United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA-738-R-96-008
January 1997

Reregistration Eligibility Decision (RED)

p-Chloro-m-cresol

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 chemical case 3046 which includes the active ingredient p-chloro-m-cresol. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 ("FQPA") became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in a tolerance is necessary, that tolerance too will be reassessed in the future pursuant to the requirements of FQPA.

If you have questions on the **product specific** data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative, Emily Mitchell at (703) 308-8583. Address any questions on required **generic** data to the Special Review and Reregistration Division representative, Tom Luminello at (703) 308-8075.

Sincerely yours,

Lois A. Rossi, Director
Special Review
and Reregistration Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months 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-e below) to the address listed in item 5.

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. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **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.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **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.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH 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

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

P-CHLORO-M-CRESOL

LIST C

CASE 3046

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

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P-CHLORO-M-CRESOL REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Assessment

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Tom Harris	Biological Analysis Branch
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Kathy Davis	Accelerated Reregistration Branch
Tom Luminello	Accelerated Reregistration Branch
Emily Mitchell	Planning and Reregistration Branch

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Steve Shapiro

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
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
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.
N/A	Not Applicable

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEC	No 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
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.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision (RED) for the pesticide p-chloro-m-cresol, case 3046, which includes the active ingredient para-chloro-meta-cresol. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. p-Chloro-m-cresol is an antimicrobial preservative used to control bacteria and fungi in the formulation of industrial materials. The Agency has concluded that all uses, as described in this document, will not cause unreasonable risks to humans or the environment and therefore, all products are eligible for reregistration.

To mitigate risks of potential toxicity to occupational handlers, the Agency is requiring use of personal protective equipment and reductions of application concentrations of p-chloro-m-cresol in the manufacture of paints. The Agency is also requiring revisions to product labels to clarify use sites, application instructions, and user safety recommendations. Revised labeling, product chemistry, and acute toxicology studies must be submitted to achieve product reregistration.

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 data base 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 p-chloro-m-cresol. The document consists of six sections. Section I is the introduction. Section II describes p-chloro-m-cresol, 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 p-chloro-m-cresol. Section V discusses the reregistration requirements for p-chloro-m-cresol. 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:** p-chloro-m-cresol (PCMC)
- **Chemical Name:** para-chloro-meta-cresol
- **Chemical Family:** phenol
- **CAS Registry Number:** 59-50-7
- **OPP Chemical Code:** 064206
- **Empirical Formula:** C_7H_7OCl
- **Trade and Other Names:** Preventol
- **Basic Manufacturer:** Bayer AG

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 the uses of p-chloro-m-cresol is in Appendix A.

Type of Pesticide: Fungicide; Microbiocide/Microbiostat (Slime-Forming Bacteria); Microbiocide/Microbiostat (Slime Forming Fungi)

Use Sites: Terrestrial Non-food
Industrial Preservatives:
Oil Recovery Drilling Muds/Packer Fluids

Aquatic Non-Food Industrial
Industrial Preservatives:
Oil Recovery Drilling Muds/Packer Fluids

Indoor Non-Food
Industrial Preservatives:
Adhesives, Industrial

Coatings, Industrial
Emulsions, Resin/Latex/Polymer
Leather Processing Liquors
Leather/Leather Products
Metalworking Cutting Fluids
Paints (In-Can)
Specialty Industrial Products
Wet-end Additives/Industrial Processing Chemicals

Target Pests:

Bacteria: Formaldehyde-resistant bacteria, *Aeromonas punctata, Bacillus subtilis, Escherichia coli, Leuconostoc mesenteroides, Proteus vulgaris, Pseudomonas aeruginosa, Pseudomonas fluorescens, Staphylococcus aureus, Desulfovibrio desulfuricans*

Yeasts: *Candida albicans, Torula rubra*

Fungi: *Aspergillus flavus, Aspergillus niger, Aureobasidium pullulans, Chaetomium globosum, Cladosporium herbarum, Coniophora puteana, Paecilomyces variotti, Penicillium citrinum, Penicillium glaucum, Trichophyton pedis, Trichoderma viride*

Formulation Types Registered: End use, manufacturing use; crystalline

Method and Rates of Application:

Types of Treatment - Hides and skins treatment; Industrial preservative treatment; Preservative treatment; Not on label (registrant must specify on label)

Equipment - Not on label (registrant must specify on label)

Timing - During manufacture; Not on label (registrant must specify on label)

Surface Type - Not Applicable

Application Rate -

Terrestrial non-food crop: From 500 to 1998 ppm of active ingredient.

Aquatic non-food industrial: From 500 to 1998 ppm of active ingredient.

Indoor non-food: From 500 to 29970 ppm of active ingredient.

Use Practice Limitations: (that apply to all uses on all products)

Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water (NPDES license restriction).

C. Data Requirements

The Agency applied the data requirements specified in 40 CFR Section 158 and the Phase II Requirements to active ingredients in this chemical case. Studies were generated and submitted for these requirements to the Agency. The data from these studies along with other available information form the basis for the Agency's scientific assessment and regulatory decisions. Appendix B includes all data requirements identified by the Agency needed to support reregistration for currently registered uses.

D. Regulatory History

p-Chloro-m-cresol was initially registered as a pesticide in the United States in 1968 for use as an industrial preservative. There are currently three products registered with p-chloro-m-cresol as an active ingredient. Each product is at least 99.9% p-chloro-m-cresol.

Data to support the continued registration of p-chloro-m-cresol were required under the Antimicrobial Data Call-In of 1987 and the Phase IV Data Call-In of 1991. These data have been submitted and are part of the data base considered in this Reregistration Eligibility Decision.

Uses of p-chloro-m-cresol include application to systems which may result in residues of p-chloro-m-cresol in paper coatings and adhesives. Tolerances for food grade adhesives and paper coatings which may contact foods are cited in the 21 CFR. The FDA has jurisdiction for establishing these tolerances.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Chemical Name: p-chloro-m-cresol

Molecular Weight: 142.58

Color: white/colorless

Physical State: crystalline solid

Odor: phenolic

Melting Point: 63-65°C

Boiling Point: approximately 239°C

Bulk Density: 49.93 lbs/ft^3 (800 g/kg/m^3)

Solubility: Water 4 g/L
Ethanol 500 g/L
Toluene 300 g/L
10% aqueous NaOH solution 320 g/L

Vapor Pressure: 0.25 mm Hg at 25°C

Dissociation constant: 9.4 ± 0.1 at 20°C

Log $K_{o/w}$ (or log P): 3.02

pH: 5.6 (saturated aqueous solution) at 20°C

Flash Point: 244.4°F (118°C)

p-Chloro-m-cresol is corrosive to metals and forms complex compounds with transition metal ions. Slow discoloration of the chemical occurs in the presence of sunlight.

B. Human Health Assessment

1. Toxicology Assessment

At present, the toxicological data base for p-chloro-m-cresol meets the requirements for antimicrobial pesticides. The data are adequate and will support a reregistration eligibility determination for the currently registered non-food uses.

a. Acute Toxicity

Results of the acute toxicity studies conducted with technical p-chloro-m-cresol are summarized below in Table 1:

Table 1. Acute Toxicity Values of Technical p-Chloro-m-cresol

Route	Species	Results	Toxicity Category
Oral	Rat	LD_{50}: Males 5129 mg/kg Females 3636 mg/kg	III
Dermal	Rat	LD_{50} >5000 mg/kg	IV
Inhalation	Rat	Waived	--
Eye Irritation[1]	Rabbit	Corrosive	I
Skin Irritation[1]	Rabbit	Corrosive	I
Dermal Sensitization[1]	Guinea Pig	Not a sensitizer	N/A

[1] Not required for TGAI, however, presented here for informational purpose.

