

Engler

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Carbaryl, 1-naphtyl methyl carbamate. Tolerances: see DATE: ¹⁶ ~~22~~ NOV 1976
below. Pesticide Petition 6E1848, and 6E1847

FROM: Toxicology Branch

TO: Special Registration Section
Ms. Patricia Critchlow

Tolerances Requested:

6E1848 0.2 ppm in or on sweet potatoes

6E1847 10.0 ppm in or on lentils
100 ppm lentil forage

Petitioner: IR-4 Project, Rutgers University, New Brunswick, N.J.

Conclusion: Grant tolerances for both petitions; Carbaryl has no substantial data gaps. A temporary tolerance for Carbaryl on lentils (6G1781) is pending; if the permanent tolerance is established the temporary one will not be necessary. The ADI for carbaryl will not be exceeded by these and the established tolerances.

Review:

1. Previous Tolerances: Tolerances for Carbaryl are established under 180.169 on a number of rac, in fact about 40% of the human diet items have tolerances for carbaryl at various levels ranging from 0.2 to 12 ppm.

2. Toxicity data: No new toxicity data were submitted with these petitions; the petitioner refers to the files of Union Carbide and he has obtained authorization to use those studies. The pertinent data for tolerances were submitted with PP 902 and 1220 and are listed below, together with other pertinent data on carbaryl:

| | |
|--------------------------|--|
| 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 tereta |
| 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
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Rat 3-generation reproduction study
"Mrak Report"

negative 400 ppm
negative 14 ppm ("Bionetic Study")
NEL 200 mg/kg/day
No oncogenic effects, testing
sufficient
negative (200 mg/kg/day)

Dominant lethal (rat)

3. Calculation of ADI and estimated human exposure.

The ADI for man can be calculated as follows: From the observed NEL in dogs (more sensitive animal) and using a 10-fold safety factor the ADI for man is 60 mg/day or 1 mg/kg b.w./day. (Even when using a 100-X safety factor the calculated ADI for man would be 6 mg/day or 0.1 mg/kg b.w./day respectively.) In contrast to this the WHO list an ADI for man of 0.01 mg/kg b.w./day or 0.6 mg/day. This figure is based on human feeding studies published by Wills et al.¹⁾ in 1967 and 1968; one of these studies shows that "total daily intake of 6-15 mg...will be noninjurious to man." The other study demonstrated that at a feeding level of 0.13 mg/kg/day the re-absorption of amino acids in renal tubules may have been impaired slightly, ChE levels, however, were normal. These studies are, at best, inconclusive and cannot be used for purposes of ADI determination as practiced in the U.S.

Established tolerances and computation of maximum expected exposure of man:
The following tolerances for Carbaryl are established;

100 parts per million in or on alfalfa, alfalfa hay, barley (green fodder and straw), bean forage, bean hay, clover, clover hay, corn fodder, corn forage, cotton forage, cowpea forage, cowpea hay, grass, grass hay, oats (green fodder and straw), peanut hay, peavines, rice straw, rye (green fodder and straw), sorghum forage, soybean forage, soybean hay, sugarbeet tops, wheat (green fodder and straw).

40 parts per million in or on almond hulls.

12 parts per million in or on blackberries, boysenberries, collards, dandelions, dewberries, garden beets (tops), kale, loganberries, mustard greens, parsley, raspberries, spinach, Swiss chard, turnips (tops)

10 parts per million in or on apples, apricots, asparagus, bananas, beans, blueberries, broccoli, brussels sprouts, cabbage, carrots, cauliflower, cherries, Chinese cabbage, citrus fruits, cranberries, cucumbers, eggplants, endive (escarole), grapes, kohirabi, lettuce, melons, nectarines, okra, olives, peaches, pears, peas (with pods), peppers, plums (fresh prunes), pumpkins, salsify (tops), sorghum grain, strawberries, summer squash, tomatoes, winter squash.

5 parts per million in or on corn (kernels plus cob, determined after removing husks present when marketed), cottonseed, cowpeas,

1) Wills et al. Effects of oral doses of carbaryl on man.
Tox & Appl. Pharmacol. 10 :390 (1967)
Clin. Tox. 1 :265 (1968)

garden beets (roots), horseradish, meat and fat of poultry, parsnips, peanuts, radishes, rice, rutabagas, salsify roots) soybeans, turnips (roots).

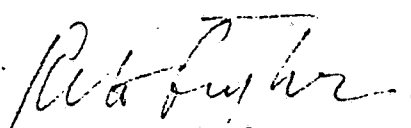
1 part per million in or on almonds, filberts (hazelnuts) pecans, and walnuts.

0.5 ppm in eggs.

0.2 part per million (negligible residue) in or on potatoes.

Zero in or on the grains of barley, oats, rye, and wheat.

From these tolerances and the appropriate food factors the maximally possible human exposure was calculated to be 3.89 mg/day or 0.065 mg/kg b.w./day respectively.²⁾ We thus conclude that the ADI for Carbaryl calculated above is not exceeded.


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OEP 11/18/76

2) The contribution by the requested tolerances to the already existing exposure from previous tolerances was not calculated, since in effect these tolerances are already included in the above figure. For example; the food factor for potatoes used in the calculation does also include sweet potatoes; the food factor for lentils is so minimal that overall exposure would not be affected.