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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB - 1 2010

Luanne Jeram LANXESS Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275-1112

Subject: Preventol CMK 40 EPA Registration No. 39967-25 Amendment Date: January 6, 2009 EPA Receipt Date: January 9, 2009

Dear Ms. Jeram:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

Proposed Amendment

- Addition of "industrial lubricants" to the product labeling
- Submission of data bridging argument

Conditions

Revise the label as follows:

- 1.) Revise the fifth sentence in the **Precautionary Statements** section to read, "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."
- 2.) Revise the FIRST AID section so that the statements are in the following order: "If in Eyes", "If on Skin or Clothing", "If Swallowed", and "Note to Physician".

Acceptable Data

The "Industrial Lubricants" use was approved by the Agency for EPA registration # 39967-12 (PREVENTOL CMK 40) on July 15, 2008. EPA registration # 39967-12 is formulated with the same pre-reaction active ingredient, *p*-chloro-*m*-cresol. After the reaction, the active ingredient becomes sodium *p*-chloro-*m*-cresolate. The difference is only in the way that the *p*-chloro-*m*-cresol is delivered to the system. The registrant has requested that the Agency bridge the data for these two chemicals.

Chemically, the addition of alkali (sodium hydroxide) increases the solubility of pchloro-*m*-cresol with the formation of p-chloro-*m*-cresolate salt of sodium. This in turn increases the deliverable concentration of p-chloro-m-cresol for a use site (ie: the industrial use as a lubricant). The two moieties (p-chloro-m-cresol and it's sodium salt) are likely to behave through the same mode of action, and therefore, data bridging can be done between the two chemicals.

The Agency's review of these data is enclosed.

General Comments

A stamped copy of the labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email at <u>garvie.heather@epa.gov</u>.

Sincerely,

Jacqueline McFarlane (Acting) Product Manager (34) Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosed: Stamped Labeling; and Agency Science Review of Data Bridging (DP# 372970)

PREVENTOL[®] CMK 40

INDUSTRIAL MICROBIOCIDE: PRESERVATIVE FOR USE IN THE MANUFACTURE OF ADHESIVES AND GLUES. POLYMER DISPERSIONS AND EMULSIONS. MATERIAL IN THE LEATHER INDUSTRY (FOR THE PROTECTION OF CHROME OR VEGETABLE TANNED LEATHER), LUBRICOOLANT AND MINERAL OIL-BASED PRODUCTS, MATERIALS IN THE PRINTING INDUSTRY, BUILDING MATERIALS SUCH AS JOINT CEMENTS AND CONCRETE ADDITIVES, MATERIALS IN THE OIL INDUSTRY, PIGMENT SLURRIES, MATERIALS IN THE TEXTILE INDUSTRY. PAPER, POLISHES, WAXES, PROTEIN SOLUTIONS, CERAMIC GLAZES, FIRE EXTINGUISHING MATERIALS, CLEANING SOLUTIONS AND DETERGENTS, INDUSTRIAL LUBRICANTS

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ACTIVE INGREDIENT: Sodium p-chloro-m-cresolate	46 13%
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OTHER INGREDIENTS:	
	<u> </u>
TOTAL	100 0%
	100.070

KEEP OUT OF REACH OF CHILDREN DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! Corrosive: Causes irreversible eve damage and skin burns. Harmful if owed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear acuales or face shield, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Prolonged and repeated contact may cause an allergic reaction in some individuals.

FIRST AID

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 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. Do not give anything by mouth to an unconscious person.

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 or label with you when calling a poison control center or doctor or when going for treatment.

ENVIRONMENTAL HAZARDS

pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, punds, 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 local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS

Avoid contact with eves and skin. Avoid inhaling vapors or mists. Do not use or store near heat or open flame. Store in original containers away from food and drink. Keep containers tightly sealed. Reseal container immediately after use. Avoid unnecessary contact.

IN CASE OF EMERGENCY, CALL: CHEMTREC 800-424-9300 **EPA REGISTRATION NUMBER: 39967-25** EPA ESTABLISHMENT NUMBER:



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 40 Technical Information Sheet. Obtain and read this information before undertaking the use of PREVENTOL® CMK 40 in order to avoid process mistakes.

NOTE TO USER: For worker protection during mixing, loading and during application, wear a hat, long sleeved shirt, and long legged trousers or overalls. In addition, during mixing and loading, wear rubber or neoprene gloves and protective goggles. Protective clothing must be laundered separately following application.