The acute oral LD_{50} in rats is 5129 mg/kg for males and 3636 mg/kg for females placing p-chloro-m-cresol in Toxicity Category III (MRID 00071335). The acute dermal LD_{50} in rats is >5000 mg/kg placing p-chloro-m-cresol in Toxicity Category IV (MRID 00075492).

The rat acute inhalation study was waived because p-chloro-m-cresol is a chunky solid and respirable particles will not be formed.

p-Chloro-m-cresol is a Toxicity Category I primary eye irritant in rabbits. The study resulted in corneal cauterization, conjunctivitis, conjunctival ulceration, iritis, and corneal opacity and ulceration. The results were not reversible in 21 days (MRIDs 00109649 and 00048548). p-Chloro-m-cresol is a Toxicity Category I primary dermal irritant in rabbits. This study demonstrated that p-chloro-m-cresol was very irritating and cauterizing at the site of administration (MRID

00109649). However, p-chloro-m-cresol is not a skin sensitizer in guinea pigs (MRID 00078837).

b. Subchronic Toxicity

Preventol CMK (technical 99.9% p-chloro-m-cresol) was tested in a subchronic feeding study in 20/sex male and female Wistar rats at dose levels of 0, 150, 500 or 1500 ppm for 13 weeks (0, 12, 41, or 120 mg/kg/day for males and 0, 17, 54, or 167 mg/kg/day for females). Clinical signs, body weights, food consumption, clinical biochemistry, urinalysis, organs weights, gross pathology and microscopic pathology were examined. At 500 and 1500 ppm, a decrease in body weight gain was observed in males but not females (5-6% less than controls). No other effects were observed. The decreases in body weight gain are not of toxicological significance. The NOEL is greater than 1500 ppm which was the highest dose tested (MRID 124844).

Preventol CMK (technical 99.9% p-chloro-m-cresol) was tested in a 21-day dermal study in New Zealand White rabbits (10/sex/dose group) at the following dose levels: 0, 10, 40 or 160 mg/kg/day. The animals were dosed 5 days/week for a total of 15 applications. It appears that the test material was applied without a vehicle. Dermal irritation was observed in all treated groups, which ranged from slight erythema and very slight edema (10 mg/kg/day) to severe erythema and slight edema (160 mg/kg/day). Other dermal effects included skin thickening, scaling, blanching, raw areas, necrosis, brown scab-like areas, and sloughing. Fissuring occurred in one mid-dose female and in two high dose males. The NOEL for dermal irritation is less than 10 mg/kg/day lowest dose tested. No systemic effects were observed at either 10 mg/kg/day or 40 mg/kg/day. At 160 mg/kg/day, a compound-related enhancing effect on nonsupporative pericholangitis (both sexes) and bile duct proliferation (females) in the liver were observed. The systemic NOEL is 40 mg/kg/day and the LOEL is 160 mg/kg/day based on enhanced liver pathology in both sexes (MRID 62905).

c. Chronic toxicity

Technical p-chloro-m-cresol (99.90 - 99.97%) was tested in a chronic feeding/carcinogenicity study in male and female Wistar rats for 24 months. Fifty/sex were tested per dose level with an additional ten/sex scheduled to be sacrificed at 53 weeks. The following dose levels were administered: 0, 400, 2000, or 10,000 ppm (0, 21.0, 103.1,

or 558.9 mg/kg/day for males and 0, 27.7, 134.3, or 743.5 mg/kg/day for females).

At some intervals, the concentration analyses were somewhat low for all dose groups. At 10,000 ppm, the following systemic effects were observed when compared to controls: an increase in the frequency of poor general condition in females; a decrease in body weight (8% males, 21% females, $p < 0.01$); a decrease in food efficiency in females (29%); an increase in water intake (14% in males, 16% in females); a decrease in urinary total protein in females (25-40%, $p< 0.01$); a decrease in brain weight in females (88.6-94.4%, $p < 0.01$); an increase in relative kidney weights (both sexes 8%, $p< 0.05$); an increase in papillary necroses in males (eight vs. two in controls, $p < 0.05$ for trend); an increase in cortical dilation and fibrosis in the kidney of males ($p < 0.05$); an increase in unilateral and combined unilateral and bilateral degeneration of seminiferous tubules in males; an increase in unilateral and combined unilateral and bilateral reduced spermatozoa in epididymides in males and an increase in brain compression in females. At 2000 ppm, the same effects in seminiferous tubules, epididymides and brain were observed. At 400 ppm, the same effects were observed in the brain. The systemic NOEL is less than 400 ppm and the systemic LOEL is 400 ppm based on poor general condition, decreased body weight and food efficiency, increased water intake, decreased urinary protein, changes in organ weights and histopathology of the kidney, brain (400 ppm and above), testes and epididymides (2000 ppm and above) (MRID 42784801). Conclusions on carcinogenicity in this study are reported below.

d. Carcinogenicity

From the above chronic toxicity study (MRID 42784801), female rats had a statistically significant increase in pituitary adenomas and adenomas and/or carcinomas combined in the mid-dose group (2000 ppm, $p=0.042$) but not in the high dose group in pairwise comparisons with the control group. There was no significant increase in the trend for these tumors. In addition, the incidences of these tumors were within the historical control range. A statistically significant increase in pituitary adenomas was also observed in low dose males, but not in the mid- or high dose males. There was a statistically significant decreasing trend for these tumors ($p <0.05$). Again, the incidences of these tumors were within the historical control range.

In addition to the pituitary tumors in females, male rats had a significant increasing trend in testicular interstitial cell tumors ($p < 0.05$). The incidences of these tumors, however, were within the historical control range. Therefore, the increased incidence of tumors seen in this study were not related to treatment with p-chloro-m-cresol. Based on the Agency's conclusions of this study and because there is no mouse study, the Agency has determined that p-chloro-m-cresol is not classifiable as a human carcinogen, Group D. This determination is also discussed in subsection j, Toxicological Endpoints of Concern.

e. Developmental Toxicity

p-Chloro-m-cresol was tested by gavage in a developmental toxicity study in rats at the following dose levels: 0, 30, 100, or 300 mg/kg/day during gestation days 6-15 inclusive. At 300 mg/kg, six dams died. Treatment-related clinical signs of toxicity included audible breathing sounds, gasping breathing, reduced motility and high stepping gait; and after dosing: lying on side, somnolence, abdominal position, spastic convulsions, rough coat, sunken flanks and bloody muzzle. Statistically significant decreases in body weight gain were observed during the dosing period and significant decreases in the corrected body weight gain were also observed during the entire gestation period. In addition, the decreased food consumption was also considered to be biologically significant. Finally, two dams totally resorbed their litters. At 100 mg/kg/day, labored breathing was observed in two animals. Statistically significant decreases in body weight gain during the dosing period were observed in addition to significant decreases in the corrected body weight gain during the entire gestation period. The NOEL for maternal toxicity is 30 mg/kg/day and the LOEL is 100 mg/kg/day based on clinical signs of toxicity and decreases in body weight gain (100 mg/kg/day and above) and death, decreases in food consumption and increases in total resorptions (300 mg/kg/day). The NOEL for developmental toxicity is 100 mg/kg/day and the LOEL is 300 mg/kg/day based on a significant decrease in the mean fetal weight per litter at 300 mg/kg/day when compared to the control group and a slight increase in the number of microphthalmias or anophthalmias at this dose level (MRID 42292901).

