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5/12/77

Tolerances for Carbaryl on Celery 10 ppm Pesticide
Petition 7E1935

Toxicology Branch

Mr. Clinton Fletcher
Special Registration Section

Petitioner: IR-4 Project.

Recommendation: TB recommends that the requested tolerances be established, CB recommendation permitting. The toxicological requirements for carbaryl are fulfilled subject, however to re-evaluation for purposes of re-registration.

The ADI for man is not exceeded by this, pending and established tolerances (see review).

Review: No new toxicity data were supplied. The toxicity data on Carbaryl were recently summarized and the ADI and maximum theoretical exposure (MTE) for man calculated PP GE1848, 1847 and 7E 1878.

The toxicity data and other findings are summarized as follows:

Oral LD₅₀ (rat)

510 mg/kg (390-670)

Teratology:

Rat

375 mg/kg no teratological effects

Guinea Pig

300 mg/kg ditto/toxic to mothers

Dog

3 mg/kg no effect/terata at higher levels

Rhesus monkey

20 mg/kg no terata

Rat 2-year feeding study

NEL 400 ppm (20 mg/kg)

Dog 1-year feeding

NEL 400 ppm (10 mg/kg)

Mouse 18-month/oncogenicity

Negative 400 ppm

Mouse 18-month/oncogenicity

Negative 14 ppm ("Bionetic Study")

- Rat 3-generation reproduction study

NEL 200 mg/kg/day

"Mrak Report"

No oncogenic effects, testing sufficient

Dominant lethal mutagen^{EN}icity (rat)

Negative (200 mg/kg/day)

ADI, MPI and MTE:

The ADI was calculated using the NEL in the dog study and using the exceptionally high (for carbamates) Safety Factor of 100X. The ADI is 0.1 mg/kg bw/day which results in a MPI for a 60 kg man of 6 mg/day.

The MTC was calculated as of November 16, 1976, (including the request of PP 6E1847 and 1848 which add negligible amounts to the MTE) to be 3.89 mg/day. Pending tolerances PP7F1878 would add 0.61 mg/day for a total of 4.5 mg/day. The presently requested tolerance would add another 0.1 mg/day for a total of 4.6 mg/day. The MPI and thus the ADI is not exceeded.

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