UNITED

DATE: December 22, 1976

SUBJECT: Carbaryl, 1-naphtyl methyl carbamate. Tolerances: see below.

PP # 7F1878 and FAP 7H5154

Toxicology Branch

TO: PM # 12 (Mr. Frank Sanders)

Tolerances Requested:

7F1978

3.0 ppm in or on grain of wheat, rye, oats, and barley

Engler

1.0 ppm in meat and fat mf and meat by-products of

cattle, sheep, goats, horses, and swine

0.2 ppm in milk

7H5154

15.0 ppm in or on hulls of barley and oats

Petitioner: Union Carbide

Conclusion: Grant the requested tolerances; Carbaryl has no substantial data gaps. The ADI for humans for carbaryl will not be exceeded by these, the pending and the established tolerances.

Review:

- 1. We refer to our recent review (November 16, 1976) in conjunction with petition 6E1848 and 6E1847, where we stated that all required data under Section # 3 for carbaryl were previously submitted. This, however, does not constitute a final validation of these data. It does mean that prior reviewers , including the Mrak Committee, have come to the conclusion that carbaryl has no oncogenic potential and that the question of teratogenicity has been satisfactorily resolved by showing that carbaryl is not a teratogen for primates, although it produces terata in dogs at levels above 3 mg/kg.
- 2. Previously the ADI for man was calculated, using a conservative 100-X safety factor; The ADI is 6 mg/day for a 60 kg man or 0.1 mg/kg b.w./day.
- 3. The total maximal exposure of man to carbaryl was calculated based on the tolerances established under 180.169 and using the appropriate food factors. This theoretical maximal exposure is 3.89 mg/day or 0.065 mg/kg b.w./day for a 60 kg man. The presently requested tolerances (see above) would add maximally 0.61 mg/day, thus bringing the total exposure to 4.5 mg/day, which is still below the ADI of 6 mg/day.

Reto Engler, Ph.D. Toxicology Kranch Registration Division

10103/16