f. Reproductive Toxicity

A reproduction study is required for antimicrobials if it is determined that developmental toxicity and/or adverse effects on the reproductive organs were observed in a 90-day dermal or inhalation

study. From the available subchronic studies (developmental, a 90-day subchronic feeding, and 21-day dermal studies) no adverse effects on the reproductive organs were observed in either of the 21-day dermal or the 90-day feeding studies. The developmental toxicity study indicated that developmental effects in the rat were only observed at maternally toxic levels. In addition, there was no indication of any mutagenic effects for p-chloro-m-cresol under the conditions of the studies. Although p-chloro-m-cresol was considered to have induced effects in the testes and epididymides in the chronic feeding study, a closer examination of the data indicated that these effects appeared late in the study in older rats at terminal sacrifice. Therefore, it is unlikely that these effects would be observed in a reproduction study, and one is not required.

g. Mutagenicity

The four acceptable studies satisfy the guideline requirements for mutagenicity studies for p-chloro-m-cresol. All of these studies indicate that p-chloro-m-cresol was not found to be mutagenic.

Technical p-chloro-m-cresol was tested for potential to induce reverse mutations in Salmonella typhimurium strains TA 1535, TA 1537, TA 100 and TA 98. Metabolic activation was provided by an S-9 mix prepared from the livers of adult male Sprague-Dawley rats, induced with an injection of Aroclor 1254. Five dose levels, ranging from 20 to 12,500 µg/plate, were used. All dose groups were tested with S-9 mix; the highest dose was also tested in the absence of the S-9 mix. Endoxan® and Trypaflavin were used as positive controls. The two highest dose levels, 2500 and 12,500 µg/plate were toxic to the cells. p-Chloro-m-cresol failed to induce a mutagenic response at any of the three lowest dose levels (20, 100, or 500 µg/plate) with all four tester strains (MRID 00078838).

Technical p-chloro-m-cresol was tested for potential to induce reverse mutations in Salmonella typhimurium strains TA1535, TA1537, TA100 and TA98. Metabolic activation was provided by an S-9 mix prepared from the livers of adult male rats, induced with an injection of Aroclor 1254. The initial assay was conducted with five dose levels ranging from 8 to 5000 µg/plate, evaluated both with and without metabolic activation. The repeat assay was conducted with six dose levels ranging from 30 to 960 µg/plate, evaluation both with and without metabolic activation. Positive control chemicals were sodium azide, nitrofurantoin, 4-nitro-1,2-phenylene diamine and 2-

aminoanthracene. In the initial assay, no revertant colonies were observed on plates containing 5000 µg/plate with and without S-9. Cytotoxicity was observed in all strains at 1000 µg/plate with and without S-9. At the other dose levels, no increase in revertants were observed. In the repeat assay, cytotoxicity was observed in all strains at 960 µg/plate with and without activation. Reduced bacterial populations were observed for all strains at 480 µg/plate and for strain TA100 at 240 µg/plate with S-9. p-Chloro-m-cresol was not found to be mutagenic under the conditions of the assay (MRID 42199901).

p-chloro-m-cresol was tested in a CHO-HGPRT assay for potential to induce forward mutations. The dose levels tested were 50, 100, 150, 200, 250, or 300 µg/ml, either with or without metabolic activation. Both the 250 and 300 µg/ml doses were cytotoxic, with and without activation. For the remaining dose levels, p-chloro-m-cresol did not induce an increase in mutations over the controls, either with or without metabolic activation (MRID 41548601).

p-Chloro-m-cresol was tested for the potential to induce chromosomal aberrations in a micronucleus assay in the mouse. It was administered as a single i.p. injection at a dose level of 125 mg/kg. The animals were sacrificed and the bone marrow was isolated and prepared at 24, 48, and 72 hours after administration of the test chemical. No increases in micronuclei in the polychromatic erythrocytes were observed under the conditions of the study. In addition, the ratio of normochromatic and polychromatic erythrocytes were unaffected by treatment at any time point. The positive control, cyclophosphamide, induced a statistically significant positive response. There were clear signs of toxicity to the animals. Therefore, the dose level used was acceptable (MRID 41598101 or 42005201).

p-Chloro-m-cresol was tested in a rat primary hepatocyte unscheduled DNA synthesis (UDS) assay. The following dose levels were tested: 0.25, 0.5, 2.5, 7.5, 10 or 20 µg/ml and 2.53, 5.06, 7.58, 10.1, 15.2 or 20.2 µg/ml. The positive control used was 2-acetylaminofluorene (2-AAF). p-Chloro-m-cresol did not cause any DNA damage or inducible repair under the conditions of the studies (MRIDs 41548602 and 42163201).

h. Metabolism

A metabolism study is not required at this time for p-chloro-m-cresol based on the Agency's requirements for antimicrobials.

Metabolism studies are required only if the Agency determines that additional information on the metabolism of the chemical is necessary to clarify unusual effects observed in chronic or reproduction studies or to clarify issues concerning structural activity relationships. For p-chloro-m-cresol, the Agency has not identified any such issues that warrant the need for metabolism data.

i. Toxicological Endpoints of Concern

For short term (1 to 7 days) and intermediate term (one week to several months) occupational or residential exposure, the NOEL of 30 mg/kg/day and the LOEL of 100 mg/kg/day for maternal toxicity (developmental toxicity study in the rat) is appropriate for risk assessment. For chronic occupational or residential exposures, a LOEL of 28 mg/kg/day for brain weight depression in females should be used for risk assessment. This LOEL was observed in the two-year feeding study in rats (MRID 42784801). Due to the lack of dermal absorption data for p-chloro-m-cresol, 100% absorption is assumed for these risk assessments.

The Agency (OPP's Health Effects Division's Carcinogenicity Peer Review Committee) has classified p-chloro-m-cresol as Group D, not classifiable as to human carcinogenicity. This determination is further discussed in subsection d., Carcinogenicity, above. In addition, there was no concern for mutagenicity. Several distant analogues tested negatively in NTP bioassays. p-Chloro-m-cresol was not tested in the mouse. However, since p-chloro-m-cresol is intended for non-food use, a mouse carcinogenicity study is not required.

2. Exposure Assessment

a. Dietary Exposure

p-Chloro-m-cresol current uses include applications to adhesives, glues, and paper which can be used in food processing, packaging, and transportation. FDA has established tolerances for these uses, as specified above in Section II, and is responsible for assuring that any potential dietary exposures attributable to these uses are acceptable in terms of toxicological risk. Therefore, EPA has not addressed dietary exposure.

b. Occupational and Residential Exposures

All current product formulations contain 99.9% p-chloro-m-cresol as a crystalline solid. As specified above in Section II and in Appendix A, the use sites include industrial adhesives, general preservatives for leather, paper products, textiles, fibers and cordage, metal-working fluids, industrial oil drilling muds and packer fluids, industrial coatings, paints, and resin/latex/polymer emulsions. The range of application rates for p-chloro-m-cresol is 0.05 to 2.0% in adhesives, coatings, emulsions, dye pigments, and materials in the paper, photo and textile industries and 0.02 to 5.0% in metal-working fluids based on the total weight of product. All products containing p-chloro-m-cresol are intended primarily for occupational use. However, people in residential settings may use or handle products, such as adhesives, leather, or paper products, which have been treated with p-chloro-m-cresol.

