5-29-78 RE-1106 FR-757

Environment Canada / Gouvernement du Canada

MEMORANDUM NOTE DE SERVICE

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Captan

#16

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Dr: H. M. Cunningham

SECURITY - CLASSIFICATION - DE SÉCURITÉ	
OUR FILE - N/RÉFÉRENCE	
YOUR FILE - V/RÉFÉRENCE	
DATE	May 29, 1979

Validation of Acute Dust Inhalation Toxicity Study on Vitavax Seed Protectant with Captan (IBT N8586)

Overall Comment:

The audit and validation of this report indicate that the figures in the raw data are correctly reproduced in the final report. However, with no preliminary period and no raw data showing the time during the one-hour test period that the air samples were taken, the amount of test material in the air inhaled by the rats could vary considerably from that reported. In addition, the fact that only 0.32% of the test material was respirable means that the information obtained in this study would only be applicable for this product when dust is manufactured containing no more fine particles than used in this study. Considering these factors and the fact that the gross pathological findings do not agree with those in the final report this study cannot be validated. In addition, neither the raw data or the report indicate the percentage of Vitavax and Captan in the test material and this information must be available before validation could be considered.

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Acute Dust Inhalation Toxicity Study on Vitavax a
Seed Protectant with Captan (IBT No. N8586)

A. Audit:

1. Report No: N8586 dated July 10, 1970.

2. Date of Study: Started on 6-5-70 and terminated on 20-5-70.

3. Protocol: None available but procedure indicates that ten rats, 5 male and 5 female, weighing about 240 g were weighed and exposed for 1 hr in separate cages in a 70 L inhalation chamber constructed so that animals could be introduced after maximum concentration of test material had been reached. Test material was introduced as a powder into the top of the chamber with an air flow rate of 9.4 L/min. Average dust concentration was determined from the total weight (in mg) of test material introduced into the chamber divided by the total liters of air passed through it. The actual dust concentration in the chamber was determined by sampling the air with a glass fiber filter. Particle size was determined from an air sample. Animals were observed for 14 days and subjected to gross pathology.

4. Test Material: 1 lb. of test material, Lot 3-1621 sent to IBT on 23-4-70 and received on 4-5-70.

5. Animal Suitability: Charles River strain albino rats purchased from the Charles River Breeding Laboratories Inc. Wilmington, Mass.

6. Raw Data: Adequate except organs on which abnormalities observed and code for abbreviations used not given.

B. Validation of Evaluation:

1. Dates: Handwritten on preprinted data sheet that was unsigned indicate that study started on 6-5-70 and terminated on 20-5-70.

2. Protocol: Study was conducted much in line with the protocol given above but there is no indication in the raw data that thre was no preliminary period during which the dust concentration was raised to the maximum operating rate.

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3. Test Material: An invoice indicates that sufficient of the test material to conduct the study was received in time for it. Calculation of the weight of particles in the 1-5 micron range from the particle distribution data indicate that only 0.32 % of the weight of test material dust was of respirable size although 77 % of the particles present were in this size range. This is not mentioned in the report.

4. Personnel: Report prepared by: Donn Hathaway
Group Leader
Inhalation Toxicity

Report approved by: M. L. Keplinger, Ph.D.
Manager, Toxicology

Otis E. Fancher, Ph.D.
Scientific Director.

C. Execution of the study:

a. Body weight: Raw data are handwritten on dated but unsigned preprinted sheets and agree with the final report.

b. Inhalation Dosage: Raw data on measuring the amount of test material used, air flow and sampling of air are handwritten on dated but unsigned sheet and agree with the final report except that there was no adjustment period and weight of respirable test material was only 0.32 %. Since the "nominal dust concentration" (94 mg/L air) obtained from the total weight of dust blown into the chamber and the filter assay dust concentration (8.3 mg/L air) are over one magnitude apart it would appear that the average particle size was quite large and that over 90 % of the test material quickly settled out on the bottom of the chamber. Since the times during the hour test period that the filter samples were taken were not given in the raw data, the actual dosage could be much lower if they were taken near the end of the 1 hr period. Even assuming that the filter assay of 8.3 mg/L was correct, multiplying this by 0.32 % = 0.0266 mg/L of respirable test material would have been used.

c. Reactions and Mortality: Handwritten, dated but unsigned observations indicate that the raw data agree with the final report in showing that there were no deaths and that only a slight nasal discharge was observed for the first 30 minutes of time spent in the chamber.

d. Pathology: Raw data handwritten but unsigned indicate that 5 of the ten rats developed a condition abbreviated as "hyp" graded as either "1" or "2". The organ in which it occurred is not given and it is not mentioned in the final report. Although it probably is hyperemia of the lungs this cannot be determined from the raw data.

Overall Comments:

The audit and validation of this report indicate that the figures in the raw data are correctly reproduced in the final report. However, with no preliminary period and no raw data showing the time during the one hour test period that the air samples were taken, the amount of test material in the air inhaled by the rats could vary considerably from that reported. In addition, the fact that only 0.32 % of the test material was respirable means that the information obtained in this study would only be applicable for this product when dust is manufactured containing no more fine particles than used in this study. Considering these factors and the fact that the gross pathological findings do not agree with those in the final report this study cannot be validated..

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