United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-97-016
January 1998

Reregistration Eligibility Decision (RED)

Paranitrophenol

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide Paranitrophenol. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions on the potential human health and environmental risks of the current product uses, and decisions and conditions under which these uses and product can be used. The RED includes the data and labeling requirements for the product reregistration decision.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." **The required response is due 90 days from the receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your product.

If you have questions on the labeling language for Paranitrophenol-containing product requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Veronica Dutch (703) 308-8585.

Sincerely yours,

Lois Rossi, Director
Special Review
and Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **APPLICATION FOR REREGISTRATION Decision--You must submit the following items for each product within ninety days of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b and c below) to the address listed in item 3.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

2. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

3. **WHERE TO SEND REREGISTRATION DECISION RESPONSES**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

REREGISTRATION ELIGIBILITY DECISION

PARANITROPHENOL

LIST B

CASE 2465

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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PARA-NITROPHENOL REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

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Ghulam Ali	Economic Analysis Branch

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
μg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

GLOSSARY OF TERMS AND ABBREVIATIONS

N/A	Not Applicable
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WP	Wettable Powder
WPS	Worker Protection Standard

ABSTRACT

The U.S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide paranitrophenol (case 2465).

Paranitrophenol, a nitrated benzene, is a nonfood use chemical that is registered for use as a fungicide for controlling fungal mold on leather and specialty industrial products used by the military. The treatment process is for protection of military leather shoes, leather combat boots and other leather items while in storage in the field, and for specified cork insulations on Air Force equipment. Paranitrophenol-treated cork is used in missile silo construction. There is a single registered paranitrophenol product, the 99.5% technical which is formulated as a flaked solid.

Paranitrophenol is acutely toxic (toxicity category II) via the oral route and is moderately toxic (toxicity category III) via the dermal route. Paranitrophenol is a corrosive eye irritant and a potential dermal irritant.

The Agency has some concerns about paranitrophenol relating to the potential for handler dermal and inhalation exposure associated with the registered uses of paranitrophenol (i.e., leather and cork treatment applied by military contractors to products used by military workers). Lacking adequate exposure and toxicity data, the Agency is unable to conduct a quantitative risk assessment. In order to assess the risk, the following data would be required to support the continued registration of paranitrophenol:

EPA Guideline	Study
81-3	Rat acute inhalation toxicity
81-5	Primary dermal irritation study in rabbit
81-6	Dermal sensitization potential study in guinea pig
83-3(b)	Rabbit developmental toxicity study
84-4	*in vivo* bone marrow cytogenetics
231	Dermal exposure
232	Inhalation exposure

Based on the Agency's contact with the sole registrant of paranitrophenol, the United States Department of the Army, regarding the data necessary to support the continued registration of paranitrophenol, the Agency received a request to cancel the registration of the product containing paranitrophenol. The cancellation will become effective on May 30, 2002.

The Agency has decided to accept the voluntary cancellation request to be effective on May 30, 2002. The Agency is basing this decision on:

1. The weight of evidence from all available toxicological data does not suggest a potent threat from dermal and inhalation exposure.

2. Exposure to paranitrophenol is believed to be very limited. It's uses are confined to leather and cork treatment applied by military contractors to few products used by military workers. The worker population exposed during treatment is likely to be small. The only large population potentially exposed is military personnel wearing treated footwear. The Agency was able to quantitatively estimate their risk and found it to be acceptably low even using the protective assumptions.

3. During the five year phase-out period, workers using and handling paranitrophenol solutions and freshly treated products are required to wear chemical resistant aprons and attached full sleeve gloves.

Revised label language as set forth in Section V of this document is required. Several of the label revisions pertain to handler safety requirements that must be established due to the acute and other adverse effects associated with paranitrophenol. Due to concerns about potentially high dermal exposures during the introduction and removal of leather or cork by hand from dip vats, and handlers participating in such hands-on operations, workers must wear chemical-resistant full-front aprons with attached full-sleeve gloves. Other required label changes address application restrictions and user safety requirements, and are found in Part V of this document.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of paranitrophenol. The document consists of six sections. Section I is the introduction. Section II describes paranitrophenol, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for paranitrophenol. Section V discusses the reregistration requirements for paranitrophenol . Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Phenol, 4-Nitrophenol
- **Chemical Name:** p-Nitrophenol
- **Chemical Family:** Nitrated benzene
- **CAS Registry Number:** 100-02-7
- **OPP Chemical Code:** 056301
- **Empirical Formula:** $C_6H_5NO_3$
- **Trade and Other Names:** PNP
- **Basic Manufacturer:** Army Nattick RD & F Center

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of paranitrophenol is in Appendix A.

For Paranitrophenol:

TYPE OF PESTICIDE:

Fungicide/Fungistat

USE SITES:

INDOOR NON-FOOD:

INDUSTRIAL PRESERVATIVE
*** Leather/Leather Products**
*** Speciality Industrial Products (cork insulation)**

TARGET PESTS: Fungi associated with leather products and cork insulation.

FORMULATION TYPES REGISTERED:

TYPE: End use product 99.5000%

FORM: CRYSTALLINE [99.5000%]

METHOD AND RATES OF APPLICATION:

Equipment - Mixer (mechanical); Not specified on label; Tank

Types of Treatment - Industrial preservative treatment

Rates of Application - 6965 ppm active ingredient by weight

Timing - During manufacture; Not specified on label

C. Data Requirements

The Agency issued a Data Call-In Notice (DCI) to the registrant of paranitrophenol February 12, 1991 under Phase IV of the reregistration program and required submission of environmental fate and toxicity data.

D. Regulatory History

The active ingredient paranitrophenol was first registered in the United States in 1963 as a fungicide. It was used at the time as a fungicidal product for preservative incorporation in leather products and hides. A second fungicidal product received registration in 1967. Both products contained a second active ingredient, salicylanilide. However, the registrations for all registered products containing salicylanilide as an active ingredient have since been canceled.

There is currently one product registered by the Agency containing paranitrophenol active ingredient. Registration for paranitrophenol was granted in 1980 for use as a fungicide for incorporation into leather for military use, at a concentration not to exceed 0.7% on a basis of dry finished leather weight. In 1983 this registration was amended to add the use of the product for incorporation into cork insulation for military use.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Identification of Active Ingredient

Paranitrophenol is a solid at room temperature. The melting point and vapor pressure of the solid is 114°C and 0.60 mm Hg at 120°C, respectively. A 30°C the vapor pressure is 3×10^{-4} mmHg.