An occupational and/or residential exposure assessment is required for a pesticide if certain toxicological criteria are triggered and there is potential exposure to handlers (mixers, loaders, and/or applicators) during use, or to persons entering treated sites after application is complete. As discussed above, the Agency believes there are toxicological endpoints of concern for p-chloro-m-cresol and it is reasonable to assume there is occupational and residential exposure from the use of p-chloro-m-cresol products. Therefore, exposure assessments are appropriate. To estimate exposures of primary occupational handlers (workers) to this chemical the Agency used the CMA Antimicrobial Exposure Assessment Study (MRID 42587501) and a complete set of product application rates for primary occupational handler exposure. Because current p-chloro-m-cresol end-use products are formulated as solids, the pour-solid data from this study were used. For secondary occupational handlers (painters) the Agency used the Pesticide Handlers Exposure Data base (PHED) to estimate the exposure.

<u>Handler (Mixers, Loaders, Applicators) Exposures and Assumptions</u>

There are potential exposures from handling p-chloro-m-cresol end-use products or products to which p-chloro-m-cresol has been added in commercial, industrial, and residential settings. The Agency calculated daily exposure estimates using the following formula:

Actual Daily Exposure (ADE) (mg/kg/day)
= ADE (μg/day) ÷ Body Weight (BW) (kg) X 1 mg/1000 μg

Where the body weight is 60 kg based on the average weight of an adult female, since the selected toxicological endpoint is a developmental effect, and dermal absorption is assumed to be 100%.

Occupational Handler Exposures

Primary Exposures to Occupational Handlers: EPA estimated exposures of p-chloro-m-cresol to handlers (mixers, loaders, and applicators) who open-pour end use products into tanks of metal working fluids and for other general industrial preservative uses. Short-term and intermediate-term average daily doses for these handlers are presented in Table 2. These uses are considered reasonable worst-case exposures.

Table 2. Exposure Estimates for Short- and Intermediate-Term Worker Exposures for p-Chloro-m-cresol

Use Scenario		UE[1] (µg/lb ai)	lb/ai used	Actual Daily Exposure (µg/kg/day)	MOE[2]
Metal-working Fluids	Mineral Oil based (conc.)[3]	479	5	40.00	751.00
	Non-Mineral Oil based (cutting fluids)[4]	479	6.5	52	578
General Preservative[5]		479	3	24.00	1,253.00

[1]UE = Unit Exposure (dermal and inhalation) was derived from CMA Study. All handlers in these exposure studies wore chemical-resistant gloves, long sleeves, and long pants.

[2] Margin of Exposure (MOE) for short and intermediate term exposures.

[3] Exposure calculation for metal-working fluid (mineral oil) tank side additives. Preventol CMK Preservative (EPA Reg. 39967-12, 99.9% a.i.), is added at concentrations of approximately 0.5 pounds of preservative per gallon of mineral oil. Assuming 10 gallons of mineral oil are treated before further dilution then, a total of 5 pounds of active ingredient is used by handler per day.

[4] Exposure calculation for metal-working fluids (non-mineral oil) tank side additives. Preventol CMK Preservative (EPA Reg. 39967-12, 99.9% a.i.), is added at concentrations of approximately 1.3 pounds of preservative per gallon of substrate. Assuming 5 gallons of mineral oil are treated everyday then, a total of 6.5 lbs of active ingredient is used by handler per day.

[5] Exposure calculation for the general preservative use of p-chloro-m-cresol in adhesives.
1000 pounds of the material being treated at a labeled maximum rate of 0.3% by weight. Assuming 1000 pounds is treated then, a total of 3 pounds of active ingredient is used by handler per day.

Secondary Occupational and Residential Exposures: Based on the use patterns, the Agency has identified three secondary exposure scenarios for occupational handlers likely to represent reasonable worst-case scenarios. These are exposures while handling paints, adhesives and metal-working fluids treated with p-chloro-m-cresol.

The Pesticide Handler's Exposure Database (PHED) was used to calculate risks to painters using p-chloro-m-cresol treated paints at the currently labeled range of concentration (0.05 to 0.40%). Exposures to homeowners using paints are expected to be of short or intermediate term, but are not expected to be significant bcause of infrequent use. Commercial painters, however, may experience significant short and intermediate term and chronic exposures.

Currently, the Agency has no specific data upon which to estimate exposures from adhesive and metal-working/cutting fluids. However, the Agency assumes that such secondary occupational exposures, whether occupational or residential, are not greater than primary occupational exposures (open-pouring the 99.9% p-chloro-m-cresol product). EPA makes this assumption of relatively low exposure because: 1) p-chloro-m-cresol is in a diluted concentration (0.02 to 5.0%) in treated products like adhesive paper coatings, textiles and leather; and 2) the length of contact time with treated products in residential settings is usually of short duration.

Secondary occupational handler exposures and risks to machinists handling metal-working/cutting fluids containing p-chloro-m-cresol are not addressed in detail in this document. Agency representatives continue to discuss with the Occupational Safety and Health Administration (OSHA) the roles and responsibilities of regulating the uses of metal-working fluids, and other products in industrial settings. Currently, OSHA is responsible for regulating machinists safety and exposure. EPA has made available this document to OSHA for their regulatory use.

Post-Application Exposures

Primary and Secondary Occupational Post-Application Exposures: Based on the use patterns, the Agency has identified two reasonable worst-case primary occupational post-application exposure scenarios: (1) exposures following applications of p-chloro-m-cresol to open vats of liquids, such as adhesives, coatings, paints, or emulsions in a commercial/industrial setting, and (2) exposures to persons

maintaining equipment, such as industrial equipment, which contains product treated with p-chloro-m-cresol. Exposures to persons occupying work areas where p-chloro-m-cresol containing adhesives have recently been applied, exposures in areas where p-chloro-m-cresol containing products are being manufactured, and exposures to p-chloro-m-cresol treated products are secondary occupational post-application exposure. These exposures include both dermal and inhalation exposures.

Primary and Secondary Residential Post-Application Exposures: Because currently there are no end-use products containing p-chloro-m-cresol intended for residential use, any exposures in these settings would be limited to those after application of a p-chloro-m-cresol treated product. Reasonable worst-case secondary residential post-application exposure scenarios are exposures while occupying areas where p-chloro-m-cresol containing adhesives and paints have recently been applied and exposures to p-chloro-m-cresol treated products, such as leather, paper or textile products. For the reasons stated above, the Agency assumes secondary post-application exposures in residential settings would be lower than primary exposures to workers in industrial settings.

