

US EPA ARCHIVE DOCUMENT

Shaughnessy No: 127201

Date Out of EAB: APR 13 1988

To: Lois Rossi
Product Manager #21
Registration Division (TS-767C)

From: Michael Firestone, Chief
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)



Thru: Paul F. Schuda, Chief
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)



Attached, please find the EAB review of:

Reg./File # : 3125-GUA, -GUT
Chemical Name : Baytan
Type Product : Fungicide
Product Name : Baytan
Company Name : Mobay
Purpose : Applicator Exposure Study

Date Received : 9/3/87 Action Code: 101

Date Completed: 4/12/88 EAB #(s): 70939-70940

Monitoring study requested: Total Reviewing Time: 2 days

Monitoring study volunteered:

Deferrals to: Ecological Effects Branch

 Residue Chemistry Branch

 X Toxicology Branch

1.0 INTRODUCTION

Mobay Corporation has applied for registration of Baytan, a dry flowable formulation containing 25% triadimenol. Baytan is a systemic fungicide intended as a seed treatment for wheat, oats, rye, barley, corn, and grain sorghum. Application rates range from 1.0 to 4.0 oz of product per 100 lb of seed.

The registrant, as part of a rebuttal, has submitted three human exposure studies, two measuring worker exposure to Baytan, and the third measuring worker exposure to carboxin, thiram, and lindane (1,2,3). Following a preliminary review of the two Baytan studies, EAB requested additional information from Mobay. The requested information was provided to EAB in an addendum on March 14, 1988 (4). The latter study has been previously reviewed by EAB and judged to be inadequate for an exposure assessment based on analytical deficiencies.

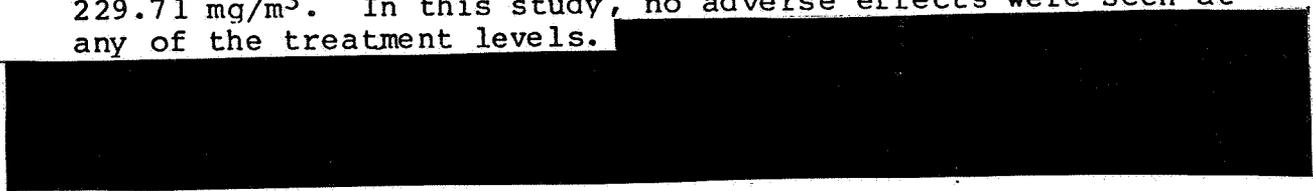
2.0 BAYTAN USE PRACTICES

Usage information provided by the Benefits and Use Division (5) indicates that Baytan application would be limited to commercial seed treatment companies. In a typical situation, a slurry would be applied by means of Mist-O-Matic seed treatment equipment at a rate of 1-4 oz product/16 oz water/100 lb seed.

Label instructions require that workers wear goggles, face shield or safety glasses, that hands, arms and face be thoroughly washed with warm water and soap after handling Baytan, and that work clothing be laundered before reuse.

3.0 COMMENTS FROM MOBAY

The registrant has stated that they disagree with the Agency requirement that a 90-day inhalation toxicity study be conducted on Baytan. As part of their argument, they reference two inhalation toxicity studies, one in which technical Baytan was administered for 21 days at concentrations of 30.39, 68.03, and 229.71 mg/m³. In this study, no adverse effects were seen at any of the treatment levels.



Mobay believes that these two studies demonstrate that both the technical and DF formulations of Baytan can be tolerated by experimental animals, and has provided worker exposure data showing inhalation exposures resulting from actual use. Mobay contends that anticipated worker exposures are going to be significantly below levels at which toxicity may be a factor, and believes that these exposure and toxicological data show that there is no need to conduct a 90-day inhalation toxicity study.

4.0 REVIEW OF EXPOSURE STUDIES

EAB believes that a full review of these exposure studies is not warranted at this time, and has limited this review to the inhalation exposures provided in the studies in order to address the concerns raised by the registrant (Section 3.0).

Two studies were submitted, measuring the dermal and inhalation exposures of workers involved in treating barley seed with Baytan. Both dry and slurry forms of the product were used. Respiratory exposure was measured in the worker's breathing zone using personal air samplers equipped with filter cartridges; samplers operated at a flow rate of 1.0 L/min.

Air concentrations of Baytan, measured during both mixing/loading and bagging operations, ranged from 0.003 to 1.2 mg/m³. Values within this range are in close agreement with the average respiratory exposure of 0.94 mg/m³ for mixer/loaders handling a wettable powder formulation of benomyl (6).

5.0 DISCUSSION AND CONCLUSIONS

EAB agrees that the air concentrations that mixer/loader/baggers are exposed to during Baytan use as a seed treatment are appreciably below the concentrations administered in the inhalation toxicity studies referenced by the registrant. EAB defers to the Toxicology Branch to establish the need to conduct further toxicological studies on Baytan.



Laurie Lewis
Special Review Section #2
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

REFERENCES

- 1) Inkmann-Koch, A. 1985. Measurements of Applicator Exposure During Dry Seed Treatment of Grain with Baytan Universal Dry Seed Treatment of Grain with baytan Universal (New) Containing Triazoxide (SAS 9244). Mobay Report No. 94805.
- 2) Inkmann-Koch, A. 1985. Comparative Measurements of Applicator Exposure during Seed Treatments with Baytan Universal Dry Seed Treatment and Baytan Universal Slurry. Mobay Report No. 94804.
- 3) Grey, W.E. et al. 1983. Potential Exposure of Commercial Seed-treating Applicators to the Pesticides Carboxin-thiram and Lindane. Bull. Environ. Contam. Toxicol. 31:244-250.
- 4) Knarr, R.D. 1988. Supplementary Information to Reports 94804 and 94805. Mobay Report No. 94804-1.
- 5) Memorandum from E. Neil Pelletier (BUD) to Laurie Lewis (EAB) titled "Report on Use Practices and Estimates of Exposure Periods for Application of Baytan as a Seed Treatment," dated November 30, 1987.
- 6) Everhart, L.P. and R.F. Holt. 1982. Potential Benlate Fungicide Exposure During Mixer/Loader Operations, Crop Harvest, and Home Use. J. Agric Food Chem. 30:222-227.