PC Code:	056301
Chemical Formula:	$C_6H_5NO_3$
CAS Registry No.:	100-02-7

B. Human Health Assessment

1. Toxicology Assessment

Additional toxicity studies or information are needed to support the reregistration of paranitrophenol. The required studies include: rat acute inhalation toxicity (81-3); primary dermal irritation study in rabbit (81-5); dermal sensitization potential study in guinea pig (81-6); rabbit developmental toxicity study (83-3b) (exposure via dermal route is required); and in vivo bone marrow cytogenetics assay (84-4). These studies should be conducted using the technical material. In addition, an acute inhalation toxicity study in rats on the formulated end-use product at the minimum dilution specified on product labels, is required.

a. Acute Toxicity

Acute toxicity data for paranitrophenol is listed below.

Table 1. Acute Toxicity Data for Paranitrophenol (TGAI).

TEST	MRID NO.	RESULT	Toxicity Category
Oral LD_{50} in rats	42539601	**LD_{50} Males = 191 mg/kg** (95% confidence limits 131 - 303 mg/kg) **Females = 170 mg/kg** (95% confidence limits 129 - 225 mg/kg)	**II**
Dermal LD_{50} in rabbits	42539701	**LD_{50} (males) = 3.69 g/kg** (95% confidence limits 2.03 - 6.71 g/kg)[1]	**III**
Inhalation LC_{50} in rats	NA	Data gap[2]	--
Eye irritation in rabbits	42539801	**Corrosive** - persistent severe conjunctival irritation, irritation and damage to iris, corneal opacity	**I**
Dermal irritation in rabbits	NA	Data gap[3]	--
Dermal sensitization in guinea pigs	NA	Data gap[4]	--

1 Females were not evaluated in this study.

2 A 28-day inhalation toxicity study was submitted but does not satisfy this data requirement (MRID 42538701). Although no mortality or signs of toxicity were observed from exposure to 0.03 mg paranitrophenol/L; particle size was larger ($\geq$5 μm) than guideline requirements.

3 A primary dermal irritation study was submitted but was not considered acceptable (MRID 42539901). Although no dermal irritation was observed, test material was not moistened or pulverized before application.

4 A dermal sensitization potential study was submitted but was not considered acceptable (MRID 42540001). There was no evidence of sensitization; however, an insufficient number of animals were tested and the challenge dose was too low.

Clinical signs seen in the acute oral toxicity study cited above included ataxia, convulsions and diarrhea at 200 mg/kg or higher in females (signs did not show dose-response). In the acute dermal toxicity study cited above, all treated animals showed signs of dermal irritation at the application site.

Additional information on acute toxicity of paranitrophenol in the "Toxicology Profile for nitrophenols" of the Agency for Toxic Substances and Disease Registry (ATSDR; TP-91/23, 7/92) provides oral LD_{50} values consistent with the submitted study. Other reported oral LD_{50} values in albino rats are 230 mg/kg (propylene glycol vehicle; same vehicle as submitted acute oral toxicity study cited above) and 620 mg/kg (corn oil vehicle). An LD_{50} of 470 mg/kg was

determined in mice (corn oil vehicle). Reported symptoms of acute toxicity include hyperthermia, respiratory depression, central nervous system (CNS) depression and methemoglobinemia. No mortality or significant toxicity was reported in rats following inhalation exposure up to 4 mg/L paranitrophenol (dust atmosphere) for 4 hrs. Exposures to 2.1 mg/L (dust atmosphere) to rats for 2 weeks (5 days/week) also caused no mortality (clinical signs observed in this study included methemoglobinemia, slightly increased SGOT levels and corneal opacities, probably due to direct effect of dust on the eye).

b. Subchronic Toxicity

The database for subchronic toxicity (Series 82) is adequate. *Oral Study in Rats:* In a subchronic toxicity study (MRID 42788801), paranitrophenol (tech., 99.81% ai) was administered for 13 weeks to 20 Sprague-Dawley Crl:CD®BR rats/sex/dose in water by gavage (volume of 10 ml/kg) at dose levels of 0, 25, 70 or 140 mg/kg/day. At 70 mg/kg/day, 1 male and 1 female died and females showed increased incidence of urine staining between weeks 7 - 9. At 140 mg/kg/day, 14 males and 6 females died and urine staining was observed in females. Clinical signs preceding death included wheezing, dyspnea, pallor, prostration and languid behavior. Death of 1 female at 25 mg/kg/day was not considered treatment-related. There were no compound related effects on body weight, food consumption, hematology, clinical chemistry or organ weight. The LOEL is 70 mg/kg/day, based on increased incidence of acute mortality and associated clinical signs and pathology, and possibly urine staining in females. The NOEL is 25 mg/kg/day.

Dermal Study in Mice: In a subchronic dermal toxicity study (range-finding study for the NTP 18-month dermal mouse cancer bioassay, summarized in MRID 43766201), paranitrophenol (tech., 97.5% ai) at doses of 0, 21.9, 43.8, 87.5, 175 or 350 mg/kg in acetone was applied to the interscapular skin of 10 Swiss-Webster mice/sex/ dose 3 times per week for 13 weeks. At 350 mg/kg, all males and 8 females died before termination; at 175 mg/kg, 3 males and 1 female died. All deaths except 1 were attributed to treatment. Statistically significantly increased incidence of epidermal inflammation (marked to severe), hyperplasia and hyperkeratosis were observed in both sexes at 175 and 350 mg/kg and dermal necrosis was observed in 2-3 males. Based on mortality and dermal irritation, a LOEL of 175 mg/kg is identified for this study. The NOEL is 87.5 mg/kg. However, the study report did not indicate whether other parameters such as body weight, clinical chemistry/hematology or clinical signs other than dermal lesions were evaluated.

c. Chronic toxicity

A chronic toxicity study which was not acceptable was submitted by the registrant. The 18-month mouse dermal carcinogenicity study provided some information on chronic toxicity and did not identify any treatment-related effects on clinical signs, body weight or gross/microscopic pathology at doses up to and including 160 mg/kg applied 3X/week. However, chronic toxicity could not be conclusively evaluated due to lack of evaluation of hematology, clinical chemistry/urinalysis parameters and microscopic examination of some

tissues.

d. Carcinogenicity

In a dermal carcinogenicity study (MRID 43766201), paranitrophenol (tech., 97.5% a.i.) was administered to 60 Swiss-Webster mice/sex/dose 3 times/week (Monday, Wednesday, Friday) at levels of 0, 40, 80 or 160 mg/kg in 100 μl acetone to the shaved interscapular skin, for 18 months (equivalent to amortized daily doses of 0, 17.1, 34.3 or 68.6 mg/kg/day). Clinical signs, body weight and gross/microscopic pathology were evaluated.

No treatment-related systemic toxicity was observed. Animals were sacrificed at 18 months due to reduced survival from amyloidosis, observed at high incidence in all groups. The NOEL for systemic toxicity is $\geq$160 mg/kg and the LOEL is >160 mg/kg.

At the doses tested, there was no treatment-related increase in tumor incidence compared to controls. Dosing was considered adequate based on a mouse 13 week dermal toxicity study in which excessive local dermal irritation at $\geq$175 mg/kg and mortality at 350 mg/kg were observed.

e. Developmental Toxicity

A dermal developmental toxicity study in the rabbit (83-3b) is required to support the reregistration of paranitrophenol. Previously, the Agency indicated that oral administration would also be acceptable for this study (RfD/Peer Review meeting of 3/21/96). However, it is requested that the study be conducted using dermal exposure because it is more appropriate. Evaluation of dermal developmental toxicity studies for other chemicals submitted to the Agency indicates that well-designed studies have been successful and able to minimize local dermal irritation (e.g., by rotating the application site).

Although there are study deficiencies, a new rat developmental toxicity study is <u>not</u> required. In the developmental toxicity study which was submitted, (MRID 42788601), paranitrophenol (tech., 99.1% a.i.) was administered to 20 pre-mated female Sprague-Dawley rats/dose in propylene glycol, by gavage at dose levels of 0, 1.4, 13.8 or 27.6 mg/kg/day from days 6 through 16 of gestation. In addition a positive control group (aspirin, 250 mg/kg/day) was included. At 27.6 mg/kg/day, decreased maternal body weight and weight gain (-12%/-45%) were observed during the dosing period. No treatment-related effects on mortality, clinical signs, food consumption or cesarean parameters were reported. Food consumption was not measured. The maternal LOEL is 27.6 mg/kg/day, based on decreased body weight/body weight gain. The maternal NOEL is 13.8 mg/kg/day.

No treatment-related developmental toxicity was observed. However, the small number of litters (10) available for examination at high dose and lack of some experimental details compromised interpretation of the results. The developmental NOEL is tentatively 27.6

mg/kg/day. A developmental LOEL was not established. The developmental toxicity study in the rat is classified as supplementary (not upgradable).

f. Reproductive Toxicity

The database for reproductive toxicity is considered to be adequate. Although there are study deficiencies, a new rat two-generation reproductive toxicity study is not required. The submitted data are considered acceptable for regulatory purposes because no evidence of potential reproductive toxicity was observed. New studies are not expected to add significant information for risk assessment purposes.

In a two-generation reproduction toxicity study (MRIDs 00146455 and 40529701), paranitrophenol (tech., 99.1% a.i.) was administered dermally in ethanol vehicle to 12 male and 24 female Crl:COBS-CD(SD) rats/dose group at doses of 0 (saline vehicle), 0 (ethanol vehicle), 50, 100 or 250 mg/kg/day (5 days/week application for about 23 - 24 weeks to the F0 adults and about 36 weeks to F1 adults). Each parental generation was bred once.

There were no indications of maternal systemic toxicity at any dose tested. However, dermal irritation at the site of treatment was observed in all treated groups (increased incidence of eschar formation, ballooning degeneration, chronic inflammation, acanthosis and/or sebaceous hypertrophy were observed microscopically). The LOEL for local dermal irritation is $\leq$50 mg/kg/day. A NOEL for local dermal irritation was not determined. The NOEL for maternal systemic toxicity is tentatively $\geq$250 mg/kg/day. A LOEL for maternal systemic toxicity was not determined.

No reproductive toxicity was observed at any dose based on the parameters evaluated. However, the conclusions regarding reproductive toxicity are considered tentative due to several study deficiencies (low pregnancy rate, resulting in low numbers of litters for evaluation in most test groups; no analysis of dosing solutions provided; errors in study reporting and data presentation). Although the reproductive toxicity NOEL is tentatively $\geq$250 mg/kg/day, and a reproductive toxicity LOEL was not determined, the study is considered adequate because there were no indications of reproductive toxicity at any dose tested in either the F1 or F2 matings.

g. Mutagenicity

The database for mutagenicity is not complete. Since an in vivo cytogenetic assay has not been submitted, it is not known whether the test material can express genotoxic activity in the whole animal. Without this information, the genetic toxicology profile for paranitrophenol is considered incomplete. It is, therefore, required that paranitrophenol be evaluated in an in vivo bone marrow cytogenetic assay which is required to satisfy the NEW mutagenicity initial testing battery guidelines.

(1) In a Salmonella typhimurium reverse gene mutation assay (MRID 42174801), strains

TA1535, TA1537, TA1538, TA98 and TA100 were exposed for 72 hours to paranitrophenol (technical, 99.7% a.i.) at concentrations of 0.01, 0.05, 0.10, 0.50 or 1.00 mg/plate in the presence or absence of S9 metabolic activation. In strain TA1535 a weakly increased frequency in revertants was observed (up to 2.7-fold above vehicle controls) at 0.5, 5.0 and 10.0 mg/plate in the presence of metabolic activation and in the absence of significant cytotoxicity.

(2) In an in vitro mammalian gene mutation assay (MRID 42271001), mouse L5178Y lymphoma TK+/- cells were exposed for 4 hours to 0, 32, 42, 56, 75, 100, 133, 178, 237, 316 or 422 μg paranitrophenol (tech., 99.7% a.i.)/ml culture media in the absence of S9 and 0, 18, 24, 32, 42, 56, 75, 100, 133, 178 or 237 μg/ml in the presence of S9. No evidence of an increased forward mutation rate at the thymidine kinase locus was observed under the conditions of these assays, including doses producing cytotoxicity ($\geq$100μg/ml).

(3) In an in vitro chromosomal aberrations assay (MRID 42270901), Chinese hamster ovary (CHO) cells were exposed to 0, 75, 100, 250, 500 or 750 μg paranitrophenol (tech., 99.7% ai)/ml culture media for 22 hours (absence of S9) or 4 hours (presence of S9). At doses >250 μg/ml and in the apparent absence of significant cytotoxicity, increased incidence of chromosomal aberrations was observed in the absence, but not presence, of S9 (lower doses not tested for mutagenicity).

In addition to the submitted studies described above, the following mutagenicity studies, conducted as part of the National Toxicology Program (NTP) 18-month mouse dermal cancer bioassay of paranitrophenol (MRID 43766201), were considered in assessing the genotoxicity of paranitrophenol:

(4) Salmonella typhimurium reverse gene mutation preincubation assay. Paranitrophenol (10-1000 µg/plate) was assayed in the absence and presence of 10% rat and hamster S9. The test was negative in all strains up to the HTD in two independent trials.

(5) Sex-linked recessive lethal assay in Drosophila melanogaster. Paranitrophenol was found to be negative when administered in feed up to levels ($\geq$6000 ppm) that caused $\approx$50% mortality but no sterility and negative by injection up to doses ($\geq$1000 ppm) that caused $\approx$40% mortality and $\approx$12% sterility.

(6) In vitro cytogenetics in Chinese hamster ovary (CHO) cells--structural chromosomal aberrations/sister chromatid exchange (SCE). Paranitrophenol was found to be negative for structural chromosome damage up to severely cytotoxic concentrations ($\geq$750 µg/ml-S9) and negative for SCE induction up to doses that cause severe cell cycle delay (25 µg/ml -S9; 1700 µg/ml+S9). However, reproducible, dose-related and significant increases in cells with structural chromosomal aberrations were seen at levels (1500 and 1700 µg/ml +S9) that induced severe cell cycle delay.

Additional information of mutagenicity and conclusions on mutagenicity of paranitrophenol:

Paranitrophenol has been tested extensively in bacterial mutagenicity assays; the results are summarized in NTP Technical Report (Series No. 417; NIH Publication No. 93-3148, 4/93) as well as in the Agency for Toxic Substances and Disease Registry (ATSDR) "Toxicology Profile for nitrophenols" (TP-91/23, 7/92). Overall the data presented in both documents indicate that while the aromatic nitro group on paranitrophenol is a structural alert for DNA reactivity, the test substance is not a mutagen for bacteria. In light of the sizable body of evidence suggesting that paranitrophenol is not a mutagen for microbial systems, the unconfirmed positive result in the S. typhimurium assay listed above (MRID 42174801) appears to be an anomalous finding. Similarly, neither the ortho-isomer nor the metabolite, para-aminophenol are microbial mutagens. Paranitrophenol was also not mutagenic in mouse lymphoma cells or active in microbial or mammalian cell DNA repair assays.

There is also a lack of agreement between the submitted (MRID 42270901) and the NTP-sponsored in vitro chromosome aberration assays. Although both studies showed evidence of clastogenicity, the response was only seen in the absence of exogenous metabolic activation in MRID 42270901 but only in the presence of S9-activation in the NTP-sponsored study. Repeating the assay would likely resolve this inconsistency, however, the available data are considered sufficient to conclude that paranitrophenol is an in vitro clastogen for mammalian cells.

h. Metabolism

The database for metabolism is considered adequate and no additional metabolism studies on paranitrophenol are required, despite study deficiencies in the submitted dermal penetration/metabolism study. Additional information on metabolism and identification of metabolites contained in the NTP and ATSDR reports, together with the submitted metabolism study, allow adequate characterization of the metabolism of paranitrophenol. A new study would not be expected to provide significant additional useful information for risk assessment purposes. The dermal absorption values in the study below are not considered reliable for risk assessment purposes, but new data were not required since dermal toxicity studies were available for characterization of toxicity from dermal exposure.

(1) In a dermal penetration/metabolism study (MRID 42539501), single doses of ^{14}C-paranitrophenol (tech., radiochemical purity 98.5%, Sp. Act. 3.9 mci/mmol) were administered to two groups of 3 male New Zealand white rabbits (1) dermally at 40.1 μg/cm^2 on 8.9 cm^2 of skin in ethanol (357 μg/animal) or (2) intravenously at 357 μg/animal in saline infusion; and to two groups of 3 male beagle dogs (1) dermally at 40.1 μg/cm^2 on 17.8 cm^2 skin in ethanol (714 μg/animal) or (2) intravenously at 714 μg/animal. Blood was collected from animals given intravenous doses at 9 intervals up to 24 hours post-dosing to evaluate plasma clearance and half life. Urine and feces were collected at 24 hrs and daily for 7 days post-dosing. Tissues were evaluated at sacrifice (day 7) for radioactivity.

Thirty-five percent of the administered dose in rabbits and 11% in dogs was estimated to

be absorbed. Paranitrophenol was rapidly cleared from the plasma following IV injection (half life estimated at 15 min). The majority of absorbed radioactivity was excreted in the urine within 1 day (IV) to 2-3 days (dermal) and no detectable radioactivity was identified in tissues except for the skin application site. Metabolites were not characterized.

The dermal penetration/metabolism study is unacceptable due to several study deficiencies including small number of animals tested, large amount of applied dose retained in the patch covering application site and lack of identification and quantitation of metabolites.

(2) Additional information on the metabolism of paranitrophenol was summarized in the literature review of the NTP mouse dermal cancer bioassay and in Chapter 2 (Health Effects) of the "Toxicological Profile for nitrophenols" prepared by the Agency for Toxic Substances and Disease Registry (ATSDR). Paranitrophenol is rapidly metabolized in the liver, primarily into conjugated glucuronide and sulfate esters; little unchanged parent compound is excreted. Small amounts of parent compound may also be reduced to 4-aminophenol or hydroxylated to 4-nitrocatechol. As seen in the submitted study, metabolites are excreted primarily in urine and to a very small extent in feces. Conjugation mechanisms are reportedly similar in male and female rats.

i. Neurotoxicity

Neurotoxicity study data are not required.

j. Other Toxicological Considerations

Methemoglobinemia is an established systemic toxic effect of nitrophenols. Animal studies and reports of human poisonings summarized briefly in the NTP and ATSDR documents indicate that paranitrophenol can induce methemoglobinemia. Reports of toxicity in humans following accidental ingestion include respiratory depression with cyanosis, along with headaches, drowsiness and nausea. Rats given inhalation exposures to paranitrophenol sodium salts for 2 weeks developed methemoglobinemia at 0.112 mg/L or higher and showed at least partial recovery 2 weeks after termination of exposures. In the rat subchronic gavage study (MRID 42788801), data on methemoglobinemia are not available. Although methemoglobin levels were measured at week 7, the results were not considered reliable due to unusually high control values (and no increases in treated groups were observed).

Although methemoglobinemia was observed in the inhalation studies, no clinical indications of methemoglobinemia were observed in the rat subchronic gavage study (e.g., cyanosis) at lethal dose levels or in dermal studies in mouse and rat at dose levels causing significant dermal irritation (rats and mice) or lethality (mice). The available toxicity data is therefore considered adequate for assessment of systemic toxicity from dermal exposure to paranitrophenol, despite the lack of methemoglobin data via the oral or dermal route.

2. Toxicological Endpoints of Concern Identified for Use in Risk Assessment

a. Reference Dose (RfD)

A Reference Dose has not been established for paranitrophenol because it is registered for non-food use applications only.

b. Carcinogenic Classification

The Health Effects Division RfD/Peer Review Committee evaluated paranitrophenol on March 21, 1996 and determined that it should be classified as Group D (inadequate information to determine cancer classification). There was no evidence of carcinogenicity in the National Toxicology Program (NTP) mouse dermal carcinogenicity study; however, a cancer study in a second species is not available. A second species study is not required at this time.

c. Other Toxicological Endpoints

The Health Effects Division Toxicology Endpoint Selection Committee considered the toxicity data available for this chemical at a meeting held on March 26, 1996 (report date 4/10/96). Based on a review of the toxicology database for paranitrophenol, toxicology endpoints and dose levels of concern have been identified for use in occupational and residential risk characterization; they are listed in Table 2.

