

39967-12

11/10/2008

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 10, 2008

Heather F. Collins
Regulatory Affairs specialist
LANXESS Energizing Chemistry
111 RIDC West Park Drive
Pittsburgh, PA 15275-1112

Subject: Product Name: Preventol CMK Preservative
EPA Reg. Number: 39967-12
Application Date: 06-Oct-2008
Receipt Date: 14-JOct-2008

Dear Ms. Collins:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable for the following reason(s):

Proposed Amendment:

- Add NSF Registration Number, Category Code, and Registration Mark to label;
- Update basic Confidential Statement of Formula (CSF).

General Comments:

Please provide the FDA 21 CFR citation which shows the approval of the active ingredient "4-Chloro-3-cresol [**PC Code:** 064206] [**CAS #:** 59-50-7]" for use as an antimicrobial preservative lubricant for incidental food contact.

Other Comments:

The CSF dated 10/09/08 is acceptable.

If you have further questions concerning this letter, please contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epa.gov or Lisa Mckelvin by telephone at (703) 308-7496 or by email at mckelvin.lisa@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Adam Heyward", written over a horizontal line.

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Preventol[®] CMK Preservative

FOR THE PRESERVATION OF ADHESIVES, GLUES, JOINT CEMENTS, POLYMER DISPERSIONS AND EMULSIONS, METALWORKING/CUTTING FLUIDS, DYES, INDUSTRIAL LUBRICANTS, PIGMENTS AND FILLER SUSPENSIONS, MATERIALS IN THE BUILDING INDUSTRY (E.G., CONCRETE ADDITIVES, JOINT CEMENTS), PAINT AND COATINGS, PAPER, TEXTILE, PHOTO, OIL INDUSTRIES AND LEATHER AT ALL STAGES OF PRODUCTION.

ACTIVE INGREDIENT: *p*-Chloro-*m*-cresol -----99.9%
INERT INGREDIENTS -----0.1%
TOTAL -----100.0%

KEEP OUT OF REACH OF CHILDREN DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! Corrosive: Causes irreversible eye damage or skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Do not breathe dust. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wear protective eye wear (goggles, face shield, or safety glasses). Wear protective clothing with a long sleeved shirt, long pants, socks, shoes, chemical resistant gloves, and an apron. Wash thoroughly with soap and water after handling and before eating, smoking, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse. Follow manufacturer's instructions for cleaning/maintaining personal protective equipment (PPE): if no such instructions, for washables use detergent and hot water. Keep and wash PPE separately from other laundry.

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told by the poison control center or doctor.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

The LANXESS Pittsburgh Emergency Response Telephone Number is 800-410-3063. Have the product container with you when calling a poison control center or doctor or when going for treatment.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. 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.

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

EPA REGISTRATION NUMBER: 30967-12

EPA ESTABLISHMENT NUMBER:

LANXESS

LANXESS Corporation

111 RIDC Park West Drive • Pittsburgh, PA 15275-1112

DIRECTIONS FOR USE

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

Detailed information on physical and chemical properties and other detailed directions for use can be found in the Preventol CMK Preservative Technical Information Sheet. Obtain and read this information before undertaking the use of Preventol CMK Preservative in order to avoid process mistakes.

STORAGE AND DISPOSAL

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

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

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

CONTAINER DISPOSAL: Completely empty liner. Empty residue into application equipment. Dispose of liner in a sanitary landfill, by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

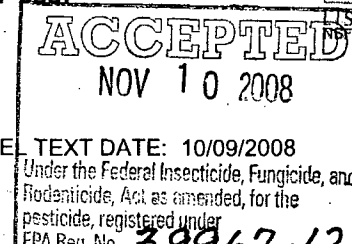
Handle and open container in a manner as to prevent spillage. If the container is leaking, invert to prevent leakage. If the container is leaking or material is spilling for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed above.

