ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

195C

Date: November 16, 1973

Reply to Attn of:

Subject: Application for experimental permit to use Kathon 893 as fungicidal seed dressing.

To: Mr. Lee TerBush, Acting Chief
Coordination Branch
Registration Division

Registration No. 707-EXP

Rohm and Haas

Formulation

Active Ingredient
2-n-Octyl-4-isothiazolin-3-one 70.0

Inert Ingredients

[redacted]

19

TOXICITY DATA

The acute oral and inhalation toxicities are presented in summary from the technical product which contains 90% active ingredient (versus 70% for Kathon 893). The acute LD_{50} for the rat was 794 mg/kg (male) and 681 mg/kg (female). The inhalation LD_{50} for the rat was 4 mg/l.

The following data on Kathon 893 are presented in detail with this application:

1) The dermal LD_{50} was determined to be 3 g/kg. Animals receiving the dose on abraded skin died within 24 hours; those receiving the dose on unabraded skin within 48 hours. The surviving animals were observed for 2 weeks; no further deaths occurred.

2) Primary skin irritation: 0.5 ml of material was applied to abraded and non abraded rabbit skin and left in contact for 24 hours. The skin irritation was scored as severe after 24 as well as 72 hours.

3) Eye irritation study: 0.1 ml of material was instilled in rabbit eyes. One group was left unwashed two other groups were washed after 2 and 4 seconds respectively. The material was severely irritating to the eyes with Draize scores of 98 in all groups up to 48 hours. After 7 days the score was 85 for the unwashed group and 60-64 for the washed eyes.

In summary the following additional data are given:

1) 90 day feeding studies in rats and dogs with a NEL of greater than 2000 ppm.

2) In a 3-week dermal application study of 10% and 1% solutions of the active ingredient mild to moderate skin damage was observed (hyperkeratosis, leukocyte infiltration and epidermitis ulceration was observed with the higher concentration).

3) Subacute inhalation studies: rats were exposed to 2 mg/l aerosols of 1% and 10% solutions [redacted]. The 1% group showed few ill effects except that the condition of chronic pneumonia (controls) was intensified. The 10% group showed several deaths after a few exposures.

4) Teratology studies with rabbits were performed at levels of 6 and 60 mg/kg. The material was toxic for the dams causing several deaths but the litters of survivors were not adversely affected.

CONCLUSION

1. The toxicity data presented are adequate.

2. The cautionary statement and signal word properly reflect the toxicity of the material, however, we object to the placement on the label. The cautionary statement must also be placed prominently on the front panel; on the submitted label it appears only on the side panel after "Directions for Use".

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Toxicology Branch
Registration Division

cc: DB, EEB, HFB, IRB, PCCritchlow, GEWhitmore, Branch File, Division File

REngler/km 11-16-73