

US EPA ARCHIVE DOCUMENT

Aldicarb Technical

21 Day Dermal Toxicity Study

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.

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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)propionaldehyde-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 Unpublished.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.