* Preventol is a registered trademark of LANXESS Corporation

INTERNATIONAL 703-527-3887

Net Contents:

Lot No.:



LABELED DATE: 10/09/2008
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 30967-12

b/e

LANXESS

Energizing Chemistry

DIRECTIONS FOR USE

PREVENTOL[®] CMK Preservative

EPA Registration Number: 39967-12

CAS# 59-50-7

PREVENTOL CMK Preservative
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The weight of PREVENTOL CMK Preservative to be used is based on the total weight of the adhesive formulation. The preservative should be incorporated into the adhesive formulation just following the initial addition of water. The adhesive formulation should be stirred to ensure homogeneous distribution.

In many cases, PREVENTOL CMK Preservative is best pre-dissolved in suitable solvent systems such as ethanol or 1,2-propanediol, or by preparation of the preservative in an aqueous caustic soda stock solution to be added to the glues and adhesives to be preserved. In the production of dry glues, PREVENTOL CMK Preservative should be added toward the end of thickening in order to minimize any losses of active substance. A 30% by weight stock solution of PREVENTOL CMK Preservative is prepared as follows: 1.85 liters of water and 0.5 kg of 50% caustic soda solution are added to 1 kg of PREVENTOL CMK Preservative and mixed until homogeneous. The dissolving process can be accelerated by gentle heating. Independent of the method chosen, the preservative must be evenly distributed throughout the adhesive or glue to be preserved in order to achieve satisfactory results.

JOINT CEMENTS:	EFFECTIVE CONCENTRATION
Vinyl latex based	0.075 - 0.20%
Protein based	0.075 - 0.20%
Other joint cement materials	0.075 - 0.20%

The weight of PREVENTOL CMK Preservative to be used is based on the total weight of the joint cement 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 preservative. To ensure homogeneous distribution, good stirring is recommended.

POLYMER DISPERSIONS: AND EMULSIONS	EFFECTIVE CONCENTRATION
Acrylic	0.05 - 0.20%
Polyvinylacetate (PVA)	0.05 - 0.20%
Vinyl/Acrylic	0.05 - 0.20%
Styrene Butadiene (SBR Latex)	0.05 - 0.20%
Other Polymer emulsions	0.05 - 0.20%

PREVENTOL CMK Preservative should be added immediately after the preparation of the polymer dispersion or emulsion during the cooling process. Losses of active ingredient caused by elevated temperatures should be taken into account and avoided by suitable measures. For quick homogeneous distribution, PREVENTOL CMK Preservative should be dissolved in suitable solvents such as ethanol, or 1,2-propanediol, or, alternatively by preparation of water dilutable alkaline solutions. These pre-dissolved solutions are then added to the polymer dispersions or emulsions.

LEATHER:	EFFECTIVE CONCENTRATION
Pickle solutions and pickled hides	0.15 - 0.25%
Chrome leather (calculated on pelt weight)	0.10 - 0.20%
Leather pasting adhesives	0.05 - 0.10%
Leather pigment finishes	0.20 - 0.40%

PREVENTOL CMK Preservative 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 PREVENTOL CMK Preservative

together with soda into the basifying solution, since PREVENTOL CMK Preservative dissolves freely in the alkaline solution.

The oil-soluble PREVENTOL CMK Preservative 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 PREVENTOL CMK Preservative.

**LUBRICOOLANTS AND
MINERAL OIL BASED PRODUCTS:**

EFFECTIVE CONCENTRATION

Straight oils (Mineral-oil based)	
(concentrates)	1.00 - 3.00%
(ready for use)	0.05 - 0.20%
Soluble oils (oil emulsions, aqueous)	
(concentrates)	1.00 - 6.00%
(ready for use)	0.05 - 0.30%
Semi-synthetic (emulsions, aqueous)	
(concentrates)	1.00 - 6.00%
(ready for use)	0.05 - 0.30%
Synthetic (solutions)	
(concentrates)	1.00 - 6.00%
(ready for use)	0.05 - 0.30%

PREVENTOL CMK Preservative can be incorporated into the original concentrate of metalworking fluids by adding the solid preservative under stirring until the preservative is completely dissolved (the compatibility of the fluid to be preserved and the preservative should be evaluated before this method is attempted). PREVENTOL CMK Preservative is equally suitable for tank side addition (maintenance). In this case, addition of the pre-dissolved preservative mixture is often more favorable. Suitable solvents for this purpose are, for example, ethanol, or 1,2-propanediol, or, alternatively by preparation of water dilutable alkaline solutions. To achieve maximum distribution within the ready-to-use dilution of the metalworking fluid, the preservative should be dosed [at a point] in the system under conditions which ensure good circulation.

