US ERA ARCHIVE DOCUMENT

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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 reevaluation 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)

Teratology:
Rat
Guinea Pig
Dog
Rhesus monkey
Rat 2-year feeding study
Dog 1-year feeding
Mouse 18-month/oncogenicity
Mouse 18-month/oncogenicity
Rat 3-generation reproduction study
"Mrak Report"
Dominant lethal mutagaricity (rat)

510 mg/kg (390-670)

375 mg/kg no teratological effects
300 mg/kg ditto/toxic to mothers
3 mg/kg no effect/terata at higher levels
20 mg/kg no termita
NEL 400 ppm (20 mg/kg)
NEL 400 ppm (10 mg/kg)
Negative 400 ppm
Negative 14 ppm ("Bionetic Study")
NEL 200 mg/kg/day
No oncogenic effects, testing sufficient
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 100k. X. 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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