TABLE 2. Summary of Toxicological Endpoints for Paranitrophenol.

EXPOSURE DURATION	EXPOSURE ROUTE	NOEL and ENDPOINT
Acute Dietary	ORAL	This risk assessment is not required since PNP has no food uses.
Short-Term (1 to 7 days) Occupational/Residential	DERMAL	This risk assessment is not required since no overt systemic toxicity was observed in the available studies within 7 days of exposure.
Intermediate-Term (1 week to several months) Occupational/Residential	DERMAL	NOEL: 87.5 mg/kg/day based on mortality at 175 mg/kg/day from a dermal toxicity study in mice.
All Duration Periods Short/Intermediate/Chronic Occupational/Residential	INHALATION	This risk assessment cannot be completed at this time due to lack of toxicity data. This will be further evaluated for potential inhalation risk concerns upon receipt and evaluation of the required inhalation toxicity data.
Chronic Exposure Occupational	DERMAL	NOEL: 87.5 mg/kg/day based on mortality at 175 mg/kg/day from a dermal toxicity study in mice.

Detailed Discussion of Short- and Intermediate-Term Endpoints

Dermal Absorption: A dermal absorption factor is not applicable since a subchronic dermal toxicity study was used as the basis for risk assessments of intermediate- and long-term occupational exposures.

Inhalation Occupational Exposure (all durations): This risk assessment cannot be completed at this time due to lack of toxicity and exposure data.

Short-Term Occupational Dermal Exposure (1 to 7 days): No acute toxic effects were seen either in a 13-week dermal toxicity study in mice, in a dermal two-generation reproduction study in rats (doses of 8, 50, 100 or 250 mg/kg/day for several months) or in a 90-day study in rats given 0, 25, 70 or 140 mg/kg/day by gavage; the LOEL was 70 mg/kg/day based on mortality and associated clinical signs and pathology, which did not occur until week 7. This risk assessment is not required.

Intermediate-Term Occupational Dermal Exposure (1 week to several months):

The NOEL is 87.5 mg/kg/day based on mortality at 175 mg/kg/day in the previously described subchronic dermal toxicity range-finding study in Swiss-Webster mice.

Comparison of oral and dermal LD_{50} values for paranitrophenol suggest that toxicity from dermal exposure is significantly lower than by the oral route. Use of available oral toxicity studies was considered inappropriate for dermal exposure risk assessment since dermal toxicity studies were available. The dermal studies did not thoroughly evaluate some parameters, but no overt toxicity was observed in the 90-day gavage study until immediately prior to death. Although a NOEL of 160 mg/kg for systemic toxicity was observed in the 18-month mouse dermal carcinogenicity study, this value was not used for risk assessment since mortality was observed in the 13-week study at 175 mg/kg. The dose of 87.5 mg/kg/day was not amortized for 3x/week application because the endpoint was considered adequately conservative, based on comparisons with NOELs from the oral toxicity studies, and because the applied doses were not later washed off.

Chronic Occupational Dermal Exposure: The NOEL for chronic dermal exposure is 87.5 mg/kg/day based on mortality at 175 mg/kg/day. See details above under intermediate-term exposure. A chronic dermal risk assessment is required.

d. Potential Risks to Infants and Children

Paranitrophenol is not registered for food uses nor is it available for use by homeowners in the residential setting. However, personnel in the military and in boot manufacturing settings could be exposed to paranitrophenol-treated leather. EPA has evaluated developmental and reproduction studies for purposes of assessing the pre- and post-natal toxicity of paranitrophenol. Neither the developmental or the reproduction study indicate pre-natal effects. This conclusion would need to be confirmed by the results of a new rabbit developmental study.

3. Dietary Exposure and Risk Assessment\Characterization

a. Dietary

There are currently no registered food-uses of paranitrophenol; therefore, a dietary exposure and risk assessment/characterization is not required.

4. Occupational Exposure and Risk Assessment/Characterization

a. Occupational Exposure

An occupational exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

Summary of Use Patterns and Formulations

Paranitrophenol is a non-food use chemical that is registered for use as a

fungicide/biocide. Paranitrophenol is incorporated into leather or cork insulation for military use. Paranitrophenol may be added to 1) a running drum or mixer during or immediately after the re-tanning, coloring, and fat liquoring operation; 2) the soaking tanks containing cut insoles during the chrome re-tanning of vegetable tanned insoles; 3) a butyl impregnating solution which is used to treat vegetable tanned cut outsoles. Paranitrophenol treated leather is then used in the manufacture of boots and shoes used by military personnel. Paranitrophenol-treated cork is used in missile silo construction. There is a single registered paranitrophenol product, the 99.5% technical which is formulated as a flaked solid.

All products containing paranitrophenol are intended for occupational use when handled directly; currently there are no uses of paranitrophenol intended for homeowner use.

The following table summarizes the occupational handler and post-application exposure scenarios.

TYPE OF EXPOSURE		OCCUPATIONAL SETTINGS -- Examples
Handler Exposure	Primary	Adding paranitrophenol to a vat solution to preserve or rehydrate hides/cut insoles or outsoles/cork; handling wet hides/soles/cork to which paranitrophenol has been added
	Secondary	Handling dry hides/cut insoles or outsoles/cork to which paranitrophenol has been added
Post-Application Exposure	Primary	Working near a vat where paranitrophenol was added
	Secondary	Wearing treated military boots and shoes

Handler Exposures & Assumptions

The Agency establishes handler safety requirements when risk assessments or general concerns suggest such requirements are appropriate. The Agency is developing standardized requirements for occupational handlers of industrial biocides, based on the acute toxicity characteristics of each end-use product. As described below, several exposure scenarios of concern are identified. The Agency is requesting additional exposure information as confirmatory data to validate these standardized requirements.

EPA has determined that there is a potential for dermal and inhalation exposures to handlers during usual use-patterns associated with paranitrophenol in commercial/industrial settings. The Agency has identified two levels of handler exposures:

- primary handlers -- persons handling aqueous solutions containing paranitrophenol as an active ingredient.

- secondary handlers -- persons handling products, such as leather products and cork insulation, to which paranitrophenol has been added.

At this time, EPA lacks information about probable dermal and inhalation exposures to primary handlers (mixers/loaders and applicators) engaged in treating leather or cork with paranitrophenol. Specifically, the Agency has insufficient information about:

(1) the amount of paranitrophenol likely to be handled in a day;

(2) how frequently (daily, weekly, monthly) paranitrophenol is likely to be handled in the occupational setting;

(3) what methods (open-pouring, meter-pump, etc.) are likely to be used to introduce the paranitrophenol into the processing water; and

(4) what methods (hand, machine, etc.) are likely to be used to remove the leather or cork from the processing water.

