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

Pesticides Registration Division

30 SEP 1977

U.S. Army Natick R & D Command
Attn: Mr. Morris Rogers
DRXNA-YPB
Natick, MA 01760

Gentlemen:

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

An efficacy review of this application for registration has indicated the following:

1. The efficacy of the product is adequately supported for a range of 0.18 to 0.7% paranitrophenol content in treated leather for the protection of finished leather against the growth of mold and mildew.

2. Although according to Military Specification MIL-L-43283A, p. 3, 3.4.2 "the leather shall contain not less than 0.13 percent nor more than 0.70 percent paranitrophenol" no directions are given as to how this material should be applied to leather.

   As a part of any application for registration, the Agency requires the applicant to submit adequate proposed use directions. In this case, these should include a specification of the paranitrophenol-containing mixture(s) which would be applied to the leather, the period of exposure required to impregnate the leather with the necessary amount of paranitrophenol, the step in the leather-processing or manufacturing operation when this treatment should be made, as well as precautionary labeling which would take into account the hazards associated with the recommended pattern(s) of use.

According to one of the submitted references (Lollar, R.M., Para-Nitrophenol as a Fungicide for Leather, The Journal of the American Leather Chemists Association, Vol. XLIX, No. 9, September 1954, p. 611): "During the latter half of 1950, it was decided that all leather procured by the Office of the Quartermaster General should contain 0.5 per cent paranitrophenol. It was estimated that this would require a minimum of 600,000 pounds of para-nitrophenol per year." On p. 616: "It is often impractical to prepare the leather both with and without para-nitrophenol. Hence, the civilian leather also must contain para-nitrophenol."

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Although this article was written in 1954, it suggests the possibility that a considerable part of the paranitrophenol production in this country is being used as a leather preservative, i.e., as a pesticide, although not registered under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for this use. There is also an indication here that the population exposure may be to civilians, as well as to military personnel, because of practices within the leather industry.

The submitted specifications (KK-L-165C, p. 13, 6.2(g); and MIL-L-43283A, p. 7, 6.2(d)) indicate that there are circumstances when paranitrophenol is not required. The following points should be addressed in this application for registration:

1. Is paranitrophenol treatment specified for all shoes (and leather products) purchased by the Army, or only for shoes which are going to be used in certain geographical areas and/or by personnel who may be transferred to these regions?

2. What is the approximate amount of paranitrophenol used annually in treatment of leather purchased by the Army? This information will assist the Agency in determining approximate individual exposure, as well as the use significance in terms of total annual paranitrophenol production.

3. What is the recommended disposal for the spent paranitrophenol-containing solution used in the leather treatment?

The toxicological data submitted by Monsanto for placement in this file were obtained from studies conducted at Younger Laboratories, St. Louis, Missouri. This is one of the laboratories whose data must be validated before they can be considered in support of an application for registration. Refer to the attached enclosure: "DATA AUDITING PROGRAM FOR CERTAIN LABORATORY STUDIES" for further information.

The chemistry requirements (Proposed Guidelines, FR 40, #123, June 25, 1975, p. 26828) indicate the types of analytical techniques and procedures required to determine the principal component in technical paranitrophenol as well as significant impurities [redacted]

Without the above data and information a review of the uses and claims proposed for this product cannot be completed. It must be understood that after these data and information are submitted and reviewed, there may be additional data and studies required, based on the expected exposure of this product to man and the environment. These additional data require-

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ments may include (but are not limited to) toxicological, efficacy, fish and wildife, chemistry, and environmental chemistry studies, as indicated on pages 28276-28277 of the Regulations (FR 40, #129, July 3, 1975).

Sincerely,

A E Castillo

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

Enclosures: