UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
Pesticides Registration Division

16 AUG 1977

US Army Natick R & D Command
Attn: Mr. Morris Rogers
DRXNM-YPB
Natick, MA 01760

Gentlemen:

Subject: PARANITROPHENOL
EPA File Symbol 40510-E
Your Application for Registration of May 4, 1977

A review of this application for registration has indicated the following:

1. The summarized studies; oral LD-50 (rat); dermal ALD (rabbit); skin irritation; skin sensitization; eye irritation; cataract study; 30 day oral study; 12-week skin painting; and mutagenicity studies must be submitted for review in detail.

2. One of the wear tests, AE40-440, is unreadable because of faulty photocopy. This study must be resubmitted in legible form.

3. The skin patch and wear tests generally show that treated leather applied directly to the skin causes some irritation, whereas the wear tests were negative. An exposure even in the wear test, however, cannot be totally excluded. In light of this, subacute and long term dermal toxicity tests as well as teratology studies must be submitted or initiated before registration can be considered. Reproduction, teratology, and lifetime studies (including dermal oncogenicity) are required.

The adequacy and acceptability of the Acute Toxicological Data submitted by Monsanto, Inc. for this application for registration have not been established.

The following Fish and Wildlife Studies are required (Proposed Guidelines, p. 26854, copy attached):

1) Avian Acute Oral LD-50 for either mallard or bobwhite quail.

2) Avian Subacute LC-50 studies (8-day protocol) for mallard and bobwhite quail.

3) Fish Acute Toxicity Studies (LC-50, 96-Hour Protocol) for rainbow trout and for bluegill.

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4) Invertebrate Acute Toxicity Study (LC-50, 48 Hour Protocol) for Daphnia

A copy of a proposed label for this product, indicating use directions, should be submitted for review.

This application has been referred to the Efficacy and Ecological Effects Review Section for their review and comments. It must be understood that, on the basis of this review, additional efficacy data may have to be developed to support this application for registration.

Sincerely,

A.E. Castillo

A.E. Castillo
Product Manager (34)
Disinfectants Branch
Registration Division (WH-567)

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