

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

File P P 5F1646
4/2

SUBJECT: Tolerance for Thiabendazole, 2-(4-Thioazol)-
benzimidazole, 0.1 ppm on soybeans. Petition
No.: 5F1646. Registration No.: 618-75

DATE: OCT 28 1976

FROM: Toxicology Branch

TO: Product Manager #21 (Mr. Wilson)
Re-Registration Task Force
Chemistry Branch

Conclusion:

1. The registrant submitted the acute dermal toxicity data requested in our memo of September 2, 1975 (above petition). The data is acceptable; the precautionary statement and the signal word of the Mertect 340-F formulation are adequate.
2. In our memo of September 2, 1976 we concluded that the requested tolerance could be supported, based on the toxicity data submitted on this chemical; for this conclusion we, however, used the criteria as they existed before the publication of the new Section #3 Guidelines, since the application reached the Agency before these Guidelines were in effect. Applying the new Guidelines (after rejection of the original application) new tolerances and registrations for this chemical can not be granted since certain data gaps exist for Thiabendazole. In the February 17, 1976 CFR the data gaps are listed as TER, and ONC (line 417, category II). A satisfactory teratology study with negative results was submitted and reviewed (memo of September 2, 1975), thus leaving only the ONC data gap. Before establishing this tolerance we request that an oncogenicity study on this chemical be submitted for review.

*See recent
Sept 18 on
reger letters
for 1.5 mil. Toss*

Review:

1. Prior Studies in support of a Tolerance:

LD50 (rat)	3.33 g/kg
LD50 (mouse)	3.81 g/kg
Subacute feeding (rat)	NEL 100 mg/kg; dose finding study 30, and 180 days, 30% deaths at 800 mg/kg
Teratology (rats)	negative at 80 mg/kg/day; 8-15th day of pregnancy
2-year rat feeding	NEL 40 mg/kg/day
2-year dog feeding	NEL 50 mg/kg/day
5-generation repro- duction (mouse)	negative at 150 mg/kg

(see file 5F1646)

2. Prior Tolerances:

Prior Tolerances are established under 180.242 as follows:

10 parts per million in or on apples, citrus fruit, and pears (from postharvest application) and sugar beet tops.

3 parts per million in or on bananas (from post-harvest application) of which not more than 0.4 part per million shall be present in the pulp after the peel is removed and discarded and potatoes (from pre- and post-harvest applications).

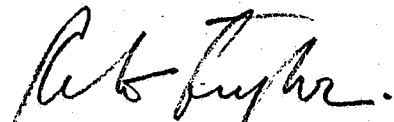
1 part per million in or on Hubbard squash.

0.25 part per million in or on sugar beets (from preharvest application) excluding tops.

0.1 part per million for combined residues of thiabendazole and its metabolite 5-hydroxythiabendazole in milk, fat, meat, and meat byproducts of cattle, goats, hogs, horses and sheep.

3. Dermal LD₅₀ determinations of Thiabendazole formulations:

Mertect 360, 360 WP, and 340-F were tested for dermal toxicity in rabbits. The LD₅₀ for all three formulations was greater than 2.0 g/kg; 0/10 animals at this level died after application of the material to intact and abraded skin for 24 hours.



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E/oe OEP. 10/27/76