

#849A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

001973 Engler

SUBJECT: Tolerance for Thiabendazole 4.0 ppm on Sugarbeets  
(from post harvest application).

DATE: APR 7 1977

FROM: Toxicology Branch

TO: Dr. E. Wilson  
Product Manager  
and Chemistry Branch

Pesticide Petition: 6F1860 and 5F1646

Petitioner: Merk Co.

Conclusion: The requested tolerance on sugarbeets and the previously requested tolerance of 0.1 ppm on soybeans can be established, provided that an assurance is obtained from the petitioner that a second oncogenicity study (second species) will be submitted within a reasonable time span, and interim reports of this study will be submitted as they become available. (The usual time required for such an oncogenicity study is 2.5 to 3 years). Furthermore, mutagenicity testing must be carried out, or initiated at the time when requirements become finalized. This conclusion is reached because:

1. The studies submitted previously show that thiabendazole is not oncogenic for the rat, is not a teratogen, and does not affect reproduction, and
2. The requested tolerances on sugarbeets and soybeans will not add an appreciable amount, if any, to the dietary burden of man; see also determination of ADI and maximal theoretical exposure (MTE) calculation in review.

Note: The previous recommendation, not to establish the soybean tolerance (memo of October 28, 1976) was based solely on the concept of a data gap with respect to proposed data requirements.

Review

No new toxicity data were submitted. We refer to our reviews of September 2, 1975, and October 28, 1976 (PP 5F1646). For convenience the toxicity tests are listed below; thiabendazole also has a history as antihelminthic drug.

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

1087

- 2 -

2-year rat feeding  
2-year dog feeding  
5-generation reproduction  
(mouse)

NEL 40 mg/kg/day  
NEL 50 mg/kg/day  
negative at 150 mg/kg

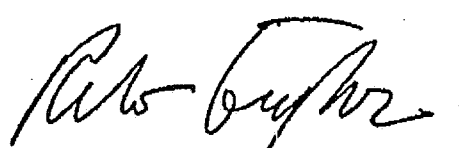
ADI, MPI, and MTE

Based on the rat 2-year feeding study the ADI for man (100-X safety factor) is 0.4 mg/kg b.w./day which results in a MPI for a 60 kg man of 24 mg/day.

Tolerances for thiabendazole are established for the following rac (180.242):

10 ppm apples, citrus, pears, sugarbeet tops  
3 ppm bananas (0.4 ppm in pulp)  
1 ppm hubbard squash  
0.25 ppm sugarbeets  
0.1 ppm milk; meat, fat and meat byproducts, cattle, goats,  
hogs, horses and sheep.  
0.02 ppm sweet potatoes.

Using the appropriate food factors the MTE (maximum theoretical exposure) of man is calculated to be 0.982 mg/day or about 4% of the MPI, the ADI is therefore not exceeded.

  
Reto Engler, Ph.D.  
Toxicology Branch  
Registration Division

*RE for OEP 4/7/77*

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