TSS/IRB PRECAUTIONARY LABELLING REVIEW 09/07/84

To: PM 16

Subject: 002724-314
Safrotin 4 EC
Zoecon Corp.
Palo Alto, CA 94304

In TSS: 08/23/84
Assign: 09/06/84
Due: 09/07/84
AC: 345
Accn: 254456
RN: 128137
OLTS: 38

Formulation: Propetamphos.....50.06%
[redacted]

BACKGROUND

Registrant wishes to replace [redacted] in the existing formulation with [redacted] has been rumored to be a mutagen and it has been indicated that the state of California now has reservations about accepting pesticides containing this solvent.

USES

Restricted Use Pesticide
Domestic and commercial use indoors as an 0.5-1.0% oil or water carrier residual spray to control crawling insect pests.

SUBMITTED DATA

A. Accession number 254456.

1. Background from [redacted]

Oral LD_{50} Rat	9050 mg/kg	3000 mg/kg
4 Hr. Inhalation of Concentrated Vapors	No mortality	17% Mortality
Skin Irritation, Rabbit	None	Trace
Eye-Rabbit	Trace	Minor Injury
Dermal LD_{50}	16500 mg/kg	3500 mg/kg

INERT INGREDIENT INFORMATION IS NOT INCLUDED

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

2. [redacted] Brief Statements only, no actual data derived from testing or complete test reports.

A. Oral- Kidney injury noted in dead animals. A 10 mg/kg daily dose gave no harmful effects in a 2 yr. study

B. Dermal- Same as reported in 1. above.

C. Inhalation- Saturated atmosphere killed 6/6 in a 4 hour exposure study (differs from chart in 1. above).

D. Skin Irritation- 141 human volunteers treated. 5 showed sensitizing reactions. No acute dermal irritation resulted.

E. Eye Irritation- 0.5 ml gave only "moderate" irritation. This also differs from the previous [redacted]

PRODUCT INFORMATION SOURCE INFO

3. Acute Dermal Toxicity. Sandoz Inc. East Hanover, NJ 07936. Report No. T-1-11/4/83. Safrotin 50 EC 63. Project T-1961. 5 M and 5 F NZ albino rabbits per dose individually housed. All sites clipped. Abrasion not reported, sites presumed intact. Topical application, exposure period not reported. 15 day observation period. Toxic signs included diarrhea, ataxia, tremors, etc. Death was delayed, most frequently occuring on day 3. Necropsies not reported. Results:

Dose, mg/kg	Percent Mortality: Males	Females
315	0	0
353	100	0
398	100	0
500	100	20
628	100	20

Supplementary Data- There are many experimental details missing. The results are insufficient to determine the actual LD_{50}.

4. Eye Irritation. Sandoz Ltd. Basel Switzerland. AGRO DOK CBK I.5555/82. Safrotin 50 EC 63. 9 albino rabbits, individually housed. 0.1 ml. product per eye. 6 unwashed and 3 washed eyes. Results:

Corneal Opacity- None
Iritis- None
Conj. Irritation- Occured in 1/6 uw and 0/3 w. All clear by day 2.

Supplementary Data- No individual reports.

5. Primary Dermal Irritation. Sandoz Ltd., Basel Switzerland. AGRO DOK CBK I.5554/82. Safrotin 50 EC 63
3 Male albino rabbits, individually housed. 0.5 g per site. All sites shaved. 4 hour occluded exposure. PDIS = 0.0.

CONCLUSIONS

1. All of the submitted studies are supplementary data.

2. The company should confirm that Safrotin 50 EC 63 as tested was indeed the formulation with [redacted] and not [redacted] This cannot be determined from the submitted data.

3. If the formulation in the submitted supplementary data is indeed the formulation with [redacted] then TSS would have no objection to the alternate formulation providing that the submission of a complete acute tox. series be made a condition of registration. It should be noted that [redacted] is a compound very closely related to [redacted] which has been rumored to have adverse chronic effects resulting in regulatory actions in California. TSS recommends, therefore, that the PM team consult with Toxicology Branch, HED prior to the approval of the alternate formulation.

Phil Hutton
TSS/IRB