

TSS/IRB SAFETY REVIEW

May 9, 1984

TO: PM 15

SUBJECT: 048598-R  
Insecto  
Natural Insecto Products  
Costa Mesa, CA 92627

IN TSS: 04-26-84  
AC: ---  
DUE: 06-21-84  
Assigned: Exp.  
ACCN: 252983  
RN: 120611  
OLTS:

FORMULATION: Diatomaceous earth.....90.00%

  
Dust

BACKGROUND

Reapplication for a new registration of a previously registered active ingredient.

USES

As a stored grain protectant: Bin Treatment- 500g/100m<sup>3</sup> or 1 lb./1000ft<sup>3</sup>. Grain treatment- 2 lbs/per ton or 1 oz per bushel.

SUBMITTED DATA

Accession number 252983. Applied Biological Sciences Laboratory Inc. Glendale CA 91201. SA # 489598 R. ABSL-2400.

1. Acute Oral LD<sub>50</sub>. 5M and 5F SD rats. group housing. Single oral dose of 5 g/kg. Administration by intubation, product suspended in water 1:3, at 0.25g/ml. 14 day observation period. No mortality occurred. Necropsy showed consolidation in the lungs of three animals, otherwise normal.

Core Minimum Data

TOXICITY CATEGORY IV

2. Acute Dermal LD<sub>50</sub>. 5 M and 5 F NZAR, dosed at 2 g/kg. Product moistened prior to application. 24 hour exposure, sites clipped and abraded. 14 day observation period. No mortality, necropsies unremarkable.

Core Minimum Data

TOXICITY CATEGORY III

INERT INGREDIENT INFORMATION IS NOT INCLUDED

3. Inhalation Toxicity. 5 M and 5 F SD rats. 392 L chamber. Spengler model A dust generator. 4 hour exposure. Actual concentrations measured at 30, 90, 150, and 210 minutes using millipore filters. Particle size measurement by Anderson 1 Cfm ambient sampler. Particle size distribution and air concentrations as follows:

<u>Concentration</u>		<u>Particle Size Analysis</u>	
<u>Time</u>	<u>Mg/L</u>	<u>Size, microns</u>	<u>% by Weight</u>
30	0.862	4.7-9.0	41
90	0.892	2.1-4.7	27
150	0.897	0.65-2.1	23
210	0.783	<0.65	7
		Unaccounted for	2
$\bar{X}$	0.859		

No mortality occurred. Animals exhibited lethargy and labored respiration. All animals returned to normal within 24 hours.

Core Minimum Data

TOXICITY CATEGORY II

4. Eye Irritation. 9 NZ white rabbits, housing not reported. 0.1 gm. per eye. Fluorescein scan pre-test. 3 washed and 6 unwashed. Results: Unwashed; No corneal opacity or iritis. Minor conjunctival irritation occurred in 4/6 animals clearing in all cases by day 2. Washed; No corneal opacity, iritis or conjunctival irritation occurred.

Core Minimum Data

TOXICITY CATEGORY III

5. Primary Dermal Irritation. 6 NZ white rabbits, housing not reported. 0.5 g per site in an unidentified solvent, probably water. All sites clipped, 1/2 of the sites abraded. Sites occluded 24 hours. No irritation occurred at any site. PDIS-0.0.

Core Minimum Data- Despite deficiency in the reporting, of the solvent, the product can be classified based upon this study and the low PDIS.

TOXICITY CATEGORY IV

SUMMARY OF THE SUBMITTED DATA

<u>Study</u>	<u>Result</u>	<u>Tox. Cat.</u>
Acute Oral LD <sub>50</sub>	> 5g/kg	IV
Acute Dermal LD <sub>50</sub>	> 2g/kg	III
Pri. Dermal Irr.	PDIS 0.0	IV
Eye Irritation	No corneal opacity or iritis. Minor conjunctival irritation clear by day 2.	III
Acute Inhalation LD <sub>50</sub>	>.859 mg/L	
Skin sensitization	Not Submitted	---

CONCLUSIONS

1. All of the submitted data are acceptable for registration purposes.
2. A dermal sensitization study is not required for this product.
3. The acute inhalation study was conducted such that the maximum dosage tested was .859 mg/L. Even though no deaths occurred at this dosage, the product would normally be in toxicity category II at this level. However, it is noted that the product carries a dust mask statement on the label and the toxicity of the active ingredient is well known. Therefore the existing signal word "Caution" and precautionary labelling are acceptable.

LABELLING

No Adverse Comments

Phil Hutton  
TSS/IRB