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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

14 JUN 1989

MEMORANDUM

SUBJECT: HANDLER EXPOSURE ASSESSMENT FOR THE SEED TREATMENT USE OF
THE FUNGICIDE TRIADIMENOL (BAYTAN)

TO: Reto Engler, Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

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THRU: Michael P. Firestone, Ph.D., Chief *M. P. Firestone*
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Attached, please find the Non Dietary Exposure Branch, NDEB, review
of....

HED Project #: 9-0764A

Reg File/Rec #: _____

Registration #: _____

Caswell #: 074A

Company Name: Mobay Chemical Company

Date Received: 3/27/89 Action Code: "SPECIAL"

Current Action Code: "EXPEDITE" as of 5/5/89

Monitoring Study Requested: _____ Reviewing Time: 2 weeks

1.0 CONCLUSIONS AND RECOMMENDATIONS

The following table summarizes the exposure estimates for Baytan following the proposed use as a seed treatment, either to the wettable powder or the liquid suspension. This exposure assessment is based on information gathered from RD and BEAD; it does not include analysis of studies received by RD after June 5, 1989. The conclusions of the authors of these studies and a brief description of the studies will be included at a later date. NDEB defers to the Science Analysis and Coordination Branch, SACB, regarding the toxicological risks to the developing fetus following maternal exposure to Baytan during seed treatment operations. Surrogate studies involving field agricultural use of closed loading liquid formulations were used for the exposure calculations as explained in the text of this review. In the absence of data for dry formulations, NDEB will assume that unit exposure for closed loading of liquid and dry formulations are identical.

SUMMARY OF DAILY EXPOSURE FOR "BAYTAN SEED TREATMENT FUNGICIDE (WETTABLE POWDER)" (MG AI/KG/D)

<u>DERMAL:</u>	0.165
<u>RESPIRATORY:</u>	0.067

SUMMARY OF DAILY EXPOSURE FOR "GUSTAFSON BAYTAN 30 FLOWABLE (A LIQUID SUSPENSION)" FUNGICIDE (MG AI/KG/D)

<u>DERMAL:</u>	0.164
<u>RESPIRATORY:</u>	0.067

NOTE: Not adjusted for actual dermal penetration (i.e., 100% dermal penetration is assumed).

These exposure estimates do not consider any potential exposure related to handling treated seed in the factory.

SACB has classified Baytan as a potential developmental toxicant.

The exposure assessment was designed to simulate commercial seed treatment at the factory, using a closed system which is expected to result in limited human handling and, thus, limited exposure to Baytan.

The 4/28/89 BEAD report states that a commercial operation would treat seeds with Baytan, 8 hr/day for 45 days/year. The wettable powder would be used, using a closed mixing and loading system (this should be a required label restriction). Exposure to farmers having fewer than 1000 acres of land is assumed to be limited to dermal and respiratory exposure following opening and emptying commercially treated and bagged seed in their seed hopper prior to planting. A label restriction prohibiting seed treatment by the

farmer is required, because insufficient data currently exist to support that use.

The total exposure for commercial seed handlers using Baytan is expected to be 0.23 mg/kg/d. Seed applicator exposure (to farmers having fewer than 1000 acres of farmland) cannot be quantified due to absence of data.

NDEB recommends that SACB, G. Ghali, be advised of this exposure estimation for the use of Baytan on seed treatment of grains. The label should also require that mixing and loading be performed only in a commercial setting using a closed system.

NDEB recommends that the registrant conduct a new study of worker exposure during the closed system seed treatment use of Baytan and subsequent exposure to treated seed. The exposure estimates included in this review are based on field agriculture surrogate studies and, thus, studies reflecting closed system application to seed would be much more appropriate.

NDEB recommends that the label be amended to restrict the seed treatment use of Baytan to a closed commercial system. Seed treatment outside the commercial setting, i.e., in the field or on the farm, should be prohibited on the label. In addition, commercial handlers of Baytan should be required (by label) to wear a long sleeved shirt and long pants, and use chemical-resistant gloves.

NDEB further recommends that the PM require that the label be clarified to include description of the formulations to be used. This is necessary for the safety of the user (to ensure that the user has the correct material) and for the accurate estimation of worker exposure and subsequent risk. According to the 1986 Farm Chemicals Handbook, Baytan is used as a seed dressing in the following forms: wettable powder, emulsifiable concentrate, emulsion-water, dry powder and dry flowable. The exact identity and nature of the intended formulation is critical for worker safety and to ensure an accurate assessment of worker exposure.

The product was called "Baytan 150 FS Seed Treatment Fungicide" prior to January 25, 1988. It is now called "Baytan Seed Treatment Fungicide." The 1/25/88 label states that 25% of the product (0.25 pound per pound) contains the active ingredient Beta-(4-Chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol. No description as to the physical state of the above compound, i.e., either liquid or physical description of the inert ingredients, comprising 75% of the formulation, is included on this label. NDEB notes that the "Baytan Seed Treatment Fungicide" and "Baytan 25% DF (Dry Flowable)" appear to have the identical formulations. The current request is for the "Baytan Seed Treatment Fungicide" powder only.

