration levels, deaths often occurred during exposure.
Inhalation LC_{50} = 0.64 mg/L with approximate 95% C.L. of 0.52-0.78 mg/L
Symptoms: typical of ChE inhibition (reduced activity, excessive salivation, body tremors, gasping, labored and/or shallow breathing). Report states survivors of the group exposed to a measured concentration of 0.62 mg/L did not fully recover until day 20. However, two of the survivors in this group showed corneal opacity on day 28. Most frequent abnormal necropsy findings of mortalities were lung discoloration and congestion, thymus discoloration and cloudy eyes.

Study Classification: Core Minimum Data (LC_{50}'s not broken down by sex).

Product Classification: Tox. Cat. III

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