3. Risk Assessment

a. Dietary

The Agency did not conduct a dietary risk assessment for p-chloro-m-cresol because of the non-food use patterns of current products and FDA's responsibility for the tolerances for food-grade adhesives and paper, as explained above.

b. Occupational and Residential

The Margin of Exposure (MOE) is a measure of how closely the estimated exposure is to the NOEL (NOEL/exposure = MOE). For substances whose NOEL is based on animal studies, the Agency's policy has been that MOEs of 100 or greater represent a negligible risk from that toxicological endpoint, that is, there is an adequate margin of the exposure from the toxicological endpoint. However, for p-chloro-m-cresol an additional factor of 3 is included in the margin of exposure for chronic exposure to account for a lack of an NOEL from the chronic rat study. For reasons given in subsection 1.j, Toxicological Endpoints of Concern, 30 mg/kg/day is the selected toxicological endpoint

(NOEL) for short- and intermediate-term risk assessments of occupational exposures. For chronic risk assessment, the toxicological endpoint is the LOEL (no NOEL) of 28 mg/kg/day from the chronic rat study. This increases the MOE threshold for chronic risk assessment from 100 to 300 because of the additional uncertainty factor of 3. For the exposure component the Agency used the calculated ADEs (Table 2 above) to calculate the MOEs for the primary occupational scenarios.

Risk from Occupational Handler Exposures

Primary Occupational Handler Exposures: The Agency estimated risks (MOEs) to occupational handlers who have primary exposures of short- and/or intermediate-term duration to p-chloro-m-cresol from the application of p-chloro-m-cresol products to metal-working/ cutting fluids and as general preservatives. In addition, the chronic risk was estimated for the primary occupational exposures from the general preservative use of p-chloro-m-cresol. The results (for the short- and intermediate-term exposures) are presented in Table 2, above. MOEs for chronic exposure would be similar to those calculated for short- and intermediate-term exposure since the LOEL (no NOEL) selected for chronic risk assessment is 28 mg/kg/day (brain weight depression in female rats) versus a NOEL of 30 mg/kg/day for short- and intermediate-term risks. MOEs are greater than 300 for all use settings and thus are not of concern to the Agency.

Secondary Occupational Handler Exposures: The Agency believes that exposures to painters using p-chloro-m-cresol treated paints represents one of the worst-case scenarios for secondary occupational handlers. To estimate these exposures, the Agency used the maximum application concentration of 0.40% and assumed that 5 gallons of paint are applied per day. In the absence of dermal absorption data, 100 % dermal absorption is assumed. Using the PHED exposure database, the short- and intermediate-term NOEL of 30 mg/kg/day, and the chronic LOEL of 28 mg/kg/day resulted in low MOEs of approximately 30 for the three terms of exposures. These compare against the Agency's acceptable risk level of 100 (300 for p-chloro-m-cresol chronic exposure as explained above). However, using the lowest application concentration (0.05%) the estimated MOEs are 247 for short- and intermediate-term and 269 for chronic exposure. While the chronic MOE for painters is 269 as compared to the Agency's regulatory standard of 300, the Agency is comfortable with this MOE because this risk estimate includes conservative assumptions. These conservative assumptions include 100% dermal absorption of p-chloro-m-cresol,

chronic exposure to occupational painters, and that all paint is treated with p-chloro-m-cresol. Therefore, this MOE may actually be greater than 269.

The Agency has assumed that secondary occupational handler exposures from handling adhesives containing p-chloro-m-cresol are not greater than the exposures of the primary occupational handler from open pouring the solid formulation of p-chloro-m-cresol in the industrial preservative use scenario. Therefore, the risks from secondary occupational exposures are assumed to be equal to or less (MOE $\geq$ 1,253) than that for primary occupational exposure in the industrial preservative use.

Using the assumption of 100% dermal absorption and the potentially worst-case dermal and inhalation exposures to machinists handling metal-working fluids containing p-chloro-m-cresol, the Agency has some risk concerns for these secondary occupational handlers. Metal-working machinists may experience high exposure from splashing of the metal-working cutting fluids. The Agency will notify OSHA of its concerns and will provide that Agency with a copy of this document and supporting information.

Risk for All Other Occupational and Residential Scenarios

As discussed above, the Agency assumes that all other primary and secondary exposures in occupational and residential settings, as described above, including post-application exposures, are expected to be no greater than, and more likely less than, estimated exposures associated with the general preservative use (Table 2). Thus, the risks associated with the other exposure scenarios are likely to be no greater, or less, than those estimated, for the general preservative use (MOE = 1,253).

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Acute Toxicity to Birds

In order to establish the acute toxicity of p-chloro-m-cresol to birds, the following test was performed using the technical grade

material: one avian single-dose oral (LD_{50}) study on one species of waterfowl or upland game bird (preferably mallard duck or bobwhite quail).

TABLE 3: Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} (ppm)	MRID	Toxicity Category
Bobwhite Quail	99.97%	1,540	42692401	Slightly toxic

There is sufficient information to characterize p-chloro-m-cresol as slightly toxic to avian species on an acute oral basis (Table 3). The guideline requirement is satisfied (MRID 42692401).

(2) Subacute Toxicity to Birds

In order to establish the subacute toxicity of p-chloro-m-cresol to birds, the following test was performed using the technical grade material: one avian dietary study (LC_{50}) on one species of waterfowl or upland game bird (preferably the mallard duck or bobwhite quail).

TABLE 4: Avian Subacute Dietary Toxicity Findings

Species	% A.I.	LC_{50} (ppm)	MRID	Toxicity Category
Bobwhite Quail	99.97%	>3,180	42692402	Slightly toxic

There is sufficient information to characterize p-chloro-m-cresol as slightly toxic to practically non-toxic to avian species on a subacute dietary basis (Table 4). The guideline requirement is satisfied (MRID 42692402).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of p-chloro-m-cresol to freshwater fish, the minimum data required on the technical grade of the active ingredient is a single 96-hour LC_{50} fish toxicity study using either a warmwater fish (preferably bluegill sunfish) or a coldwater fish (preferably rainbow trout).

TABLE 5: Freshwater Fish Acute Toxicity Findings

Species	% A.I.	LC_{50} (ppm)	MRID	Toxicity Category
Rainbow trout	99.97%	0.9	42692403	Highly toxic

There is sufficient information to characterize p-chloro-m-cresol as highly toxic to freshwater fish (Table 5). The guideline requirement for freshwater fish acute toxicity is fulfilled (MRID 42692403).

(2) Freshwater Invertebrates

The minimum testing required to assess the acute toxicity of p-chloro-m-cresol to freshwater invertebrates is a single 48-hour LC_{50} test.

TABLE 6: Freshwater Invertebrate Acute Toxicity Findings

Species	% A.I.	LC_{50} (ppm)	MRID	Toxicity Category
Daphnid (Daphnia magna)	99.97%	2.3	42692404	Moderately toxic

There is sufficient information to characterize p-chloro-m-cresol as moderately toxic to freshwater invertebrates (Table 6). The guideline requirement is satisfied (MRID 42692404).

2. Environmental Fate

The Agency has not required data on the dissipation of p-chloro-m-cresol in the environment. However, the currently registered uses are of such a nature that little or no environmental exposure is likely to occur and no further information is currently necessary. Based on the very limited information available, it appears that this chemical may be relatively stable in the environment. Eventual degradation would depend on the solubilization of the chemical and microbial-aided degradation. Solubility in water is reported in the Ninth Edition of The Merck Index as 1 gram of p-chloro-m-cresol in 260 milliliters of water at 20° C with solubility increasing with temperature.

