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DATA EVALUATION REPORT

STUDY TYPE: Acute Oral Toxicity Study-Mouse

MRID NO.: 116480 TOX. CHEM. No.: 320

TEST MATERIAL: 2,4-DP Acid (purity not specified)

SPONSOR: Amchem Products, Ambler, PA

CITATION: Matthews, R.; Carey, P.; Panasevich, R. (1977) Acute Oral LD_{50} (Mouse): 2,4-DP Acid. Final rept. (Unpublished study received Mar 26, 1979, under 264-231; prepared by Pharmakon Laboratories, submitted by Union Carbide Agricultural Products Co., Inc., Research Triangle Park, NC; CDL:237875-F)

METHODS and MATERIALS: Groups of Blue Spruce CF mice (6/sex/dose) were fasted for 4 hrs; they were orally administered 2,4-DP acid once at doses of 100, 200, 400, 600, 800, and 1,000 mg/kg. The treated mice were observed daily for 14 days. At day 14, the surviving mice were sacrificed, and gross necropsy was performed on each animal.

RESULTS:

a). At all dose levels, the mice showed ataxia and hypersen sitivity . Straub tail was seen in lower dose animals. Severe writhing and tonic behavior were seen in higher dose animals.

b). At autopsy, distented and discolored small intestine, distented uterus and stomach, and discolored lungs and liver were observed.

c). Deaths of treated mice were observed one to six days after dosing. The death rates were the following:

Table 1. Mortality of 2,4-DP Treated Mice*

Dose(mg/kg):	100	200	400	600	800	1,000
Death Rates: Males:	0/5	1/5	2/5	3/5	0/5	5/5
Females:	0/5	0/5	0/5	2/5	5/5	3/5

* The data presented in this table were tabulated from the individual animal data (MRID: 116480) by this reviewer.

According to the report the calculated LD_{50} for 2.4-DP is 620 mg/kg with a confidence limit of 453 to 620 mg/kg. This value of LD_{50} was accepted by the former reviewer; however, male mice appeared to be more sensitive to 2.4-DP than female mice (Table 1).

DISCUSSION AND CONCLUSION: This study had been reviewed previously (Holder: Tox. Doc. No. 001995). and it was classified as Core Guideline. However, this reviewer does not agree with the conclusions derived by the previous reviewer for the following reasons:

1). The report did not clearly indicate how the test animals were dosed (i.e. by gavage or by some other means).

2). The data presented in Table 1 indicate there might be an experimental error in either reporting or in recording the number of males died in the 800 mg/kg group. It seems odd that none of the males died in this group whereas 3/5 and 2/5 males died in 600 and 400 mg/kg groups. respectively.

3). The observations of the toxic effects should be reported as no. of observations/sex/dose.

4). The death rate should also be reported as no. of death/sex/dose.

5). The purity and stability of the test agent should be tested and reported.

Based upon the extracted data in Table 1. the LD_{50} for males should be approximately 500 mg/kg, and that for females should be approximately 620 mg/kg. The acute oral toxicity of 2.4-DP is category III in mice.

Although the study has many minor deficiencies. it has provided information for establishing the value of LD_{50} and toxicity category. The study is, thus, classified as Core Minimum.