MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 618-91/46

Zephr 0.15 EC

FROM: Lucy D. Markarian
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

E 1/15/91

TO: George La Rocca
Registration Division (H75-05C)

APPLICANT: Merck, Sharp & Dohme Research Laboratories
Hillsborough Road, Three Bridges
New Jersey 08887

FORMULATION FROM LABEL:

Active Ingredient(s):
Avermectin B1a mixture of avermectin containing
30% Avermectin B1a (5- deoxy avermectin A1a)
30% Avermectin B1b (5- deoxy avermectin 1b de(1- methyl propyl)lis
(l- methyl ethyl) avermectin A1a)

% by wt.
2.0%

Inert Ingredient(s): ................................................. 98.0%

Total 100.0%
Merck Sharp and Dohme Research has forwarded published articles on Acute Oral, Eye, and Dermal irritation and Acute Dermal Toxicity of [BLACKED OUT]. Included is their proposal to use one of the inert currently used in three of their formulations: Acid (EPA 618-96), Zephyr (EPA 618-97), and Agri-Mek (EPA 618-98). All three are identified in composition [BLACKED OUT].

The proposed change will replace and increase [BLACKED OUT].

The original toxicity data (EPA 618-96) were reviewed by W. Dijkstra, and carried the signal word "Caution". On 3/15/89 a new eye study was presented and again reviewed by W. Dijkstra and the eye toxicity category was changed from III to II with the resultant change in the signal word from "caution" to "warning". As it stands now, the toxicity classification is as follows:

- Acute Oral LD50: Greater than 5.0g/kg
- Acute dermal LD50: Greater than 2000 mg/kg
- Acute Inhalation: Greater than 1.062ml/kg
- Primary eye irritation: Corneal opacity slightly day 4 eye irritable moderate irritation cleared by day 7
- Primary dermal irritation: Not a sensitizer.