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

JAN 13 1993

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

SUBJECT: Submission of Three New Chemical's for Food/Feed Use: DE-498 (98% technical manufacturing use product); XRM-5019 (74.9% end-use product); and XRM-5313 (36% end-use product)

IDENTIFICATION NUMBERS: 062719-EEG DE-498; DP Code: D181971
062719-EEU XRM-5019; DP Code: D181977
062719-EEE XRM-5313; DP Code: D181983

FROM: SanYvette Williams, D.V.M. 1/12/93
Review Section IV, Tox. Branch II (H7509C)

TO: Joanne Miller, PM 23
Registration Division

THRU: Elizabeth Doyle, Ph.D. E. a Doyle 1/12/93
Section IV, Tox. Branch II (H7509C)

and

Marcia van Gemert, Ph.D., Chief 1/13/93
Toxicology Branch II
Health Effects Division (H7509C)

Registrant: DowElanco

Action Requested: The registrant, DowElanco, has requested a review of submitted studies in support of three new chemicals, 1) DE-498 (98% technical manufacturing use product); 2) XRM-5019 (74.9% end-use product); and 3) XRM-5313 (36% end-use product), for food/feed uses. The Confidential Statement of Formula, Label and Data Matrix for each was also submitted.

The following studies have been previously reviewed by Toxicology and the results are included below:

Data Considered:

Study	Results
Acute Oral	Acceptable
Acute Dermal	Acceptable
Acute Inhalation	Minimum
Primary Eye Irritation	Acceptable
Primary Dermal Irritation	Acceptable
Dermal Sensitization	Acceptable
21-Day dermal-rabbit	Guideline
90-Day feeding-mice	Guideline
90-Day feeding-dog	Supplementary
90-Day feeding-rat	Minimum
1-Year feeding-dog	Guideline
2-Year chronic/onco-mice	Minimum
2-Year chronic/onco-rat	Minimum
Developmental toxicity	
-rabbit	Guideline
-rat	Minimum
2-Generation reproduction	
-rat	Supplementary
Ames Salmonella Gene Mutation	Acceptable
Unscheduled DNA Synthesis	Acceptable
In Vitro Gene Mutation	Acceptable
In Vivo Mouse Micronucleus	Acceptable
Metabolism and Pharmacokinetics	Acceptable

Conclusions:

After review of these studies, Toxicology Branch finds that the data base is incomplete. The 2-generation reproduction study, classified supplementary, had reporting deficiencies regarding food consumption and test compound intake. Therefore, we defer accepting this data package to support registration of DE-498 (98% technical manufacturing use product), XRM-5019 (74.9% end-use product), and XRM-5313 (36% end-use product) for food/feed uses until the deficiencies have been satisfied.