3. Exposure and Risk Characterization

Acceptable laboratory studies demonstrate that p-chloro-m-cresol is slightly toxic to birds, highly toxic to fish, and moderately toxic to aquatic invertebrates. The oil recovery drilling mud (aquatic and terrestrial) uses are expected to result in minimal to no exposure if proper procedures are employed in the disposal of contaminated drilling muds.

While the hazard to aquatic organisms from p-chloro-m-cresol has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from this use are regulated under the NPDES permitting program of EPA's Office of Water. The labels for all p-chloro-m-cresol products must require that discharges to aquatic environments comply with an NPDES permit.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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 ingredients 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 p-chloro-m-cresol active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all current products containing p-chloro-m-cresol. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of p-chloro-m-cresol, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of p-chloro-m-cresol and to determine that p-chloro-m-cresol can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing p-chloro-m-cresol as the active ingredient, and as specified in this document, are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base 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. Although the Agency has found that all uses of p-chloro-m-cresol are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing p-chloro-m-cresol, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients p-chloro-m-cresol, the Agency has sufficient information on the health effects of p-chloro-m-cresol and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that p-chloro-m-cresol products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing p-chloro-m-cresol for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of p-chloro-m-cresol are eligible for reregistration.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for p-chloro-m-cresol. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Occupational and Residential Labeling Rationale/Risk Mitigation Measures; Personal Protective Equipment (PPE)/Engineering Controls for Handlers

<u>Occupational-Use Products</u>

The Agency has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for primary occupational handlers is necessary for products containing p-chloro-m-cresol. Because data from the CMA study were collected with the handlers wearing long sleeved shirt, long pants, shoes, socks and chemical-resistant gloves, the Agency is requiring these PPE as active-ingredient based minimum (baseline) PPE for primary handlers of p-chloro-m-cresol.

The Agency has determined that for the other occupational and residential exposure scenarios (except machinists using p-chloro-m-cresol treated metal-working fluids and painters using p-chloro-m-cresol treated paint), including post-application exposure, concerns for toxicological risks are unwarranted. For this reason, active ingredient-based minimum PPE

requirements, or entry restrictions are not being imposed. The Agency notes, however, that there are possible concerns about secondary occupational handlers who are machinists handling p-chloro-m-cresol treated metal-working fluids. These concerns will be conveyed to OSHA for their consideration of regulatory measures to protect these workers.

2. Reduction in Percentage of Active Ingredient

Also the Agency notes that short- and intermediate- term and chronic toxicity risks to painters may be unacceptable when paints are formulated at higher application concentration of p-chloro-m-cresol. At the lowest application concentrations (0.05%) these risks are significantly reduced. The sole registrant with products for use in paint, Bayer, has agreed to reduce the concentration to 0.05% in paints.

3. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing p-chloro-m-cresol. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of all p-chloro-m-cresol products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of p-chloro-m-cresol for the above eligible uses has been reviewed and determined to be substantially complete.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into a microbiocide for the following use(s): industrial adhesives, general preservatives for leather, paper products, textiles, fibers and

cordage, metalworking (cutting) fluids, industrial oil/ gas drilling muds and packer fluids, industrial coatings, and resin/latex/ polymer emulsions." An MP registrant may, at his/her discretion, add one of the following statements to an MP label under:

"Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for p-Chloro-m-cresol Products

a. Environmental Hazards

The following statement is required to appear in the Environmental Hazards section of the label, in accordance with 40 CFR 156.10:

"This pesticide is highly toxic to fish."

b. Directions for Use Clarification

Registrants must specify on labeling the complete directions for use for each use pattern: site of application, type of application, timing of application, equipment used for application, and the rate of application (dosage).

The labeling must be amended to specify a maximum application rate to achieve a concentration of 0.05% of p-chloro-m-cresol in paints.

The following statement must be added to the precautionary labeling:

"Do not apply in marine and/or estuarine oil fields."

The following statement must be added to the labels for aquatic non-food industrial oil drilling muds and packer fluids:

"For use in offshore wells only."

For use in both terrestrial and offshore oil drilling muds and packer fluids, the following statement must be added:

"This product may be used for terrestrial and off-shore oil/gas drilling muds and packer fluids."

Clarification of Oil Drilling Mud Use

To clarify the intent of the oil recovery drilling muds/packer fluids use (as an aquatic or terrestiral non-food use pattern), the following statement must be added to the labels for terrestrial non-food oil drilling muds and packer fluids:

"For use in terrestrial wells only."

c. Worker Protection Labeling

PPE/Engineering Control Requirements for Pesticide Handlers

For sole active-ingredient end-use products that contain p-chloro-m-cresol, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements

set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For multiple active-ingredient end-use products that contain p-chloro-m-cresol, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Minimum (Baseline) PPE/Engineering Control Requirements

The Agency is establishing active-ingredient-based minimum (baseline) PPE/engineering control requirements for p-chloro-m-cresol end-use products that are intended primarily for occupational use. The minimum (baseline) PPE for all occupational uses of p-chloro-m-cresol end-use products is:

Applicators and other handlers must wear:

--long-sleeved shirt, long pants, socks and shoes, and
--chemical-resistant gloves.

For the glove statement, use the statement established through the instructions in Supplement Three of PR Notice 93-7. Although this PR Notice addresses products within the scope Worker Protection Standard (WPS), that is products are generally of agricultural use, the certain parts of the guidance are applicable to all pesticide products.

Determining PPE Requirements for End-use Product Labels

1. Any necessary PPE for each p-chloro-m-cresol occupational end-use product will be established on the basis of the end-use product's acute toxicity category. NOTE: All end-use products will also be required to specify minimum work attire for all handlers. If the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required for all handlers. If the end-use product is classified as toxicity category I or II for skin irritation potential or acute dermal toxicity, a chemical-resistant apron is also required for all handlers.

2. The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active

ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

d. Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing p-chloro-m-cresol:

Application Restrictions

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

User Safety Requirements

Add the following statement to all end-use product labeling:

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

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."

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/ labeling for 26 months from the date of the issuance of this RED. Persons other than the registrant may generally distribute or sell such products for 50 months from the data of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell p-chloro-m-cresol products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to your products.

VI. APPENDICES

APPENDIX A REPORT

Case 3046[p-Chloro-m-cresol] Chemical 064206[4-Chloro-m-cresol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
The uses in Appendix A were evaluated for reregistration. These do NOT include changes in application rates, deletion of uses, frequency or timing of applications, restricted entry intervals, etc. that may have been mandated in this document.												
NON-FOOD/NON-FEED												
ADHESIVES, INDUSTRIAL				Use Group: INDOOR NON-FOOD								
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	P/T	W 500	W 19980	*	NS	NS	NS	NS	NS	NS		C18, C24
COATINGS, INDUSTRIAL				Use Group: INDOOR NON-FOOD								
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	P/T	W 500	W 3996	*	NS	NS	NS	NS	NS	NS		C18, C24
EMULSIONS, RESIN/LATEX/POLYMER				Use Group: INDOOR NON-FOOD								
Industrial preservative treatment, During manufacture, Not on label, Not Applicable, Not applicable for this use	P/T	W 500	W 1998	*	NS	NS	NS	NS	NS	NS		C18, C24
LEATHER PROCESSING LIQUORS				Use Group: INDOOR NON-FOOD								
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	P/T	W 1499	W 2498	*	NS	NS	NS	NS	NS	NS		C18, C24
LEATHER/LEATHER PRODUCTS				Use Group: INDOOR NON-FOOD								
Hides and skins treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	P/T	W 999	W 3996	*	NS	NS	NS	NS	NS	NS		C18, C24
METALWORKING CUTTING FLUIDS				Use Group: INDOOR NON-FOOD								
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	P/T	W 500	W 29970	*	NS	NS	NS	NS	NS	NS		C18, C24
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS				Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	P/T	W 500	W 1998	*	NS	NS	NS	NS	NS	NS		C18, C24
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	P/T	W 500	W 1998	*	NS	NS	NS	NS	NS	NS		C18, C24
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS				Use Group: TERRESTRIAL NON-FOOD CROP								
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	P/T	W 500	W 1998	*	NS	NS	NS	NS	NS	NS		C18, C24

APPENDIX A REPORT

Case 3046[p-Chloro-m-cresol] Chemical 064206[4-Chloro-m-cresol]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
The uses in Appendix A were evaluated for reregistration. These do NOT include changes in application rates, deletion of uses, frequency or timing of applications, restricted entry intervals, etc. that may have been mandated in this document.													
NON-FOOD/NON-FEED (continued)													
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS (continued)			Use Group: TERRESTRIAL NON-FOOD CROP										
Preservative treatment, Not on label, Not P/T on label, Not Applicable, Not applicable for this use	W	500	W 1998	*	NS	NS	NS	NS	NS	NS			C18, C24
PAINTS (IN-CAN)			Use Group: INDOOR NON-FOOD										
Industrial preservative treatment, During P/T manufacture, Not on label, Not Applicable, Not applicable for this use	W	500	W 3996	*	NS	NS	NS	NS	NS	NS			C18, C24
SPECIALITY INDUSTRIAL PRODUCTS			Use Group: INDOOR NON-FOOD										
Industrial preservative treatment, During P/T manufacture, Not on label, Not Applicable, Not applicable for this use	W	500	W 19980	*	NS	NS	NS	NS	NS	NS			C18, C24
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS			Use Group: INDOOR NON-FOOD										
Industrial preservative treatment, During P/T manufacture, Not on label, Not Applicable, Not applicable for this use	W	500	W 2997	*	NS	NS	NS	NS	NS	NS			C18, C24

APPENDIX A REPORT

Case 3046[p-Chloro-m-cresol] Chemical 064206[4-Chloro-m-cresol]
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LEGEND
444444

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate, Maximum Number of Applications at Maximum Rate, Maximum Dose per Crop Cycle or per Year, Minimum Interval Between Applications (Days), Restricted Entry Interval (Days), Allowed/Disallowed Geographical Areas, Use Limitations Codes.

HEADER ABBREVIATIONS
Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
P/T : PELLETED/TABLETED

ABBREVIATIONS
AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE
DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).
C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case p-Chloro-m-cresol covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to p-Chloro-m-cresol in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of p-Choloro-m-cresol

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	C,F,M	41962601
61-2A	**Start. Mat. & Mnfg. Process**	C,F,M	41962601
61-2B	**Formation of Impurities**	C,F,M	41962601
62-1	**Preliminary Analysis**	C,F,M	41962601
62-2	**Certification of limits**	C,F,M	41962601
62-3	**Analytical Method**	C,F,M	41962601
63-2	**Color**	C,F,M	41962601
63-3	**Physical State**	C,F,M	41962601
63-4	**Odor**	C,F,M	41962601
63-5	**Melting Point**	C,F,M	41962601
63-6	**Boiling Point**	C,F,M	41962601
63-7	**Density**	C,F,M	41962601
63-8	**Solubility**	C,F,M	41962601
63-9	**Vapor Pressure**	C,F,M	41962601
63-10	**Dissociation Constant**	C,F,M	41962601
63-11	**Octanol/Water Partition**	C,F,M	41962601
63-12	**pH**	C,F,M	41962601
63-13	**Stability**	C,F,M	41962601
63-14	**Oxidizing/Reducing Action**		

Data Supporting Guideline Requirements for the Reregistration of p-Choloro-m-cresol

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**		
63-16	**Explodability**		
63-17	**Storage stability**		
63-18	**Viscosity**		
63-19	**Miscibility**		
63-20	**Corrosion characteristics**		
63-21	**Dielectric breakdown volt**		
64-1	**Submittal of Samples**		
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	C,F,M	42692401
71-2A	**Avian Dietary - Quail**	C,F,M	42692402
72-1C	**Fish Toxicity Rainbow Trout**	C,F,M	42692403
72-2A	**Invertebrate Toxicity**	C,F,M	42692404
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	C,F,M	71335
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	C,F,M	75492
81-3	**Acute Inhalation Toxicity - Rat**		
81-4	**Primary Eye Irritation - Rabbit**	C,F,M	48548, 109649
81-5	**Primary Dermal Irritation - Rabbit**	C,F,M	48548, 109649
81-6	**Dermal Sensitization - Guinea Pig**	C,F,M	78837

Data Supporting Guideline Requirements for the Reregistration of p-Choloro-m-cresol

REQUIREMENT		USE PATTERN	CITATION(S)
82-1A	**90-Day Feeding - Rodent**	C,F,M	124844
82-2	**21-Day Dermal - Rabbit/Rat**	C,F,M	62905
83-1A	**Chronic Feeding Toxicity - Rodent**	C,F,M	42784801
83-2A	**Oncogenicity - Rat**	C,F,M	42784801
83-3A	**Developmental Toxicity - Rat**	C,F,M	42292901
84-2A	**Gene Mutation (Ames Test)**	C,F,M	42199901, 41548601
84-2B	**Structural Chromosomal Aberration**	C,F,M	42005201, 41598101
84-4	**Other Genotoxic Effects**	C,F,M	42163201, 41548602
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
233	**Estimation of Dermal Exposure at Indoor Sites**	C,F,M	41412201, 42587501
234	**Estimation of Inhalation Exposure at Indoor Sites**	C,F,M	41412201, 42587501

GUIDE TO APPENDIX C

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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MRID	CITATION

00062905 Rutter, H.A., Jr.; Dewey, J.M.; Wolfe, G.W.; et al. (1980) Subchronic Dermal Study in Rabbits: Preventol CMK: Toxicology Report No. 109. Rev. final rept. (Unpublished study received Dec 4, 1980 under 39967-1; prepared by Hazleton Laboratories Ameriknown admin. no.; CDL:223571-A)

00048548 Lamb, D.W.; Matzkanin, C.S. (1976) The Eye and Dermal Irritancy of Mobay Sample, p-Chloro-m-cresol: Report No. 50847. (Unpublished study received Jan 24, 1977 under 39967-1; submitted by Mobay Chemical Corp., Pittsburgh, Pa.; CDL:227654-C)

00071335 Hixson, E.J.; Lamb, D.W.; English, T.D.; et al. (1981) Acute Oral Toxicity of PCMC (p-Chloro-m-cresol) to Rats: Study No. 80-011-14. (Unpublished study received Jan 26, 1981 under 39967-1; submitted by Mobay Chemical Corp., Pittsburgh, Pa.; CDL:244164-A)

00075492 Hazleton Laboratories America, Incorporated (1979) Final Report: Acute Dermal Administration in Male and Female Rabbits: Project No. 339-108. (Unpublished study received Mar 16, 1981 under 39967-1; submitted by Mobay Chemical Corp., Pittsburgh, Pa.; CDL:244849-A)

00078837 Bomhard, E.; Loeser, E.; Lorke, D. (1981) Preventol CMK: Evaluation To Determine the Sensitization Effect by Means of the Open Epicutaneous Test: Report # 9447. A translation of: Preventol CMK: Untersuchungen auf sensibilisierende Wirkung im offenen Epikutan-Test. (Unpublished study, including German text, received Jul 1, 1981 under 39967-1; prepared by Bayer, AG, West Germany, submitted by Mobay Chemical Corp., Pittsburgh, Pa.; CDL: 245551-B)

00078838 Herbold, B.; Lorke, D. (1980) Preventol CMK: Salmonella/Microsome Test for Detection of Point Mutagenic Effects: Report No. 9122. A translation of: Preventol CMK: Salmonella/Mikrosomen-test zur Untersuchung auf Punktmutagen Wirkung. (Unpublished study, including German text, received Jul 1, 1981 under 39967-1; prepared by Bayer, AG, West Germany, submitted by Mobay Chemical Corp., Pittsburgh, Pa.; CDL:245551-C)

00109649 Thyssen, J. (1978) Tests Regarding Skin and Mucosa Tolerance: Preventol CMK. (Unpublished study received Jun 13, 1979 under 39967-1; Submitted by Mobay Chemical Corp., Pittsburgh, PA; CDL: 238740-E) 00124844 Eiben, R.; Bomhard, E.; Loeser, E.; et al. 1981 (Preventol CMK: Subchronic Toxicological Tests on Rats: 3-month Feeding Test: Report # 10283. (Unpublished study received Sep 20, 1982 under 39967-1; prepared by Bayer Toxicological Institute, W Ger., submitted by Mobay Chem. Corp. Pittsburgh, PA. CDL: 248361-A)

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MRID	CITATION
41548601	Lehn, H. (1989) Parachlorometacresol (Preventol CMK): Mutagenicity Study for the Detection of Induced Forward Mutations in the CHO-HGPRT Assay in vitro: Lab Report No.: T1029785; 17755. Unpublished study prepared by Bayer AG, Dept. of Toxicology. 36 p.
41548602	Cifone, M. (1988) Parachlorometacresol (Preventol CMK) in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay: HLA Study No.: 10285-0-447: Sponsor Study No.: T3027707. Unpublished study prepared by Hazleton Laboratories America, Inc. 30 p.
41598101	Herbold, B. (1990) Preventol CMK: Micronucleus Test on the Mouse: Lab Project Number: T 3033061. Unpublished study prepared by Bayer Ag. 45 p.
42005201	Herbold, B. (1991) Preventol CMK: Micronucleus Test on the Mouse: Supplement to: Lab Project Number: 18686A: T 3033061. Unpublished study prepared by Bayer Ag. 12 p.
42163201	Van Goethem, D. (1991) Mutagenicity Test on Preventol CMK in the in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay: Lab Project Number: 10285-0-447: T3027707. Unpublished study prepared by Hazleton Labs America, Inc. 6 p.
42199901	Herbold, B. (1991) Preventol CMK: Salmonella/Microsome Test: Lab Project Number: T 4038030. Unpublished study prepared by Bayer AG. 45 p.
42292901	Bartman, K. (1991) Parachlorometacresol (Preventol CMK); Study for Embryonic Effects in the Rats after Oral Administration: Lab Project Number: T3038066: 20869. Unpublished study prepared by Bayer AG, Wuppertal. 250 p.
42587501	Popendorf, W.; Selim, M. Kross, B. (1992) Chemical Manufacturers Association Antimicrobial Exposure Assessment Study: Second Replacement to MRID 41761201: Lab Project Number: Q626. Unpublished study prepared by the University of Iowa. 316 p.
42692401	Hancock, G. (1993) Preventol CMK: An Acute Oral LD50 with Bobwhite Quail: Lab Project Number: PR711701: 105005. Unpublished study prepared by Miles Inc. 24 p.
42692402	Hancock, G. (1993) Preventol CMK: A Subacute Dietary LC50 with Bobwhite Quail: Lab Project Number: PR721701: 105006. Unpublished study prepared by Miles Inc. 44 p.

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42692403 Gagliano, G.; Bowers, L. (1993) Acute Toxicity of Preventol CMK Technical to the Rainbow Trout (Oncorhynchus mykiss) Under Static Renewal Conditions: Lab Project Number: PR812201: 105020. Unpublished study prepared by Miles Inc. 48 p.

42692404 Gagliano, G.; Bowers, L. (1993) Acute Toxicity of Preventol CMK Technical to the Waterflea (Daphnia magna) Under Static Conditions: Lab Project Number: PR820701: 105021. Unpublished study prepared by Miles Inc. 45 p.

42784801 Leser, K. (1993) Preventol CMK: Chronic Toxicity and Carcinogenicity Study in Wistar Rats: Lab Project Number: T9030673: 22168. Unpublished study prepared by Bayer Ag Institute of Industrial Toxicology. 1359 p.

The Merck Index, Ninth Edition

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list

of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICESISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed

schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also

inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the

requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

    a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

    b. fulfill the commitment to develop and submit the data as required by this Notice; or

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an “existing stocks” provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution,

and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

P-CHLORO-M-CRESOL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing p-Chloro-m-cresol.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of p-Chloro-m-cresol. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this p-Chloro-m-cresol Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for p-Chloro-m-cresol are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on p-Chloro-m-cresol are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible p-Chloro-m-cresol products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Emily Mitchell at (703) 308-8583.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Emily Mitchell
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **p-Chloro-m-cresol**

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and

only if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or

Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you

have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

EPA'S BATCHING OF P-CHLORO-M-CRESOL PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing p-chloro-m-cresol as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the

choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Three active products containing p-chloro-m-cresol have been identified, Registration Nos. 39967-8, 39967-12 and 49403-19. All three products contain greater than 99% p-chloro-m-cresol; two are identified as technicals and one is identified as a ready-to-use solution. They are all considered to be in the same batch. The data reviewed and considered acceptable in the RED chapter will support all three products. However, as noted in the chapter, and acute inhalation study, or an acceptable data waiver request is still required.

Table 1

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	13808-7	1.0	Liquid
	35975-4	1.0	Liquid
	35978-8	1.0	Liquid
	39508-2	1.0	Liquid
	46779-1	1.0	Liquid
	56228-22	1.0	Liquid

The following table lists a product that was either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. The registrant of this product is responsible for meeting the acute toxicity data requirements separately.

Table 2 (No Batch)

EPA Reg. No.	% Active Ingredient	Formulation Type
56228-26	90.0	Solid

Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

United States Environmental Protection Agency
Washington, D.C. 20460

Certification of Offer to Cost Share in the Development of Data

Form Approved OMB No. 2070-0106, 2070-0057 Approval Expires 3-31-99

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below:

Company Name	**Company Number**

Product Name	**EPA Reg. No.**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firms on the following date(s):

Name of Firm(s)	**Date of Offer**

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	**Date**

Name and Title (Please Type or Print)

EPA Form 8570-32 (5/91) Replaces EPA form 8580 which is obselete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires
3-31-99

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for p-Chloro-m-cresol 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 Emily Mitchell at (703)-308-8583.

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 p-Chloro-m-cresol.

The following documents are part of the Administrative Record for p-Chloro-m-cresol 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