**MATERIALS IN THE
PRINTING INDUSTRY:**

EFFECTIVE CONCENTRATION

Inks	0.05 - 0.20%
Fount solutions	0.05 - 0.20%
Printing pastes	0.20 - 0.30%
Other printing materials and auxiliaries	0.05 - 0.30%

PREVENTOL CMK Preservative is incorporated preferably after pre-dissolution in suitable systems such as ethanol or 1,2-propanediol, or alternatively by preparing water dilutable alkaline solutions, which are added to the products to be preserved. Stirring is recommended to achieve homogeneous distribution of the preservative.

MATERIALS IN THE BUILDING INDUSTRY:

EFFECTIVE CONCENTRATION

Bitumen emulsions	0.15 - 0.40%
Concrete additives	0.15 - 0.40%
Other building materials and auxiliaries	0.15 - 0.40%

PREVENTOL CMK Preservative can be added directly to concrete additive solutions having an alkaline pH-value. The additive solution should be stirred well to dissolve the preservative material efficiently. In the case of neutral or acid concrete additives, it is preferable to incorporate PREVENTOL CMK Preservative first by dissolving it in a suitable solvent such as ethanol or 1,2-propanediol or by converting it to a water dilutable alkaline concentrate. In this pre-dissolved form PREVENTOL CMK Preservative can easily be incorporated into the concrete additives in such a way that preservative is homogeneously distributed throughout the product.

MATERIALS IN THE COATINGS INDUSTRY:

EFFECTIVE CONCENTRATION

Dyestuff paste, knifing fillers and plastic putty	0.10 - 0.15%
Casein based coatings	0.30 - 0.40%
Paints	0.05 - 0.40%
Other auxiliaries and coating materials	0.05 - 0.40%
Synthetic resin dispersions	0.05 - 0.25%

PREVENTOL CMK Preservative can be incorporated directly into pigments and fillers for coatings applications, or it can also be dissolved in a suitable solvent to be incorporated into the make-up water during the grind. For best results, the preservative should be dispersed homogeneously throughout the paint material. Depending on the ingredients, discoloration may occur and should be evaluated before conducting lab trials.

MATERIALS IN THE PAPER INDUSTRY:

EFFECTIVE CONCENTRATION

Rosin paper sizes	0.05 - 0.15%
Filler suspensions and coating compounds	0.05 - 0.20%
Starch slurries	0.10 - 0.30%
Pigment slurries	0.05 - 0.30%
Other materials and auxiliaries	0.05 - 0.20%

PREVENTOL CMK Preservative can be metered directly into the products to be preserved following the concentrations as indicated above. Good stirring is recommended to ensure fast and even distribution of the preservative throughout the products. In many cases it might be preferable to first pre-dissolve PREVENTOL CMK Preservative in suitable solvent systems such as ethanol or 1,2-propanediol, or alternatively by preparation of water dilutable alkaline solutions which then are added to the products to be preserved. Stir well to achieve homogeneous distribution of the preservative. Losses of active ingredient at elevated temperatures should be taken into account and avoided by suitable measures.

Incorporation of PREVENTOL CMK Preservative in dry components of suspensions is possible, if temperature during grinding does not exceed 60°C.

**MATERIALS IN THE
TEXTILE INDUSTRY:**

EFFECTIVE CONCENTRATION

Spinning Preparations	0.05 - 0.15%
Sizes and finishing agents	0.10 - 0.15%
Yarn humidifiers	0.05 - 0.10%
Printing thickeners (solid)	0.05 - 2.00%
Printing thickeners (liquid)	0.10 - 0.15%
Other materials and auxiliaries	0.05 - 0.20%

PREVENTOL CMK Preservative may be incorporated into the dry thickener by evenly mixing with the preservative to result in a pre-preserved, dry product.

