CASWELL FILE

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

SEP 10 1985

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANC

SUBJECT: Triazolylalanine (THS 2212); Diet Analysis for Subchronic Feeding Study in Rats

EPA Reg. #: 3125-320; Record #: 155160
Accession #: 258662
Caswell #: 862 B
Data Submitted By: Mobay Chemical Corporation
(Mobay Report No. 86476)

TO: Henry M. Jacoby
Product Manager (21)
Registration Division (TS-767)

FROM: Alan C. Katz, M.S., D.A.B.T. 9/3/85
Toxicology Branch
Hazard Evaluation Division (TS-769C)

THRU: Robert P. Zendzian, Ph.D. 9/4/85 9/10/85
Acting Head, Review Section IV

Action Requested:

Review captioned data (Mobay Report No. 86476: "Summary of Diet Analysis Results"; dated April 15, 1985). This data was not included in the original submission of data pertaining to a 90-day rat feeding study with triazolylalanine, and was requested by the Toxicology Branch (see attached memo, ACK to HMJ, 2/8/85).

Discussion:

Homogenicity results require additional clarification. The data presented were generated in association with Study Number T8015 796; however, the subchronic rat study under primary review is identified as Study No. T9015 049. In order to evaluate the relevance of these data, it must be demonstrated that the methods and materials used in both studies were identical with respect to diet preparation. Also, it is not stated whether the 3 samples tested at each of the 2 concentrations were taken from the same batch of blended feed. Further, we note that 2 values are presented for each sample tested; it is not clear whether these individual values represent determinations on "replicate" portions from each sample, or duplicate determinations on the same sample. The registrant should address the issues of sensitivity of the method used, and the reasons for any apparent intra-sample variability. Methods used in diet preparation and sampling should be more fully explained.

Conclusions:

The data presented are considered adequate to establish purity of the test substance (97.5%) as well as stability and concentration in the diet for this study. Homogenicity data could not be evaluated, and is therefore considered unacceptable. The Toxicology Branch, however, does not find this deficiency alone to be sufficient cause to consider this particular study invalid, and will complete its evaluation based on the merits of other data provided.

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