UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PP1829

SUBJECT: Temik, Aldicarb, 2-methyl-2(methylthio) propionaldehyd O-(methylcarboamoyl) oxim. Tolerance on oranges and dried citrus pulp. Caswell No.: 11A

DATE: September 30, 1976

FROM: Toxicology Branch

TO: Pesticides Science Officer (WH-567) and Product Manager #12 (Sanders)

Pesticide Petition	Food Additive Petition
6F1829	6H5141
0.3 ppm in oranges	0.6 ppm on dried citrus pulp

Petitioner: Union Carbide

Conclusion:

1. Tolerance: Other comments permitting the requested tolerances can be toxicologically supported, and they are found to protect the public health,

2. Registration: (a) A rebuttable presumption arises for the 10 G and 15 G Temik formulation, since the dermal LD_{50} of both formulations is well below 40 mg/kg.

   (b) The registrant must address the problem of reentry after use of the pesticide. This is especially important for use on orange trees, since workers are present more frequently than in the other crops for which the formulations are currently registered (cotton, potatoes, peanuts, sugar beets, sugar cane, and sweet potatoes).

Review: We refer to two prior reviews on aldicarb, petition No. 6G1689, November 8, 1975, and petition No. 6E1792, September 8, 1976. The toxicological testing on aldicarb is complete with respect to requirements of Section 3 Guidelines and Regulations, with the exception of re-entry data.

Summary of tests and results:

Test	Result
Oral LD_{50} rat (tech)	0.6 mg/kg
90-day dog feeding	NEL 0.3 mg/kg
Teratology Rat	no terata at 1 mg/kg (highest level)
Delayed Neurotoxicity (hen)	no effects at 4.5 mg/kg
18-month mouse (carcinogenicity) (2 studies)	no increase in tumors (0.7 mg/kg)
2-year rat feeding/oncogenicity	NEL 0.3 mg/kg, no tumor increase
2-year rat feeding/oncogenicity	NEL 2 ppm*
3-generation rat reproduction	NEL 0.7 mg/kg
3-generation rat reproduction	NEL 2 ppm*
Rat dominant lethal mutagen.	NEL 0.7 mg/kg
2-year dog feeding	NEL 3.3 ppm*

*Some of the older studies show a somewhat lower observed NEL, this could, however, be attributed to non homogenous mixing of the chemical with the animal diet. Upon repeating the studies the diet was more carefully prepared and the observed NEL was increased by about 3-x. For the calculation of the ADI for man we can thus use the observed NEL in the 2-year rat feeding study of 0.3 mg/kg b.w. or 6 ppm in the diet.

Human exposure from dietary intake

The ADI for man is calculated to be 0.18 mg/day, based on an observed NEL of 6 ppm in the rat and using a safety factor of 100-x. Previously established tolerances (180.269) would result in a maximum exposure of 0.101 mg/day, the tolerance on bananas (6E1792, pending) would add maximally 0.004 mg/day, and the tolerance on oranges adds maximally 0.020 mg/kg, for a total of 0.125 mg/day, which is less than the calculated ADI for man.

Safety for livestock

With the temporary tolerance request for aldicarb on orange pulp (PP 6G1689) the petitioner has submitted evidence that cattle could be exposed to maximally 0.86 ppm aldicarb in their diet. Based on the NEL observed in laboratory animals this dietary intake of domestic animals can be toxicologically supported.

Rebuttable presumption against registration

With the petition 6E1792 the registrant submitted dermal LD_{50} values for the 10 G and 15 G formulation of Temik. These LD_{50} values were about 2.5 mg/kg for the dry granules and about 0.8 mg/kg for moistened granules. This, according to 162.11(a)(3)(i)(A)(1) (risk criteria), triggers a rebuttable presumption based on acute dermal toxicity.

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OPP 9/30/76