

TSS/IRB PRECAUTIONARY LABELLING REVIEW

February 1, 1984

PM: 16

SUBJECT: 3125-330
Amaze 5% Granular

IN TSS: 12-14-83
DUE: 02-08-84
AC: 435
RN: 11047
ACCN: 251918
OLTS: 38

FORMULATION: Isofenphos.....5% G

BACKGROUND

This is a letter accompanied by data disputing current Agency requirements for immediately watering-in all isofenphos granular products used on turf.

USES

The product is currently registered for application to commercial, domestic, and recreational turf for the and chicken eggs. Label rates are 1.45 oz. ai per 1000 ft², with no more than 1.45 oz. ai per 1000 ft² per year.

SUBMITTED DATA

Accession Number 251918.

1. Report 80049. This is a field study using the 5G at 2.0 lbs. ai per acre. Bobwhite Quail and rabbits were caged over treated turf for 14 days. There was 0.22 inches of rain on day 3. There was no mortality. Cholinesterase inhibition was measured over the course of the study but there were no preapplication baseline measurements.
2. Report 80744. This is a study with beagle dogs caged over treated turf. A flowable formulation was used for this study. There was rainfall on days 0, 1, 4, and 5, making the study questionable as data to show that postapplication irrigation is unnecessary. There was no mortality. Cholinesterase inhibition was debatable (according to BTB).

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3. Report 82466. This is a beagle dog feeding study with Amaze 5G. 2 M and 2 F per dose were fed at 500 mg/kg and 1000 mg/kg. The dogs were not fasted prior to administration by gavage in a water carrier. The 500 mg. group showed no signs of intoxication but 1 dog died on day 5. All 4 dogs fed at 1000 mg. showed signs of intoxication which reversed quite slowly, but there was no mortality at this dosage. Both groups showed cholinesterase inhibition which did not reverse over the 14 day observation and test period.

4. Letter from Mobay debating the requirement for immediate watering-in. The essential points of this letter are as follows:

- a. Diazinon is not adequate for grub control by the lawn-care industry, as it is not sufficiently effective.
- b. A statement to require immediate watering-in is not necessary for this product because "Label statements not supported by data or sound reasoning are unnecessary".
- c. The requirement for immediate watering-in will restrict the use of this product by the lawn care industry.

CONCLUSIONS

1. The submitted data are inconclusive as to the relative hazards to humans (especially children or infants) from isofenphos 5G granules remaining on treated lawns. The data do show that an 0.5 gram per Kg dose administered orally causes significant cholinesterase depression and possible death. Report 80049 seems more appropriate as fish and wildlife data. Little can be said for this study from the human toxicity standpoint as there were no pre-exposure cholinesterase levels. Study 80744 does not represent a situation where no irrigation is used because of rainfall at day 0 and 1. Also, this study used a flowable formulation instead of the subject granular material.

2. The relative effectiveness of diazinon has nothing to do with the potential hazards of this product applied to lawns and turf normally frequented by humans and pets. We will state, however, that diazinon can be used quite effectively for grub control if properly timed. For this reason diazinon is still used by many turf care professionals as part of their pest management program. Also, there are other turf insecticides which are effective for the control of grubs.

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3. Contrary to statements by Mobay, immediate watering-in is indeed supported by sound reasoning. Isofenphos is a potent cholinesterase inhibitor, and immediate watering-in removes the granules from the surface of the lawn and hence reduces the potential exposure of humans and pets. The effectiveness of the product is not reduced by this practice, and may actually be enhanced. The fact that having to water-in a granular compound immediately after application is inconvenient to the lawn care contractor does not outweigh the potential benefits from reduced exposure to the pesticide in question. This apparently, is the main objection of the registrant to having these label instructions.

LABELLING

1. The label statement to immediately water in the applied granules must remain on the label.

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