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.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or 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 spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionarv 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. ACCEPTED

PREVENTOL is a registered trademark of LANXESS Corporation the COMMENTS

INTERNATIONAL 703-527-3887

Net Contents:

Lot No.:

in EPA Letter Doted:

FEB 2010

Inder the Federal Inse-rungicide, and Rodenticide Acru-amended, for the pesticide, registered under EPA Reg. No. 399967-25

LABEL TEXT DATE: 1/21/2010

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LANXESS Energizing Chemistry

PRODUCT INFORMATION

PREVENTOL[®] CMK 40

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EPA Registration Number: 39967-25 CAS#: 15733-22-9

PRESERVATIVE FOR USE IN THE MANUFACTURE OF ADHESIVES AND GLUES, POLYMER DISPERSIONS AND EMULSIONS, MATERIAL IN THE LEATHER INDUSTRY (FOR THE PROTECTION OF CHROME OR VEGETABLE TANNED LEATHER), LUBRICOOLANT AND MINERAL OIL-BASED PRODUCTS, MATERIALS IN THE PRINTING INDUSTRY, BUILDING MATERIALS SUCH AS JOINT CEMENTS AND CONCRETE ADDITIVES, MATERIALS IN THE OIL INDUSTRY, PIGMENT SLURRIES, MATERIALS IN THE TEXTILE INDUSTRY, PAPER, POLISHES WAXES, PROTEIN SOLUTIONS, CERAMIC GLAZES, FIRE EXTINGUISHING MATERIALS, CLEANING SOLUTIONS AND DETERGENTS, INDUSTRIAL LUBRICANTS.

Directions for use

ADHESIVES AND GLUES

The weight of PREVENTOL[®] CMK 40 to be used is based on the total weight of the adhesive formulation. PREVENTOL[®] CMK 40 can be metered directly into the products to be preserved following the concentrations as indicated below. Stir to achieve fast and homogeneous distribution throughout the entire product. In the production of dry glues, add PREVENTOL[®] CMK 40 toward the end of thickening in order to minimize any losses of active substance.

EFFECTIVE CONCENTRATION

Bone glues	0.25 – 0.40 %
Skin glues	0.40 – 0.75 %
Casein containing glues	0.45 – 0.90 %
Other animal glues	0.25 – 0.90 %
Starch based glues (liquid)	0.25 – 0.60 %
Methyl Cellulose adhesives	0.40 – 0.60 %
Other plant based adhesives	0.25 – 0.60 %
Polyvinyl alcohol adhesives	0.25 – 0.60 %
Acrylic adhesives	0.25 – 0.60 %
Styrene butadiene adhesives	0.25 – 0.60 %
Other adhesive emulsions	0.25 – 0.60 %
Gumarabic and similar adhesives	0.30 – 0.55 %

POLYMER DISPERSIONS AND EMULSIONS

Add PREVENTOL[®] CMK 40 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. Stir to ensure fast and homogenous distribution of the preservative throughout the product.

EFFECTIVE CONCENTRATION

Acrylic	0.25 – 0.60 %
Polyvinylacetate (PVAc)	0.25 – 0.60 %
Styrene Butadiene (SBR Latex)	0.25 – 0.60 %
Other polymer emulsions	0.25 – 0.60 %

LEATHER

The weight of PREVENTOL[®] CMK 40 to be used is based on total weight of the product to be protected. Meter PREVENTOL[®] CMK 40 can be metered directly into the products to be preserved following the concentrations as indicated below. Stir to ensure fast and homogenous distribution of the preservative throughout the products.

In the case of chrome leather, incorporate PREVENTOL[®] CMK 40 into the basifying solution as an effective protection against mold attack.

EFFECTIVE CONCENTRATION

Pickle solutions and pickled hides	0.40 – 0.60 %
Chrome leather (on pelt weight)	0.25 – 0.60 %
Leather pasting adhesives	0.25 – 0.60 %
Leather pigment finishes	0.45 – 1.00 %

METAL WORKING FLUIDS

PREVENTOL[®] CMK 40 can be incorporated into the original concentrate of metalworking fluids. However, the compatibility with the fluid to be preserved must be evaluated before this method is attempted. PREVENTOL[®] CMK 40 is equally suitable for tank-side addition.

To achieve fast distribution within a ready-to-use dilution of a metalworking fluid, dose the preservative at a point in the system where good circulation is provided. Pre-dissolution in water may improve distribution.

EFFECTIVE CONCENTRATION

Straight oils (Mineral-oil	based)	
U	(concentrates)	3.0 – 7.5 %
	(Preliminary testing for compati	tibility is essential)
	(ready for use)	0.3 – 0.75%
Soluble oils (oil emulsio	ns, aqueous)	
	(concentrates)	2.50 – 15 %
	(Preliminary testing for compare	
	(ready for use)	0.125 – 0.75 %
Semi-synthetic (emulsic	ons, aqueous)	
-	(concentrates)	2.50 – 15 %
	(Preliminary testing for compare	tibility is essential)
	(ready for use)	0.125 – 0.75 %
Synthetic (solutions)	· · · ·	
	(concentrates)	2.50 – 15 %
	(Preliminary testing for compati	tibility is essential)
	(ready for use)	0.125 – 0.75 %

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MATERIALS IN THE PRINTING INDUSTRY

The weight of PREVENTOL[®] CMK 40 to be used is based on total weight of the product to be protected. Meter PREVENTOL[®] CMK 40 can be metered directly into the products to be preserved following the concentrations as indicated below. Stir to ensure fast and homogenous distribution of the preservative throughout the product.