Therefore, at this time, EPA is unable to determine a reasonable worst-case scenario for primary handlers engaged in treating leather and cork with paranitrophenol.

EPA, lacks information about probable dermal and inhalation exposures to secondary handlers engaged in handling products, such as leather products and cork insulation, to which paranitrophenol has been added. Specifically, the Agency has insufficient information about:

(1) the amount of paranitrophenol-treated leather or cork likely to be handled in a day;

(2) how frequently (daily, weekly, monthly) paranitrophenol-treated leather or cork is likely to be handled in the occupational setting;

(3) what methods are likely to be used in handling the treated leather or cork (frequent hand contact, mostly mechanized, etc.); and

(4) how soon following treatment with paranitrophenol will workers be handling the treated leather or cork while still wet.

Therefore, at this time, EPA is unable to determine a reasonable worst-case scenario for secondary handlers engaged in processing or handling treating leather and cork. However, EPA does believe, based on the limited use information available, that dermal and inhalation exposures to secondary handlers handling dry hides/cork/insoles or outsoles would be much less than handling wet hides/cork/insoles or outsoles. EPA believes that inhalation and ocular exposures for secondary handlers (handling dry materials) are minimal.

Post-Application Exposures & Assumptions

As stated in the handler exposures and assumptions section, the Agency established handler safety requirements when risk assessments or general concerns suggest such requirements are appropriate. The Agency is developing standardized requirements for occupational handlers of industrial biocides, based on the acute toxicity characteristics of each end-use product. As described below several exposure scenarios of concern are identified. The Agency is requesting additional exposure information as confirmatory data to validate these standardized requirements.

EPA has determined that there are potential intermediate and chronic primary post-application dermal and inhalation occupational exposures to persons in and near treatment sites during use of paranitrophenol end-use products in occupational (commercial and industrial) settings. However, as explained above under "Handler Exposures & Assumptions," the Agency lacks information about probable exposures to persons in or near treatment sites during the use of paranitrophenol to treat leather or cork products. Therefore at this time, the Agency is unable to determine a reasonable worst-case scenario for primary post-application exposures.

EPA also has determined that there are potential intermediate-term and chronic secondary post-application dermal exposures to military personnel from wearing the treated leather products. Based on the use information available, a plausible worst-case post-application secondary exposure scenario would entail the wearing of treated military footwear. EPA believes that potential inhalation and ocular secondary post-application exposure (wearing treated footwear) is not significant.

b. Occupational Risk Assessment

Risk from Handler Exposures

Dermal Risk Concerns

Based on the available toxicity data and exposure scenarios for paranitrophenol, EPA has determined that a quantitative risk assessment for primary and secondary handlers is appropriate for intermediate- and chronic-term dermal exposures. However, at this time, EPA is unable to perform a quantitative risk assessment for dermal exposures to primary and secondary handlers due to the lack of information about: 1) the probable exposures to primary handlers engaged in treating leather and cork with paranitrophenol; and 2) the probable exposures to primary handlers engaged in processing or handling treated leather and cork while it is still wet. EPA does believe dermal exposure to secondary handlers handling dry hides would be much less than handling wet hides. Exposure data for primary handlers are required.

Inhalation Risk Concerns

At this time, EPA has no data upon which to conduct a quantitative exposure or risk

assessment for primary and secondary handler inhalation concerns. At the present time, a risk assessment for inhalation exposure cannot be completed due to lack of adequate toxicity and exposure data. Acute inhalation toxicity data are required. In addition, the Agency requests information about the vapor pressure and the acute inhalation toxicity of paranitrophenol after being introduced to aqueous solution. The need for inhalation exposure data will be further evaluated upon receipt and evaluation of the required inhalation toxicity data.

Additional Dermal and Ocular Risk Concerns: EPA is also concerned about potential dermal and ocular exposures to primary handlers from paranitrophenol, since it is classified as toxicity category I for eye irritation potential and there is a data gap for skin irritation potential. The Agency believes that risk reduction measures may be appropriate for persons who are dermally or ocularly exposed to paranitrophenol. Such persons should wear personal protective equipment (such as chemical-resistant gloves, a chemical-resistant apron, and protective eyewear) in addition to the basic attire of long-sleeve shirt, long pants, shoes, and socks (refer to Section V for details). Depending on the probable dermal and ocular exposure, the Agency may impose engineering controls, such as meter pumps, instead of or in addition to PPE. However, such a decision cannot be made until the Agency receives further information about primary and secondary handler exposures to paranitrophenol in the commercial/industrial setting.

Risk From Post-Application Exposures

Primary Post-application Dermal Risk Concerns: At this time, EPA is unable to perform a quantitative risk assessment for primary post-application dermal exposures due to the lack of information about probable exposures to persons in commercial/industrial sites during the use of paranitrophenol to treat leather or cork products. However, the Agency believes that dermal exposures incurred during primary handler application are likely to be much higher than dermal exposures incurred during primary post-application.

Primary Post-application Inhalation Risk Concerns: EPA is unable to perform a quantitative risk assessment for primary post-application inhalation exposures due to the lack of information about paranitrophenol's inhalation toxicity and about probable inhalation exposures to persons in commercial/industrial sites during the use of paranitrophenol to treat leather or cork products. At this time, primary post-application inhalation risk concerns are considered equivalent to primary handler risk concerns which will be assessed upon receipt and evaluation of the required acute toxicity data. The need for primary post-application inhalation exposure data will be further evaluated upon receipt and evaluation of the required inhalation toxicity data.

Secondary Post-application Dermal Risk Concerns: In assessing the potential risk from secondary dermal exposures to military personnel from wearing treated leather products, EPA considered information provided in a leather leaching/efficacy study (MRID 41896801). The data from this study were found to be insufficient, but have been utilized for worst case exposure assumptions. The study indicated that 80% ai PNP leached out of treated leather after 24 hours of soaking in a tank of water where the water was exchanged five times per hour. A more

realistic, but still conservative percentage of leaching would be 10% ai PNP available in the first 24 hour period. Taking into consideration this worst case exposure estimate, the unique route of exposure (total contact skin area of feet only) and the permeability coefficient for paranitrophenol adjusted for factors of skin thickness, pH, and temperature, the total dermal absorption exposure for the average 60 or 70 kg military worker is 3-fold less than the level considered to be a potential risk concern.

Secondary Post-application Inhalation Risk Concerns: At this time, EPA does not believe that possible risks from **inhalation** exposures to paranitrophenol would be of concern for secondary post-application exposures (military personnel wearing treated leather items, such as boots), since inhalation exposures in these situations are likely to be minimal.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of paranitrophenol to birds. The preferred test species is either the mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of this test are tabulated below.

