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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Henry Jacoby (21)
Registration Division (TS-767)

THRU: William Burnam, Acting Chief
Toxicology Branch/HED (TS-767)

SUBJECT: Addendum to Memo of December 21, 1982: Review of Acute Studies and Subchronic Inhalation Study of Vorlex; Acc. No. 249736 CASWELL#175 & 573

Registrant: Nor-Am Agricultural Products
350 West Shuman Blvd.
Naperville, Illinois 60566

Background Information:

My memo of December 21, 1982 classified these studies as Supplementary Data primarily because these studies did not have a description of the experimental procedures employed. My memo of March 22, 1983 stated that, if the acute studies were upgraded, "Toxicology Branch will not object to the requested new use".

Recommendation:

It is recommended that studies 1-4 discussed below be upgraded to Core-Minimum. Although it is recommended that studies 5-6 below remain classified as Core Supplementary, the need for further testing should be waived and the material labeled as a Toxicity Category I eye irritant. Toxicology Branch does not object to the requested new use of Vorlex on utility poles.

Review of Data:

(Note: The results for each of these studies were presented in my memo of December 21, 1982, attached. Recently submitted information consists only of a more complete description of the study procedures; thus the results presented in my original memo remain unchanged. Presented below are the experimental procedures used in 6 of the acute studies).

1) Acute Oral Rats. Conducted by Schering AG, Berlin, Germany, April 12, 1979, Protocol No. 496/78, and submitted by Nor-Am.

Five male and five female Wistar/SPF rats per dose level were administered a 2% formulation of Vorlex technical at doses of either 0, 0.1, 0.2, 0.4, 0.6 and 0.8 g/kg by gavage after starvation for 18-20 hours.

Observation of animals occurred 3 times on day 1 and daily for the following 21 days. Body weights were recorded on days 1 and 22. Method of sacrifice on day 22 was not reported. Gross necropsies were conducted on all sacrificed animals.

2) Acute Dermal, Rabbits. Conducted by Schering AG, Berlin, Germany, May 11, 1979, Protocol 1/79 and submitted by Nor-Am.

Three male and 3 female New Zealand white rabbits per dose level were treated dermally with either 0, 0.4, 0.5, 0.6, 0.8 or 1.0 ml/kg of Vortex technical. Test material was applied to a shaven area 10 x 15 cm and kept under occlusive conditions for 24 hours.

Observations were conducted 3 times on day 1 and daily for the following 21 days. Body weights were recorded on days 1 and 22. The animals were sacrificed on day 22 (method not reported) and grossly necropsied.

3) Acute Dermal, Rats. Conducted by Schering AG, Berlin, Germany, April 11, 1979, Protocol No. 497/78 and submitted by Nor-Am.

Five male and five female Wistar/SPF rats per dose level were treated dermally with either 0, 500, 630, 750, 880, or 1000 mg/kg of Vortex technical with controls receiving 10 ml/kg of sesame oil. The test material was applied as a 10% (w/v) solution in sesame oil. The test site was a shaved area of skin 3.0 x 8.3 cm. The test material remained occluded on the skin for 24 hours after which it was removed with tap water.

Observations were conducted 3 times on the first day and daily for the remaining 21 days. Body weights were recorded on day 1 and 22. Animals were sacrificed (method not specified) on day 22 and grossly necropsied.

4) Acute Intraperitoneal, Rats. Conducted by Schering AG, Berlin, Germany, May 26, 1979, Protocol No. 94/79 and submitted by Nor-Am.

Five male and 5 female Wistar/SPF rats per dose level were dosed i.p. with 1% w/v solution of Vorlex technical in sesame oil at concentrations of 0, 0.15, 0.20, 0.25, 0.30, and 0.35 g/kg. Controls were administered 35 ml/kg of the vehicle.

Observations were conducted 3 times on the first day and daily for the remaining 27 days. Body weights were recorded on day 1 and 27. The animals were sacrificed on day 27 (method not specified) and grossly necropsied.

5) Eye Irritation, Rabbits. Conducted by Huntingdon, England, December 23, 1976 and submitted by Nor-Am. Study No. 6912/133D/76.

(The experimental procedures were described in my memo of December 21, 1982.) A letter from the testing laboratory, dated February 15, 1983, indicated that the eyes were not washed following treatment and that only two animals were used because "It is contrary to our normal procedure to continue an eye test where undue suffering is likely to ensue or to expose further animals to a known severe eye irritant."

6) Eye Irritation of Methylisothiocyanate, Rabbits. Conducted by Huntingdon Research Centre, Huntington, England, December 23, 1976 (Report No. 6913/134D/76) and submitted by Nor-Am.

(The experimental procedures were described in my memo of December 21, 1982.) A letter from the testing laboratory, dated February 15, 1983, indicated that the eyes were not washed following treatment and that only two animals were used because "It is contrary to our normal procedure to continue an eye test where undue suffering is likely to ensue or to expose further animals to a known severe eye irritant."

Gary J Burin 4/13/83

Gary J. Burin, Toxicologist
Review Section V
Toxicology Branch/HED (TS-769)

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