Mobay should clarify whether they wish to include use of Baytan 25% DF for the seed treatment of grains as well.

According to information received by M. Fiol on 6/6/89, the formulations to be used also include Gustafson Baytan 30 Flowable (a suspension).

As of 6/9/89, the Agency is awaiting a FAX from Mobay granting Gustafson permission to use Mobay's proprietary studies in support of their registration.

NDEB defers to SACB as to calculation of developmental toxicant risk due to use of Baytan as a seed treatment.

2.0 INTRODUCTION

The Science Analysis and Coordination Branch, SACB, has requested that the NDEB calculate an exposure assessment for handlers (mixers, loaders, and applicators) using Baytan as follows (See 3/14/89 memo from G. Ghali to C. Trichilo):

- *Baytan 25% DF (dry flowable) on grapes,
- *Baytan 3% G on imported bananas, and
- *Baytan 150 FS seed treatment.

As of 5/5/89, this request was granted "Expedite" status according to a conversation between M. Firestone and F. Sanders. At that time, the decision was also made for NDEB to only do an exposure assessment for the seed treatment use. SACB should re-request an exposure assessment for the other two uses of Baytan if and when they are needed.

The Baytan 150 FS seed treatment formulation has been replaced by the formulation called "Baytan Seed Treatment Fungicide Formulation." The 1/20/88 label does not clearly state the physical nature of the compound. In addition, the identity and physical state of the inerts are not given. However, the label does require that the product be applied "as a water-based slurry to the seed and not a dry seed treatment." According to information given by D. Hansen following a 5/26/89 conversation with Mobay, the formulation to be used for the seed treatment of grain is a wettable powder. This updates and contradicts the previous information provided by G. Ghali (SACB), M. Fiol (RD) and D. Szuhay (BEAD) that the formulation was Baytan 25% DF or a liquid. However, according to RD, Gustafson would also like to register "Gustafson Baytan 30 Flowable," a liquid.

3.0 LABEL INFORMATION

More recent 1/20/89 labeling for Baytan Seed Treatment Fungicide (the powder) requires the following:

*Wear goggles, face shield or safety glasses.

*Recommended ... to be applied as a water-based slurry as through a standard slurry or mist type commercial seed treatment equipment.

*Use 4 oz/100 lb of seed for head smut in corn.

*Use 1-2 oz/100 lb of seed for smut, blotch, and rot of wheat, barley, oats, and rye.

Gutafson Baytan 30 Flowable label dated 6/15/89 (reviewed 6/6/89 by NDEB) labeling states:

*Contains 30% ai (2.65 lb ai/gal) for use on wheat, barley, oats, rye, corn.

*Use up to 3 fl. oz/100lb seed in corn, applied as a water-based slurry.

4.0 METHODOLOGY AND ASSUMPTIONS

Baytan exposure and risk to mixers, loaders, and applicators was estimated based on analysis of surrogate exposure data. Risk estimates were calculated for typical application scenarios.

Assumptions made in exposure calculations are as follows:

*Mixing and loading is done commercially using a closed system. (RD should ensure that the label includes this restriction).

*The surrogate study used for estimating exposure in the commercial seed treatment plant was estimated from the closed loading agricultural surrogate from Dubelman and Peoples, and not a seed treatment plant. It is only a rough estimate.

*On small farms of less than 1000 acres, the handler is exposed dermally and via respiration to commercially treated seed, but does not treat seed in the field themselves.

*On farms of greater than 1000 acres, the handler is not exposed to treated seed (according to the 4/28/89 BEAD memo by D. Hansen).

*Applicators wear long pants and long-sleeved shirts and chemical resistant gloves (which should be added as a label requirement).

*Chemical resistant gloves provide 90% protection from dermal contact.

*Dermal absorption of 100% is assumed for Baytan.

If the actual absorption is less than 100%, and chemical resistant gloves are required throughout mixing and loading of Baytan, exposure to handlers of Baytan would be reduced.

The registrant is strongly urged to conduct a new seed treatment study. This may be required by SACB if the risk proves to be unacceptable to workers exposed to Baytan.

5.0 PESTICIDE USE INFORMATION

***The proposed use is for commercial mixing and loading to be done, via a closed system, for 8 hours/day, up to 45 days/year. The formulation to be used is a wettable powder and a 30% liquid.

Applicator exposure, in small farms of under 1000 acres, is expected to be limited to that caused by the emptying and unloading of 50 pound bags of commercially treated seed into the farmer's hopper for planting. Exposure is expected via the dermal and respiratory routes. A label restriction prohibiting farmer seed treatment in the field needs to be imposed by RD.

