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%
[redacted]
Dust

BACKGROUND

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

USES

As a stored grain protectant: Bin Treatment- 500g/100m^3 or 1 lb./1000ft^3. 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_{50}. 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 occured. Necropsy showed consolidation in the lungs of three animals, otherwise normal.

Core Minimum Data

TOXICITY CATEGORY IV

2. Acute Dermal LD_{50}. 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

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:

Concentration		Particle Size Analysis	
Time	Mg/L	Size, microns	% by Weight
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
$\overline{X}$	0.859		

No mortality occured. 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 occured in 4/6 animals clearing in all cases by day 2. Washed; No corneal opacity, iritis or conjunctival irritation occured.

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 occured 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

Study	Result	Tox. Cat.
Acute Oral LD_{50}	> 5g/kg	IV
Acute Dermal LD_{50}	> 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_{50}	>.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 occured 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