Supplement to Document#013268 -DER for MRID No. 44636101: 21 Day Dermal Toxicity Study in Rats. This supplement provides a new Executive Summary amending the original DER to remove the NOAEL/LOAEL.

EPA Reviewer: William F. Sette, Ph.D. William F Sette 5-19-00
Science Analysis Branch, Health Effects Division (7509C)

William Burnam, Chief 5/19/00
Science Analysis Branch, Health Effects Divison (7509C)

DATA EVALUATION RECORD

STUDY TYPE: 21 Day Dermal Toxicity Study in Rats

OPPTS Number: 870.3200 OPP Guideline Number: 82-2

PC CODE: 098301 TOX CHEM Number: 011A

TEST MATERIAL: Aldicarb technical

CHEMICAL NAME: 2-methyl-2-(methylthio)proprionaldehyde-0-(methylcarbamoyl) oxime.

CITATION: RW Tyl. Assessment of Cholinesterase Activity in CD® Rats Following Topical Application of Temik 15G® Grit for Three Weeks. Research Triangle Institute, Research Triangle Park, NC. RTI Report No. 65C-7202. August 14, 1998. MRID 44636101. Unpublished.

SPONSOR: Rhône Poulenc Ag Company, Research Triangle Park, NC 27709.

EXECUTIVE SUMMARY: In this 21 day dermal toxicity study (MRID 44636101), Temik 15G® grit (14.75% aldicarb) was dermally applied to a 1" square area on the backs of 8 albino CD® Sprague-Dawley rats/sex/dose at levels of 0, 100, 250, or 500 mg/kg/day, for 6 hours/day, 5 days/week, for 3 weeks. In preliminary studies, Temik was applied once at 1000 mg/kg to 3 rats/sex for 6 hours (I), and to 5 male rats at 0, 250, 500, or 1000 mg/kg/day for 6 hours/day for 3 days (II). In II, a positive control group of 5 male rats were given a oral gavage dose of 0.1

mg/kg of aldicarb technical (99.5% a.i.).

There were no deaths or treatment related clinical signs noted in the study. In males, there were significant reductions in overall body weight gain (based on effects on days 15-19) at 100 mg/kg (21%) and 250 mg/kg (27%) but the decrease at 500 mg/kg group(11%) was not significant. There were correlative significant decreases in food consumption for days 15-19 in the 250 mg/kg males.(12.7 %, g/day) but not at 100 mg/kg. In II, plasma and red blood cell (RBC) cholinesterases were significantly decreased at 500 mg/kg (plasma 46-50%; RBCs 14-26%) and 1000 mg/kg (plasma 35-72%; RBC 31-40%). In the definitive study, statistically significant ChEI was seen only in the plasma of males at the mid-dose 250 mg/kg (18-25%). No significant effects at 500 mg/kg in either ChEI or in body weights were seen. There were no significant effects on brain ChEI in II (9.9% at 1000 mg/kg) or the 21 day study (3.4% at 500 mg/kg).

The study should be regarded as unacceptable, not upgradable based on the inconsistent findings in body weights and ChE inhibition in the definitive study, and concerns for several aspects of the study conduct, including the adequacy of : skin contact with the test material; wetting of the test material; amount of exposed skin; and limited data on the active ingredient.