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

APR 2 1 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Submission of Additional Information for the Chemical XRD-498

CHEMICAL: 129016 XRD-498 (129016 Triazolo)

TOX. CHEM. NO.: 348B

SUBMISSION: S425838 **DP BARCODE:** D182888

FROM: SanYvette Williams, D.V.M. 3/29/93
Review Section IV, Tox. Branch II (H7509C)

TO: Steven Robbins/Joanne Miller PM 23
Registration Division

THRU: Elizabeth Doyle, Ph.D.,
Section IV, Tox. Branch II (H7509C) E. A. Doyle 4/7/93

and

Marcia van Gemert, Ph.D., Chief
Toxicology Branch II
Health Effects Division (H7509C) M van Gemert 4/19/93

Registrant: DowElanco Chemical Co.

Action Requested:

Toxicology was requested by the Registrant to review additional information submitted on the two generation rat reproduction toxicity study (MRID# 419317-10) in response to some reporting deficiencies and to advise as to its acceptability:

Response to EPA-OPP, Data Evaluation Report for XRD-498: Two-Generation Reproduction Toxicity Study in Fischer 344 Rats MRID# 424740-01

Deficiency 1: An incorrect statement was made by the author regarding data gaps that represented dead animals or missing values. The reviewer stated that only one female died.

The Registrant's agreed with this, but also listed other "data gaps" due to other reasons (i.e. feed consumption values not being recorded at different intervals due to hurricane threats and occasional occurrence of a feed jar being spilled by an animal).

This deficiency has been adequately addressed.

Deficiency 2: "Since the mode of administration of the test compound was orally via the diet, actual weekly and overall test compound intake, and statistical analysis of food consumption should be presented..."

The Registrant addressed these two issues by showing that: 1) using the procedures for test diet preparation [bw gain/day, feed consumption/day, and concentration of test material required to deliver the targeted mg/kg bw/day] would render the calculation of the actual test material intake redundant because of the precautions taken to administer the test material on a mg/kg/day basis and 2) since feed consumption is not a primary index of toxicity (but intended for use in weekly adjustment of test diet according to body weights), there is no need to test whether group differences are circumstantial or treatment-related.

This deficiency has been adequately addressed.

Deficiency 3: "Additional data that were not submitted included a protocol, results of the stability analysis of the test compound, and data on the environmental conditions."

The registrant has adequately addressed these deficiencies by 1) submitting the study protocol, 2) showing that the test material was stable in the diet for 28 days, and 3)showing that the environmental conditions were adequately maintained (temp. - 75°F and relative humidity 50 - 70%).

Conclusion(s):

This supplementary information has adequately addressed the deficiencies listed by the reviewer. Therefore, the 2-generation study (MRID# 419317-10) in conjunction with the supplement can be upgraded to core - minimum.