UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

002004

DATE: June 8, 1979

SUBJECT: Results of eye irritation studies with BAYLETON formulations as performed by EPA Pharmacology Laboratory, Beltsville, MD. Reg. No's 3125-GRO (319), -Gen (320), - GRI (318). Caswell No. 862AA.

FROM: John Doherty (6/11/79)
Toxicology Branch, (TS-769)

TO: H.A. Jacoby, Product Manager #21
RD, (TS-767)

In a previous review (see J. Doherty, memo dated Jan. 18, 1979 to E. Wilson and H. Jacoby), Toxicology Branch requested that the manufacturer of Bayleton send samples of the technical product, the 50% and 25% formulations to EPA's facilities in Beltsville for clarifying the eye irritation potential of these products.

The results of these tests, as conducted under the direction of Dr. W. Teeters, are reviewed herein as follows:

For all three products, the eyes of six albino rabbits were instilled with the sample (the amount instilled is not explicitly stated). No attempt was made to irrigate the eyes once the material was instilled.

Results		Total Draize	Toxicity Category
Product	Corneal Opacity	Score (at 72 hours)	
Technical 3125-GRO	No	0	III
50% WP 3125-GEN	Yes (mild)	10.7	II
25% WP 3125-GRI	No	2.3	III

These tests are Core-Minimum. The exact amount instilled is not stated, the eyes were not washed.

Conclusion:

The 50% and 25% formulations already have WARNING signal words. Based on the previous study with the 25% formulation (see review by J. Doherty Feb. 15, 1978) corneal opacity developed for this preparation. Therefore, no further change in the labelling for the 25% formulation (3125-GRI) or other formulations are required.

RD initial EBudd 6/8/79:lf
TOX/HED/OPP

EPA FORM 1320-6 (REV. 3-76)