

11-15-78

November 15, 1978

Subject: Sign-in - Request to amend CIR 40, 180.11, Malathion; "From preharvest application: 50 ppm in or on almond hulls; and from post-harvest application: 50 ppm in or on almond shells." Petition # 8E2114 Caswell 855

FROM:

Carlos A. Rodriguez
NOV 15 1978

TO:

Henry M. Jacoby
Product Manager No. 21

1. Toxicity data considered in setting the tolerance for the Pesticide Petition:

- Rat Oral LD₅₀ - 1,000 - 1,850 mg/kg
- Mouse Oral LD₅₀ - 720 - 3,321 mg/kg
- 47-Day Human Feeding Study - NEL = 0.2 mg/kg/day
- 2-Year Rat Feeding Study #1 - NEL = 100 ppm
- 2-Year Rat Feeding Study #2 - NEL = < 100 ppm
- Rat Assay Mutagenicity - negative
- Reversion Assay Mutagenicity Study - negative
- Delayed Neurotoxicity Study - negative
- 1-Generation Reproduction Study - reproductive effects observed at 4,000 ppm
- Single Dose Intraperitoneal Teratogenic Study - negative

2. The following studies and data are considered desirable but currently lacking:

- a. Carcinogenic Studies - 2 species
- b. 3-Generation Reproduction Study
- c. Teratogenicity (Feeding) Study

3. All the above studies were previously requested on 11/12/76 in review of PP# 6E1880 and on 12/5/76 in review of PP# 7E1881. It is expected that these studies will be required at the time of reregistration.

4. The following tolerances have been granted for the pesticide Malathion:

- a. PP# 19
- b. PP# 89
- c. PP# 135
- d. PP# 137
- e. PP# 7E2001
- f. PP# 015146
- g. PP# 7E1381

5. Approval of the requested ^{to be granted} will not affect the ADI for the following reason:

a. Tolerances are presently in existence for residues of Malathion in meat, milk and meat by-products extending from tolerances on other forage crops.

b. The ADI was determined from a 47-Day Human Feeding Study in which the no observable effect level (NOEL) was 0.2 mg/kg/day. A ten fold safety factor was employed in calculation of the ADI.

NOEL = 0.2 mg/kg/day

ADI = 0.02 mg/kg/day

7. No regulatory actions are pending against registration.

8. One consideration in recommending that the tolerance be established is that the latest Total Dietary Survey indicates that residues of Malathion in the U.S. food supply do not exceed the WHO ADI of 0.02 mg/kg/day.

TOX/HED:REngler:11/9/78:ssr