UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: January 18, 1979

SUBJECT: EPA Reg #'s 3125-GRI/GRO/GEN, Bayleton, eye irritation studies and signal words for formulations. Caswell No: 862 AA

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Eye Irritation Studies

Eye irritation studies with technical Bayleton, 50% and 25% formulations were previously reviewed and classified for adequacy of data and for labelling requirements. The results were as follows: (see memo from Doherty to Wilson, Feb. 15, 1978).

	Amt. Instilled	TOX. Category	Core Classification
Technical	Not stated	?	Invalid
25%	50 mg	II	Minimum
50%	50 mg	II	Minimum

Based on these data the 25% and 50% products must bear the signal word WARNING and the precautionary statements for an eye irritation included. These products are presently labelled CAUTION.

TOXICOLOGY BRANCH has no objection to approving the 25% and 50% formulations for general non-domestic use.

However, the signal word of these products must be changed from CAUTION to WARNING. In addition the precautionary statement must read as:

WARNING: Causes eye irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. If in eyes, wash 15 min. with water. If irritation persists consult a physician.

The technical product is labelled WARNING, but the eye test was declared INVALID because it was not stated precisely how much technical BAYLETON was instilled into the eye. Since the 50% formulation (5/6 rabbits) showed a higher incidence of corneal opacity than did the 25% formulation (2/6 rabbits), it was surprising that the technical material did not also cause corneal opacity. The technical material was tested in Germany. The formulations were tested in the USA. Three years elapsed between testing the technical material and the formulation.

Examination of the confidential statements of the formulations make it unlikely that the corneal opacity produced resulted from the inerts.

Thus the eye irritation potential of the technical Bayleton is unresolved. The exact amount of material instilled and other test conditions must be verified and submitted in writing to EPA before this product can be registered.

In addition, Toxicology Branch requests that the manufacturer send 3-4 gms of Bayleton Technical, 25% and 50% formulations to EPA's toxicity testing laboratory in Beltsville for confirmation of the test results. The manufacturer must also provide the protocol for this eye test so that EPA's laboratories will be able to duplicate the prior studies.

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