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CIBA-GEIGY

July 11, 1978

gistration Division (WH-567)
ffice of Pesticide Programs
nvironmental Protection Agency
M Street, S.W.
ashington, D.C. 20460

ttention: Mr. Henry M. Jacoby
Product Manager #24

entlemen:

UBJECT: DUAL® 8E HERBICIDE - EPA FILE SYMBOL 100-LOT
ENVIRONMENTAL SAFETY REVIEWS FOR CLASSIFICATION

uring my meeting of June 23, 1978 with Mr. Henry Craven of the ish and Wildlife Branch, it was agreed that CIBA-GEIGY would address questions raised during the reviews of the Environmental afety Data and if answered satisfactorily, he could recommend avorably for general classification of Dual 8E herbicide.

he questions raised by Mr. Craven and our responses are presented below:

1. Question: In the report on an acute oral LD_{50} study with technical metolachlor in Mallard ducks (EPA Accession No. 226955), there appears to be an error in the statistically determined LD_{50} for metolachlor, based on the mortality data presented in the report.

   Response: The original report on the Acute Oral LD_{50} study issued by the Wildlife Research Division of Truslow Farms, Inc. contained an error in the statistics for the LD_{50}. This error was pointed out in a November 22, 1976 letter from Mr. Robert Fink to Dr. John Barnett (Report 1), which enclosed revisions to the report correcting this error. The copy of the report submitted to EPA apparently was the original version without the subsequent revision. The revised, final report of this study which shows the acute oral LD_{50} of technical metolachlor to be 4,640 (2,398 - 8,977) mg/kg is submitted herewith as Report 2.

2. Question: In the above acute oral LD_{50} study in Mallard ducks, group body weights on Day 0 show greater variability among the Dieldrin control and negative control groups than among the CGA-24705 treatment groups. This difference in the degree of variability raises questions on the randomization and/or the age uniformity of birds in the various treatment groups.

   Response: We have discussed this point with Mr. Robert Fink who conducted the study. Mr. Fink confirmed that all birds were 14 days of age and that they were randomly assigned to the different treatment groups as reported without respect to weight. The low variability in average body weights among the CGA-24705 treatment groups in comparison to the Dieldrin control and untreated control groups is regarded to be simply coincidental. This question does not have a bearing on the determination of the CGA-24705 LD_{50} (4,640 mg/kg), which was the primary objective of this study.

3. Question: The acute toxicity study on Rainbow trout (EPA Accession No. 094220) was judged to be invalid because the water was aerated during the study. Nevertheless, since Dual 8E is not being registered for aquatic use and since none of the other environmental safety studies would indicate restricted classification, Mr. Craven was of the opinion that he could probably classify Dual 8E without the trout study.

   Response: Pursuant to the meeting with Mr. Craven, we have received the final reports on new acute fish toxicity studies (rainbow trout and bluegill) from EG&G, Bionomics (Reports 3 and 4). We believe that these studies should suffice to resolve any questions concerning the acute fish toxicity of metolachlor for classification of Dual 8E.

On an active ingredient basis, the proposed labeling for Dual 8E on corn is identical to EPA registered labeling for Dual 6E. After Dual 8E is registered, it will eventually replace Dual 6E. From the standpoint of human safety, Dual 8E is a more desirable product because it causes less eye irritation. It is our understanding that Dual 8E can be registered under Mr. Edwin Johnson's May 12, 1977 memo after Dual 8E is classified. We believe that the above explanations and the enclosed information should suffice to answer Mr. Craven's questions and thereby allow general classification and registration of Dual 8E herbicide.

Please forward the EPA Accession Number assigned to the enclosed data. CIBA-GEIGY considers the enclosed data to be trade secret and requests that they be protected from disclosure as provided for in Section 10 of FIFRA as amended.

Please call if you or Mr. Craven have any questions.

Sincerely,

Jack A. Norton/js

Jack A. Norton, Ph.D.
Regulatory Specialist

JAN/3Ø/3-12

Enclosure

cc: Mr. R. L. Feulner

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