**The Biological and Economic Analysis Division, BEAD, provided an assessment for the expected use of Baytan on seed. (See D. Hansen memorandum dated 4/28/89).

6.0 EXPOSURE CALCULATIONS:

6.1 MIXER/LOADER EXPOSURE TO BAYTAN

NDEB assumes that mixer/loaders wear long sleeved shirts and long pants as well as chemical resistant gloves (as recommended by NDEB for the proposed label) and that the system involves closed loading only (another label restriction). Using these assumptions and label restrictions, exposure may be estimated from the agricultural surrogate studies by Dubelman, S., et al., ("Operator Exposure Measurements During Application of the Herbicide Diallate" Journal Agriculture Food Chemistry 30 [3]:528-532) and Peoples, S., et al., ("Monitoring of Potential Exposure of Mixer, Loaders, Pilots and Flaggers During Application of DEF and FOLEX to cotton Fields in the San Joaquin Valley of California in 1979," Report 45-676. California Dept. of Food and Agriculture). These studies reported that for 18 replicates, dermal exposure to mixer-loaders using closed loading was 0.015 mg/lb ai handled. Assuming exposure was roughly the same for the two formulations, and is only dependent on the amount of Baytan used on the seed (because the system is closed), the following exposure estimates would result.

Respiratory exposure to Baytan on grains was estimated to be about 0.5 mg ai/hr, using two replicateds from Grey, et al. data, ("Potential Exposure of Commercial Seed-Treating Applicators to the Pesticides Carboxin-Thiram and Lindane," 1983). Assuming that the handler performs this task 8 hr/d, as BEAD suggests, and that 60,000 kg of seed/hr is treated in the seed treatment plant, as given in the example in Grey, et al. (p. 246), NDEB estimates for the commercial seed treater wearing gloves while handling Baytan:

Dermal exposure for "Baytan Seed Treatment Fungicide" (Wettable Powder) =

$$\begin{aligned} & (0.015 \text{ mg ai/lb ai}) \times 60,000 \text{ kg seed treated/hr} \times 2.2 \text{ lb/kg} \\ & \times 0.25 \text{ lb maximum formulation used/100 lb seed corn treated} \\ & \times 0.25 \text{ lb ai/lb formulation} \\ & \times 8 \text{ hr/day} \times 1/60\text{kg} \\ & = 0.165 \text{ mg ai/kg/day} \end{aligned}$$

Dermal exposure for "Gustafson Baytan 30 Flowable" Liquid Suspension=

$$\begin{aligned} & (0.015 \text{ mg ai/lb ai}) \times 60,000 \text{ kg seed treated/hr} \\ & \times 2.2 \text{ lb/kg} \times 2.65 \text{ lb ai/gal Baytan 30 Flowable Liquid} \\ & \text{Formulation} \\ & \times 3 \text{ fl oz formulation/100 lb seed corn treated} \\ & \times \text{gal/128 fl oz} \\ & \times 8 \text{ hr/day} \times 1/60\text{kg} \\ & = 0.164 \text{ mg ai/kg/day} \end{aligned}$$

Respiratory exposure may be easily calculated as follows, using the respiratory data reported by Grey, et al., as a surrogate:

$$\text{Respiratory exposure} = (0.5 \text{ mg ai/hr}) \times 8 \text{ hr/d} = 4.0 \text{ mg ai/d}$$

$$\begin{aligned} & \text{or in terms of body weight, for a 60 kg female,} \\ & = 0.067 \text{ mg ai/kg/d} \end{aligned}$$

Adding the dermal and respiratory exposures, the expected exposure to a individual weighing 60 kg who is mixing and loading Baytan commercially, using protective gloves, would be on the order of 0.23 mg ai/kg/d for either the Baytan Seed Treatment Fungicide or the Baytan 30 Flowable formulation.

NDEB notes that the surrogates used include an only marginally acceptable number of replicates and cautions SACB and RD that if the risk to workers using Baytan is excessive, additional studies should be submitted by the registrant. The closed loading scenario used herein as a surrogate to estimate exposure to handlers of Baytan (proposed to be used in a closed loading, in an indoor factory setting) represent outdoor closed agricultural loading, and may not be a good estimate for indoor use. If the use involves an open loading system, or the handler does not wear gloves and other protective clothing, the exposure will likely be much higher.

6.2 APPLICATOR EXPOSURE AND DOSE TO BAYTAN

If we assume that commercial applicators wear long sleeve shirt and long pants, and also gloves, then exposure can be estimated based on the previous estimates.

For the farmer handling treated seed, all the exposure will be from handling bags of treated seed, however, data are unavailable to permit quantification of exposure.

cc: Albin Kocialski, SACB
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Susan Lewis, Acting PM (H7505C)
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Baytan File
Circulation File
Correspondence File
Chronological File