EFFECTIVE CONCENTRATION

Inks	0.25 – 0.60 %
Fount solutions	0.25 – 0.60 %
Printing pastes	0.45 – 0.75 %
Other printing materials and auxiliaries	0.25 – 0.75 %

MATERIALS IN THE BUILDING INDUSTRY

The weight of PREVENTOL[®] CMK 40 to be used is based on the total weight of the product to be preserved. The preservative is best incorporated into the materials just following the initial addition of water or other liquid components sufficient to dissolve the preservative. If incorporation happens at later production stages, stir to ensure homogeneous distribution of the preservative throughout the product.

EFFECTIVE CONCENTRATION

Joint cements materials	0.25 – 0.60 %
Bitumen emulsions	0.40 – 1.00 %
Concrete additives	0.50 – 1.00 %
Other materials and auxiliaries	0.30 – 1.00 %

MATERIALS IN THE COATINGS INDUSTRY

The weight of PREVENTOL[®] CMK 40 to be used is based on the total weight of the coating material. The preservative is best incorporated into the products just following the initial addition of water or other liquid components sufficient to dissolve the preservative. If incorporation happens at later production stages, stir to ensure homogeneous distribution of the preservative throughout the product.

EFFECTIVE CONCENTRATION

Dyestuff paste, knifing fillers and plastic putty	0.25 – 0.45 %
Casein based coatings	0.55 – 1.00 %
Synthetic resin dispersions	0.25 – 0.60 %
Other auxiliaries and coating materials	0.25 – 1.00 %

MATERIALS IN THE PAPER INDUSTRY

Meter PREVENTOL[®] CMK 40 directly into the products to be preserved following the concentrations indicated below. Due to good water solubility the preservative can be predissolved in water if necessary. Stir to ensure fast and homogenous distribution of the preservative throughout the entire product.

EFFECTIVE CONCENTRATION

Filler suspensions and coating compounds	0.25 – 0.55 %
Rosin paper sizes	0.30 – 0.60 %
Starch slurries	0.30 – 0.75 %
Other materials and auxiliaries	0.25 – 0.75 %

MATERIALS IN THE TEXTILE INDUSTRY

Meter PREVENTOL[®] CMK 40 directly into the products to be preserved following the concentrations indicated below. Due to good water solubility the preservative can be predissolved in water if necessary. Stir to ensure fast and homogenous distribution of the preservative throughout the entire product.

In the production of dry printing thickeners, add PREVENTOL[®] CMK 40 toward the end of thickening to minimize any loss of active substance.

EFFECTIVE CONCENTRATION

Printing thickeners (liquid)	0.30 – 0.60 %
Sizes and finishing agents	0.30 – 0.60 %
Yarn humidifiers	0.25 – 0.55 %
Other materials and auxiliaries	0.25 – 0.60 %

MATERIALS IN THE OIL INDUSTRY

The weight of PREVENTOL[®] CMK 40 to be used is based on the total weight of the product to be preserved. Stir to ensure fast and homogenous distribution of the preservative throughout the product. In the production of dry products, add PREVENTOL[®] CMK 40 toward the end of thickening to minimize any loss of active substance.

EFFECTIVE CONCENTRATION

Biopolymers, liquid (drilling muds) Other materials and auxiliaries 0.30 - 0.75 % 0.30 - 0.75 %

PIGMENT SLURRIES

The weight of PREVENTOL[®] CMK 40 to be used is based on the total weight of the product to be preserved. The preservative is best incorporated into the materials just following the initial addition of water or other liquid components sufficient to distribute the preservative. If incorporation happens at later product stages, stir to ensure homogeneous distribution of the preservative throughout the product. For use in Kaolin, Calcium Carbonate, Talcum, Iron oxide etc. slurries.

EFFECTIVE CONCENTRATION

Kaolin slurry	0.04 – 0.20 %
Calcium carbonate slurry	0.03 – 0.15 %
Talcum slurry	0.04 – 0.20 %
Iron oxide slurry	0.03 - 0.20 %

ADDITIONAL MATERIALS

The concentration of PREVENTOL[®] CMK 40 as indicated is based on the total weight of the products to be preserved. For satisfactory results, the preservative must be distributed evenly throughout the product.

EFFECTIVE CONCENTRATION

Polishing and wax materials	0.30 – 0.90 %
Protein solutions	0.45 – 0.75 %
Ceramic glazes	0.30 – 0.45 %
Fire extinguishing materials	0.30 – 0.75 %
Cleaning solutions, detergents	0.25 – 0.45 %
Industrial Lubricants	0.25 – 2.50 %
Industrial Lubricants with incidental food contact	0.25 – 1.00 %*

*Note: The FDA has approved p-chloro-m-cresol 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.

LANXESS Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275 412-809-1000

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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