Table 4. Avian Acute Oral Toxicity

Species	% ai	LD50 in mg/kg (C.I.)	Toxicity Category	MRID No. Author/Year	Study Classification[1]
Northern bobwhite quail *(Colinus virginianus)*	?	577 (464-719)	Slightly toxic	Unknown Beavers, 1979	Core

[1] Core (study satisfies guideline). Supplemental (study is scientifically sound, but does not satisfy guideline)

Since the LD_{50} falls in the range of 501-2000 mg/kg, paranitrophenol is slightly toxic to avian species on an acute oral basis. The guideline (71-1) is fulfilled.

Two subacute dietary studies using the TGAI are required to establish the toxicity of 4-nitrophenol to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

Table 5. Avian Subacute Dietary Toxicity

Species	% ai	5-Day LC50 (ppm)[1]	Toxicity Category	MRID No. Author/Year	Study Classification
Northern bobwhite quail *(Colinus virginianus)*	?	>5620	Practically nontoxic	31682 Beavers, 1979	Core
Mallard duck *(Anas platyrhynchos)*	?	>5260	Practically nontoxic	31683 Beavers, 1979	Core

[1] Test organisms observed an additional three days while on untreated feed.

Since the LC_{50} is greater than 5260 ppm, paranitrophenol is practically nontoxic toxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled (MRID 31682 and 31683).

Birds, Acute and Subacute

Birds, Chronic

Avian reproduction studies using the TGAI are not required for paranitrophenol because birds are not expected to be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season, and the pesticide is not expected to be stable in the environment to the extent that potentially toxic amounts may persist in animal feed.

Mammals

Acute laboratory mammalian studies (submitted to the Agency's Health Effects Division, MRID 42539601) found an LD_{50} of 191 (131-303) mg/kg for male rats and an LD_{50} of 170 (129-225) for female rats. Therefore, paranitrophenol is characterized as being moderately toxic to mammals on an acute basis.

b. Toxicity to Freshwater Aquatic Animals

Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of paranitrophenol to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these tests are tabulated below.

Table 6. Freshwater Fish Acute Toxicity

Species/ (Flow-through or Static)	% ai	96-hour LC50 (ppm) (measured/nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Warm water fish Bluegill sunfish *(Lepomis macrochirus)* static	99.1	5.9 (Adjusted Nominal)	Moderately to slightly toxic	94659 Wyatt, 1979	Core
	99.7	19.7(19-27) (Adjusted Nominal)		42382601 Bowman, 1981	Core
Cold water fish Rainbow trout *(Oncorhynchus mykiss)* static	99.1	4.0 (Adjusted Nominal)	Moderately to slightly toxic	94659 Wyatt, 1979	Core
	99.7	11.6 (9-16) (Adjusted Nominal)		42382601 Bowman, 1981	Core
Fathead minnow (*Pimephales promelas*)	98	53.4 (50-55) 36.7 (34-40), & 33.3 (30-37) (Adjusted Nominal)	Slightly toxic	4403601 Geiger, 1985	Supplemental

[1] Supplemental (study is scientifically sound, but does not satisfy guideline)

All of the first three studies reviewed above were performed in 1977 to 1980 and do not have measured concentrations. The minnow study (1985) measured the concentration at 24, 48, and 72 hours (but not at 96 hours). The Agency used the measured concentrations from this study to calculate a 96-hour degradation constant and applied it to the other aquatic studies. Its use did not change the results substantially. Toxicity was, therefore, characterized with nominal values. New studies with measured endpoints will not be required.

Since the LC_{50} falls in the range of 10-100 ppm, paranitrophenol is slightly toxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled (MRIDs 94659, 4403601 and 42382501).

Freshwater Fish, Chronic

A freshwater fish early life-stage test using the TGAI was not required for paranitrophenol.

Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of paranitrophenol to aquatic invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Table 7. Freshwater Invertebrate Toxicity

Species/(Static or Flow-through)	% ai	48-hour LC50/ EC50 (ppm) (measured/nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna*)	99.1	5, 19, and 15 (Adjusted Nominal)	Moderately toxic	94659 Wyatt, 1979	Core
Ostracod *(Cyprinotus incongruens)*	99.1	28 and 25 (Adjusted Nominal)	Slightly toxic	94659 Wyatt, 1979	Core
Waterflea (*Daphnia magna*)	99.5	34 (17-53) NOEC 17 (Adjusted Nominal)	Slightly toxic	42382501 Bowman, 1981	Core

Since the LC_{50}/EC_{50} falls in the range of 10-100 ppm, paranitrophenol is slightly toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRIDs 94659 and 42382501).

Freshwater Invertebrate, Chronic

A freshwater aquatic invertebrate life-cycle test using the TGAI was not required for paranitrophenol.

2. Environmental Fate

a. Environmental Fate Assessment

Since paranitrophenol has only been registered for indoor uses, there are limited environmental fate data available. No guideline environmental fate studies are available. However, based on available literature data (for which the study methodology has not been evaluated), the major route of dissipation appears to be microbial mediated processes (literature reported half-life = 16 days for aerobic soil metabolism). Under anaerobic conditions, paranitrophenol appears to undergo nitroreduction (no half-life reported). In addition, when exposed to sunlight or an artificial light source, paranitrophenol appears to degrade (no half-life reported). However, the sterility of the treated river water was not reported in the photolysis study.

There are no mobility data available except for a Koc of 214. Paranitrophenol has been detected in ground water monitoring wells (EPA Pesticides in Ground Water Database, 1971-1991). In addition, based on the reported vapor pressure (1×10^{-3} mm Hg at 25°C), the log K_{ow} (1.91), and Henry's Law Constant (3.0×10^{-5} atm^{-m3}/mol @ 20°C), 4-nitrophenol appears to have low volatility and is not expected to accumulate in fish.

There is limited data on the persistence and mobility of the paranitrophenol metabolites. However, the nitroreduction compound produced under anaerobic conditions was identified as p-aminophenol. The degradates identified in the photodegradation studies were hydroquinone,

4-nitrocatechol, and 4-aminophenol. Quantitation data for the degradates were not furnished. Therefore, it is difficult to do any quantitative or qualitative assessment of paranitrophenol residues.

