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TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

201-16017

Re.: Aldicarb oxime (CAS #1646-75-9)

Dear TSCA Coordinator:

As the final component of the Screening Information Data Set required to complete the dossier for aldicarb oxime (ADO), an oral 1-generation reproduction study was conducted. The doses were administered by oral gavage to rats daily, for 10 weeks prior to mating, for two weeks during mating, for 3 weeks during gestation (females only) and for three weeks during lactation (females only). Following a range finding study, dose levels of 0 (control), 5, 25 and 75 mg ADO/kg body weight were selected. The ADO was administered in corn oil.

In the ADO treated rats, apart from decreased activity seen in the 75 mg/kg treated rats, no clinical signs of toxicity were reported. There were occasional reports of body weight gain depression in the 75 mg/kg male rats and decreased food consumption in animals in both the 75 and 25 mg/kg treatment groups. More significantly, oral administration of ADO did not affect fertility, reproductive performance or estrus cycle. There were also no effects on litter size, the number of pup abnormalities, sex ratios or pup weight. However, at 75 mg/kg there was an increase in the number of stillborn pups and a decrease in the number of live pups which was considered related to treatment. As expected for an oxime, effects were seen on red cell parameters, spleen weights, white cell parameters and kidney weights at 75 mg/kg. Microscopic examination of selected tissues revealed changes in the spleen of males in the high dose and in the liver at all doses (females) and high dose (males). Thus maternal toxicity, (effects on the liver) was seen at all levels. Based on the higher number of stillborn pups seen at 75 mg/kg body weight, the NOEL for ADO for reproductive parameters following oral (gavage) administration is 25 mg/kg body weight.

While the effect on pup survival was almost certainly related to the hemolysis and concurrent poor oxygen transport, and thus is not unexpected, given the concern that E.P.A. has regarding effects in reproduction studies, Honeywell has elected to submit this finding under TSCA section 8e. There is currently only one customer for this product and they use it as a wholly consumed intermediate. Therefore the risk of exposure is minimal. We will inform them of this finding.

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This study completes our evaluation on ADO for the HPV program. These results, along with the results from the algal toxicity and biodegradation studies, will be incorporated into the SIDS dossier submitted with the test plan. The revised dossier will then be submitted to EPA for their evaluation in the ICCA HPV program. Should you have any additional questions, please contact Dr. Rusch at your convenience (george.rusch@honeywell.com).

Sincerely,

Sheri Blystone, Ph.D.
Global Product Regulatory Leader

Georgé M. Rusch, Ph.D., DABT, FATS
Director of Toxicology and Risk Assessment

Cc.: Amy Benson (U.S. EPA HPV program)
John Jones
Chip Woltz