Alternatively, incorporation of the preservative can be done at the stage of the ready-to-use thickener solution. In this case, PREVENTOL CMK Preservative is best pre-dissolved in suitable solvents such as ethanol or 1,2-propanediol, or an aqueous caustic soda stock solution is prepared and then added to the thickener solutions to be preserved. For fast and homogeneous distribution of the preservative, stirring is recommended.

**MATERIALS IN THE
PHOTO INDUSTRY:**

EFFECTIVE CONCENTRATION

Gelatin	0.05 - 0.20%
Other materials and auxiliaries	0.05 - 0.20%

Incorporation of PREVENTOL CMK Preservative in concentrations as indicated above should be done after pre-dissolving the preservative in suitable solvent systems such as ethanol or 1,2-propanediol or others which are compatible with the individual production process.

**MATERIALS IN THE
OIL INDUSTRY:**

EFFECTIVE CONCENTRATION

Biopolymers, solid (xanthan, starch, galactomannan, etc.)	0.50 - 2.00%
Biopolymers, liquid (drilling muds)	0.05 - 0.20%
Other materials and auxiliaries	0.05 - 0.20%

PREVENTOL CMK Preservative may be incorporated into the solid by evenly mixing with the preservative to result in a pre-preserved, dry product.

Alternatively, incorporation of the preservative can be done at the stage of the ready-to-use drilling mud. In this case, PREVENTOL CMK Preservative is best pre-dissolved in suitable solvents such as ethanol or 1,2-propanediol, or an aqueous caustic soda stock solution is prepared and then added to the thickener solutions to be preserved. For fast and homogeneous distribution of the preservative, stirring is recommended.

ADDITIONAL MATERIALS:

EFFECTIVE CONCENTRATION

Polishing and wax material	0.10 - 0.40%
Protein solutions	0.20 - 0.30%
Cleaning solutions, detergents	0.05 - 0.20%
Ceramic glazes	0.10 - 0.20%
Fire extinguishing materials	0.10 - 0.30%
Materials and auxiliaries in the leather industry	0.10 - 0.30%
Cosmetic and toiletry raw materials	0.10 - 0.30%
Industrial Lubricants	0.10 - 1.00%*

The concentration of PREVENTOL CMK Preservative as indicated is based on total weight of the products to be preserved. Depending on the type of product to be protected, PREVENTOL CMK Preservative can be incorporated either directly or after pre dissolution in suitable solvent systems such as ethanol or 1,2-propanediol, or by preparation of water dilutable alkaline solutions (e.g. in caustic soda). Independent of the method chosen, for satisfactory results, the preservative must be achieved for example, by incorporation of the preservative into the make-up water at the beginning of the production and/or generally by stirring at every appropriate production stage.

*Note: The FDA has approved this material as a Food Contact Substance with intended use at levels up to 1% as an antimicrobial preservative in lubricants that may have incidental contact with food.

The conditions of your use and application of our products, technical assistance and information (whether verbal, written or by way of production evaluations), including any suggested formulations and recommendations, are beyond our control. Therefore, it is imperative that you test our products, technical assistance and information to determine to your own satisfaction whether they are suitable for your intended uses and applications. This application-specific analysis at least must include testing to determine suitability from a technical as well as health, safety and environmental standpoint. Such testing has not necessarily been done by LANXESS Corporation. All information is given without warranty or guarantee. It is expressly understood and agreed that the customer assumes and hereby expressly releases LANXESS from all liability, in tort, contract or otherwise, incurred in connection with the use of our products, technical assistance and information. Any statement or recommendation not contained herein is unauthorized and shall not bind LANXESS. Nothing herein shall be construed as a recommendation to use any product in conflict with patents covering any material or its use. No license is implied or in fact granted under the claims of any patent.

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