

1 MAR 1994

Ms. Christina L. Cocciardo
 Miles, Inc.
 Mobay Road
 Pittsburgh, PA 15205-9741

Subject: Parachlorometacresol
 EPA Registration No. 39967-8
 Your Resubmission of May 14, 1993

The materials forwarded to EPA in response to the Agency's letter of April 21, 1993 concerning an alternate formulation for the subject product and revised labeling has completed review. The following comments are a result of this review.

Product Chemistry

1. The proposed alternate "pelletized" formulation for this registration is acceptable. The submitted chemical identity of "Baysilone Fluid M 100", the pelletizing agent of the proposed alternate formulation, is satisfactory. A pesticide code has been assigned to this component and has been recorded in the product file.

2. For the Agency's records, please submit updated Confidential Statements of Formula (CSFs) for the both the alternate and basic formulations used for this product. Please enter the amount and the certified limits for each intentionally added component to the formulation and for the impurities present in the technical grade material.

Product Labeling

The revised product labeling, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. Submit five copies of the finished printed labeling which incorporates these comments into the text before you release the product for shipment.

CONCURRENCES

SYMBOL	7555						
SURNAME	Zappala						
DATE	1 MAR 1994						

1. In the Storage and Disposal statement, revise the "Pesticide Disposal" instructions to read: "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use in accordance with label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative of your EPA Regional Office for guidance." (Note that 4-chloro-m-cresol is a RCRA List "F" Toxic Commercial Pesticide Product Active Ingredient.)

2. Revise the statement on page 2 of the draft label "See Technical Information Sheet No. 121 for use directions" to "See Technical Information Sheet No. 121 for suggested/recommended uses." The Agency apologizes for not bringing this matter to your attention earlier.

3. Please note that the net contents of the container should be declared on the product label or on the container.

4. The collateral labeling entitled "Technical Information Sheet No. 121" enclosed with this amendment application in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comment listed below. A stamped copy is enclosed for your records. Submit five copies of the finished, printed collateral labeling which incorporate this comment into the text before you release the product for shipment.

a. On page one of the collateral labeling underneath the product name "Parachlorometacresol (PCMC)" insert the statement: "For Manufacturing Use Only".

If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,



Ruth G. Douglas
 Product Manager (32)
 Antimicrobial Program Branch
 Registration Division (7505C)

3-78

U. S. Label

Reason for Issue: To propose an amendment to market the alternate formulation, "Pellets."
To propose an amendment to add the uses "Metalworking Fluids" and "Disinfection" to the label.

Date of Draft: May 4, 1993

EPA Reg. No.: 39967-8

TO BE PRINTED AS A SINGLE PANEL

Parachlorometacresol (PCMC)

N-121

DRAFT

Active Ingredient:

Parachlorometacresol.....99.9%

Inert Ingredients:.....0.1%

DANGER • KEEP OUT OF REACH OF CHILDREN • SOLD FOR MANUFACTURING USE ONLY

FOR INFORMATION ONLY
in EPA Letter D-93-001

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER**

1 MAR 1994
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 39967-8

CORROSIVE: Causes severe eye and skin damage. Do not get in eyes, skin or on clothing. May be fatal if swallowed or absorbed through skin. Precautions should include the use of eye shields, rubber gloves and protective clothing. Do not breathe spray dust. Use with adequate ventilation. Wash thoroughly after handling. In case of severe burns medical attention should be obtained immediately. Remove and wash contaminated clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS

May be allergenic, avoid skin contact. (Gleason, Gosselin, Hodge: Clinical Toxicity of Commercial Products: Williams & Wilkings: 2nd Edition 1963)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Do not induce vomiting. Drink large quantities of fluid and call a physician immediately.

IF ON SKIN: Wash thoroughly with soap and water for at least 15 minutes.

IF IN EYES: Hold the lids open and flush immediately with a slow stream of water: continue this procedure for 15 minutes.

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DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Only for formulation as a preservative against bacteria for the (1) following uses:

Adhesives, Joint Cements, Latex Emulsions, Leather

(2) uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

(3) uses for experimental purposes that are in compliance with U. S. EPA requirements.

MILES INC. DISCLAIMS ALL LIABILITY BASED ON BREACH OF WARRANTY, NEGLIGENCE, STRICT TORT LIABILITY OR ANY OTHER THEORY OF LIABILITY FOR ANY INJURIES, DAMAGES, OR FAILED EFFICACY RESULTING FROM THE USE OF THIS MILES INC. PRODUCT AS AN INGREDIENT IN ANY FORMULATION WITH A USE NOT SPECIFICALLY LISTED IN ITEM (1) UNDER "DIRECTIONS FOR USE" ON THIS LABEL.

REFORMULATORS AND REPACKAGERS OF THIS PRODUCT MUST OBTAIN THEIR OWN REGISTRATIONS FROM THE ENVIRONMENTAL PROTECTION AGENCY.

See Technical Information Sheet No. 121 for use directions.

ADDITIONAL
with COMMENTS
to EPA Letter Dated:

1 MAR 1996

STORAGE AND DISPOSAL

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

PROHIBITIONS. Do not contaminate water, food or feed by storage or disposal.

399678

PESTICIDE DISPOSAL. Pesticide, spray mixture, rinsate or waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

STORAGE INSTRUCTIONS. Product should be stored in an area that is not subject to extreme temperatures. Proper protective equipment, as indicated above, should be worn when opening, transferring, and using product. Close drum tightly when not in use. Spill-leak procedures and additional handling information is contained on the material safety data sheet.

BEST AVAILABLE COPY

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NET CONTENTS 110 LBS.
EPA REGISTRATION NUMBER 39967-8
EPA ESTABLISHMENT NUMBER 39967-WG-002

Hazardous Material Identification System

CAS No. 59-50-7
HEALTH 2
FLAMMABILITY 1
REACTIVITY 1
PERSONAL
PROTECTION E

IN CASE OF EMERGENCY, CALL CHEMTREC 800-424-9300

MILES INC.
ORGANIC PRODUCTS DIVISION
Mobay Road
Pittsburgh, PA 15205-9741

DRAFT

APPROVED
with COMMENTS
in EPA Letter Draft

MAR 10 1993
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
39967-8

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Product Information

APPROVED
with COMMENTS
in EPA Lower Docket

1 MAR 1994

TECHNICAL INFORMATION SHEET NO. 121

Under the Federal Insecticide, Fungicide, and Herbicide Act as amended, for the pesticide registered under EPA Reg. No. 39967-8

PARACHLOROMETACRESOL (PCMC)

E.P.A. Reg. No. 39967-8

DRAFT

PRODUCT: Parachlorometacresol (PCMC) is a high purity chemical suggested as a preservative against bacterial deterioration for industrial water based compositions, such as adhesives, joint cements and latex emulsions to impart package stability, and leather at all stages of production. When Miles PCMC is used at the recommended levels, the shelf life of the unopened package is a minimum of twelve (12) months. After opening the package the duration of effectiveness should be maintained for the useful service life of the product.

Parachlorometacresol, Miles PCMC, is approved for use under Title 21, Chapter 1, Food and Drug Administration, Department of Health and Human Services, Subpart B, Section 175.105, as a preservative component of adhesives intended for use in packaging, transporting or holding of food. It is also approved for use under Section 178.3120 as a preservative in the manufacture of animal glue intended for use in packing, processing, preparing, treating, packaging, transporting, or holding of food.

THE EXACT CONCENTRATION OF MILES PCMC REQUIRED WILL VARY WITH THE COMPOSITION TO BE PROTECTED. FOR SPECIFIC RECOMMENDATIONS, PLEASE CONTACT MILES INC. MICROBIOLOGICAL ASSAY CAN DETERMINE THE LEVEL REQUIRED FOR YOUR PARTICULAR FORMULA AND DESIRED END USE. THE MILES INC. LABORATORIES ARE READY TO SUPPLY THIS GUIDANCE.

RECOMMENDED USE: The following concentration of Miles Parachlorometacresol must be used to provide preservative efficiency:

Adhesives:	Effective Concentration
Polyvinyl acetate	0.05-0.075%
Polyvinyl alcohol	0.05-0.075%
Acrylic	0.05-0.075%
Casein	0.1-0.15%
Dextrin	0.075-0.1%
Hydroxyethyl cellulose	0.05-0.075%
Methyl cellulose	0.05-0.075%
Styrene butadiene	0.05-0.075%

The weight of Miles PCMC to be used is based on the total weight of the formulation. The preservative should be incorporated into the adhesive formulation just following the initial addition of water.

Joint Cements: Effective Concentration

Paste type, vinyl latex	0.075-0.15%
Paste type, protein	0.075-0.15%

The weight of Miles PCMC to be used is based on the total weight of formulation. The preservative should be incorporated into the joint cement formulation just following the initial addition of water or other liquid components sufficient to disperse the PCMC.

Latex Emulsion: Effective Concentration

Acrylic	0.05-0.075%
Polyvinyl acetate	0.05-0.075%
Vinyl acrylic	0.05-0.75%
Styrene butadiene	0.05-0.75%

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The weight of PCMC to be used is based on the total weight of formulation. The preservatives should be post-added to the emulsion following the cool-down cycle.

Leather: Effective Concentration

Pickle solutions and pickled hides	0.15-0.25%
Chrome leather calculated on Leather pelt weight	0.1-0.2%
Pasting adhesives	0.05-0.1%
Leather pigment finishes	0.2-0.4%

REGISTERED WITH COMMISSIONER IN EPA Letter D-2626

1 MAR 1994
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 39967-8

PCMC may be dissolved in five times the amount of alcohol and then stirred into pickle solutions. In the case of chrome leather, an effective protection against mold attack may be obtained without additional labor by stirring PCMC together with soda into the basifying solution, since PCMC dissolves freely in the alkaline solution.

The oil-soluble PCMC can also be dissolved in the fat liquor and applied in the drum simultaneously. Finished vegetable-tanned leathers and chrome leathers may also be protected against mold attack by a treatment on both sides of the material with an 0.2% - 0.4% solution of Miles PCMC.

SPECIFICATIONS:

Active content (nominal concentration)	99.9%
Physical form	crystalline solid
Boiling Point (760mm)	230.5°C
Boiling Point (10mm)	111.0°C
Melting Point	63-64°C
Solubility	soluble in most organic solvents, limited solubility in water
Specific Gravity	1.215
Apparent Density	loose 0.88/
Stamped	0.912

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DANGER: MAY BE ALLERGENIC, AVOID SKIN CONTACT. "MAY BE FATAL IF SWALLOWED OR ABSORBED THROUGH SKIN! MAY PRODUCE SEVERE BURNS! DO NOT GET IN EYES, ON SKIN OR ON CLOTHING. AVOID BREATHING SPRAY MIST. WASH THOROUGHLY AFTER HANDLING."

NOTICE: This product is for industrial use only by persons having technical skill in formulating coatings, adhesives, elastomers, paints, and the like. MILES INC. MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE GOODS. WHEN NOT USED IN STRICT ACCORDANCE WITH DIRECTIONS AND RECOMMENDATIONS GIVEN HEREWITH. Recommendations for the use of this product are based on laboratory tests that Miles considers to be reliable. The performance of this product is dependent on many formulation factors which may vary from manufacturer to manufacturer. Miles is not responsible for results when the product is used with incompatible or contaminated raw materials; when the product is used under unsanitary conditions; or when manufacturing equipment is constructed of such raw materials as to inactivate the product. Under no circumstances will Miles be liable for consequential damages or damages to anyone in excess of the purchase price of the product. User assumes all risks of use, storage, and handling, not in strict accordance with the precautionary statements and storage recommendations on the labeling.

REFORMULATORS AND REPACKAGERS OF THIS PRODUCT MUST OBTAIN THEIR OWN REGISTRATIONS FROM THE ENVIRONMENTAL PROTECTION AGENCY.

DRAFT

**APPROVED
with COMMENTS
to EPA Letter Dated:**

21 MAR 1984

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
59967-8**

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