Again it should be noted that this environmental fate assessment is tentative. The data are from sources that have not been internally reviewed by EPA. In addition, except for hydrolysis data no guideline environmental fate studies have been required. Unless guideline environmental fate data are submitted, an environmental fate assessment of paranitrophenol with supporting data cannot be made. Given the use patterns of this chemical, however, the present assessment is considered to be sufficient.

b. Environmental Fate and Transport

For indoor non-food use patterns, only hydrolysis data (161-1) are required. The guideline requirement is not fulfilled.

c. Water Resources

Ground Water

Paranitrophenol is an environmental breakdown product of several natural and synthetic compounds. Therefore, detections of paranitrophenol in ground water may not have resulted from its uses as a fungicide, and the source of contamination is difficult to determine. In the EPA Pesticides in Ground Water Database - A compilation of Monitoring Studies: 1971-1991 National Summary, there were three detections (all in Mississippi) in ground water out of 344 monitoring wells tested in MS and WA. The source(s) of these detections was not discussed in the data. However, based on the limited use pattern, the Agency believes that these detections were not from the present fungicide use pattern. It should be noted that even though there are no guideline mobility studies available for paranitrophenol, its chemical properties (Koc=214) and the data in the literature indicate that paranitrophenol may move in the soil profile.

Surface Water

Paranitrophenol has been discernible in surface water at low concentrations (at or near detection limits). The Agency believes these paranitrophenol detections are not due to the present fungicide use pattern (limited to military leather clothing and cork insulation for missle equipment). Paranitrophenol is an environmental breakdown product of several natural and synthetic compounds; therefore, the source of surface water contamination is difficult to determine. There are no guideline adsorption/desorption data requirements for indoor uses. Therefore, no adsorption/desorption data are available for paranitrophenol. However, based on the chemical properties reported (Koc of 214 and solubility in water = 1.6 g/100 ml), paranitrophenol contamination of surface water is believed to be due to dissolved paranitrophenol rather than soil bound paranitrophenol in runoff.

3. Exposure and Risk Characterization

Paranitrophenol is used as a fungicide in cork insulation and leather for military uses. It is applied at a concentration that may not exceed 0.7% of the treated material's weight. It is moderately to slightly toxic to birds and aquatic animals. Since it is not applied outside of a factory, it is not expected that any wild animals or plants will be exposed to it. Therefore, paranitrophenol is not expected to pose a risk to nontarget organisms.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Reregistration Decision

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing paranitrophenol. The Agency has completed its review of these generic data, and has made a reregistration decision. Appendix B identifies the generic data requirements that the Agency reviewed as part of its decision on paranitrophenol, and lists the submitted studies that the Agency found acceptable.

The Agency based its reregistration decision upon the target data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B.

Based on the reviews of the generic data for the active ingredient paranitrophenol, the Agency has some concerns about paranitrophenol relating to the potential for handler dermal and inhalation exposure associated with the registered uses of paranitrophenol (i.e., leather and cork treatment applied by military contractors to products used by military workers). Lacking adequate exposure and toxicity data, the Agency is unable to conduct a quantitative risk assessment. In order to assess the risk, the following data would be required to support the continued registration of paranitrophenol:

EPA Guideline	Study
81-3	Rat acute inhalation toxicity
81-5	Primary dermal irritation study in rabbit
81-6	Dermal sensitization potential study in guinea pig
83-3(b)	Rabbit developmental toxicity study
84-4	*in vivo* bone marrow cytogenetics
231	Dermal exposure
232	Inhalation exposure

The Agency contacted the sole registrant of paranitrophenol, the United States Department of the Army, regarding the data necessary to support the continued registration of paranitrophenol. Subsequently, the Agency received a request to cancel the registration of the sole product containing paranitrophenol from the Department of the Army to take effect on May 30, 2002. In the letter submitted requesting cancellation of the registration, the registrant stated the following: there are no supplies of PNP in stock; the product would only be used in a national security emergency situation; a commitment to rely on available alternative fungicides registered for use to treat leather and cork products and to pursue efficacy testing of these alternative products.

The Agency has decided to accept the voluntary cancellation request to be effective on May 30, 2002. The Agency is basing this decision on:

1. The weight of evidence from all available toxicological data does not suggest a potent threat from dermal and inhalation exposure.

2. Exposure to paranitrophenol is believed to be very limited. It's uses are confined to leather and cork treatment applied by military contractors to few products used by military workers. The worker population exposed during treatment is likely to be small. The only large population potentially exposed is military personnel wearing treated footwear. The Agency was able to quantitatively estimate their risk and found it to be acceptably low even using the protective assumptions.

3. During the five year phase-out period, workers using and handling paranitrophenol solutions and freshly treated products are required to wear chemical resistant aprons and with attached full sleeve gloves.

Revised label language as set forth in Section V of this document is required. Several of the label revisions pertain to handler safety requirements that must be established due to the acute and other adverse effects associated with paranitrophenol. Due to concerns about potentially high dermal exposures during the introduction and removal of leather or cork by hand

from dip vats, and handlers participating in such hands-on operations, workers must wear chemical-resistant full-front aprons with attached full-sleeve gloves. Other required label changes address application restrictions and user safety requirements, and are found in Part V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

A. Labeling Language for Paranitrophenol-Containing Products

1. Personal Protective Equipment Label statements

a.The personal protective equipment requirements must be placed on the end-use product labeling in the format and language as specified and must be placed in the "Hazards to Humans" section of the pesticide labeling. The label language is indicated in quotation marks.

"Mixers, loaders, applicators and other handlers must wear:

-- Long-sleeve shirt and long pants,
-- Shoes plus socks."
-- "Protective eyewear."
-- "Chemical-resistant apron, and attached full sleeve
-- Chemical-resistant gloves*."

*For the glove statement, use the statement established for PNP through the instructions in Supplement Three of PR Notice 93-7. In addition, the concentrated PNP product, the corrosiveness and penetration of PNP must be considered. Appropriate chemical-resistant materials must be listed on the product labeling.

b. Since this product is toxicity category II for acute inhalation toxicity, a respirator requirement must be added. The type of respirator must be specified in the statement and is based on the acute toxicity category and the vapor pressure. EPA will assist the registrant in determining the appropriate type of respirator.

c. In addition to the minimum PPE specified above, the following specific PPE requirements must be added to labels:

"Handlers participating in hands-on operations, including introduction of materials to and removal from the dip, and handling leather or cork still wet with the treatment, must wear chemical-resistant full-front aprons with attached full-sleeve gloves."

2. Application Restrictions

"Do not use this product in a way that will contact workers or other persons."

3. Restrictions For Use Statement

"This product can not be used after May 30, 2002."

4. User Safety Requirements

"Follow manufacturer"s instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

5. User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible wash thoroughly."

VI. APPENDICES

GUIDE TO APPENDIX A

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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APPENDIX B - LIST OF AVAILABLE RELATED DOCUMENTS

The following is a list of available documents for PARANITROPHENOL that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Veronica Dutch at (703)-308-8585.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for PARANITROPHENOL.

The following documents are part of the Administrative Record for PARANITROPHENOL and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1.Health and Environmental Effects Science Chapters.

2.Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria