

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 21, 2016

Sarah Plittman Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, MO 63122

Subject: Label Amendment – Updating to include Technical Information Sheet

Product Name: PREVENTOL CMK PRESERVATIVE

EPA Registration Number: 39967-12 Application Date: March 21, 2016

Decision Number: 515576

Dear Ms. Plittman:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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

Page 2 of 2 EPA Reg. No. 39967-12 Decision No. 515576

If you have any questions, please contact Stacey Grigsby by phone at 703.305.6440, or via email at grigsby.stacey@epa.gov.

Sincerely,

Stacey Grigsby Risk Manager

Stacey Grigoly

Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosure

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%

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 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.

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 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.

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 highly 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: 39967-12**

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 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 STORAGE: Product must be stored in an area that is not subject to extreme temperatures. Proper protective equipment, as indicated, must 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.

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 quidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stav 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 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.

LABEL TEXT DATE: 4/22/15

[®] Preventol is a registered trademark of LANXESS Corporation

INTERNATIONAL 703-527-3887 Net Contents: Lot/Batch No.:

Under the Federal Insecticide, Fungicide

and Rodenticide Act as amended, for th pesticide registered under EPA Reg. No. 39967-12





PREVENTOL® CMK Preservative

EPA Registration Number: 39967-12

CAS# 59-50-7

PREVENTOL® CMK Preservative

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

bacteria, mold fungi and yeast deterioration for industrial water based compositions, such as adhesives, joint cements, and latex emulsions to impart package stability, leather at all stages of production and metalworking fluids and cutting oils. The shelf life of the unopened package is a must be maintained for the useful service life of the product. minimum of twelve (12) months. PREVENTOL CMK Preservative is a high purity chemical suggested as a preservative against After opening the package the duration of the effectiveness

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL INCONSISTENT WITH ITS LABELING. OF FEDERAL LAW 7 USE SIHT PRODUCT Z ⊳ MANNER

REQUIRED WILL VARY WITH THE COMPOSITION TO BE PROTECTED. TO REACH OPTIMUM EFFECTIVENESS, FIELD TESTING MUST BE CONDUCTED, IN ADDITION TO CONTACTING YOUR LANXESS REPRESENTATIVE. MICROBIOLOGICAL ASSAY CAN DETERMINE THE LEVEL REQUIRED FOR YOUR PARTICULAR APPLICATION/USE. **EXACT** CONCENTRATION OF LANXESS PREVENTOL CMK PRESERVATIVE

provide preservative efficiency: Directions for use: The following doses of PREVENTOL CMK Preservative must be used to

ADHESIVES AND GLUES:	EFFECTIVE CONCENTRATION
Bone glues	0.10 - 0.15%
Skin glues	0.15 - 0.25%
Fish glues	0.15 - 0.25%
Leather glues	0.15 - 0.25%
Gelatin based glues	0.10 - 0.20%
Casein containing adhesives	0.20 - 0.30%
Other animal glues	0.10 - 0.25%
Starch based glues (liquid)	0.10 - 0.15%
Starch based glues (solid)	0.20 - 1.00%
Dextrin adhesives	0.05 - 0.10%
Hydroxyethyl cellulose adhesives	0.05 - 0.10%
Methyl cellulose adhesives	0.05 - 0.10%
Other plant based adhesives	0.05 - 0.25%
Polyvinyl acetate adhesives	0.05 - 0.25%
Polyvinyl alcohol adhesives	0.05 - 0.25%
Acrylic adhesives	0.05 - 0.25%
Styrene butadiene (SBR latex) adhesives	0.05 - 0.25%
Other adhesive emulsions	0.05 - 0.25%

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

soda stock solution to be added to the glues and adhesives to be preserved. In the production of dry glues, PREVENTOL CMK Preservative must 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 preservative must be evenly distributed throughout the adhesive or glue to be preserved in order dissolving process can be accelerated by gentle heating. Independent of the method chosen, the are added to 1 kg of PREVENTOL such as ethanol or 1,2-propanediol, or by preparation of the preservative in an aqueous caustic to achieve satisfactory results. In many cases, PREVENTOL CMK Preservative is best pre-dissolved in suitable solvent systems CMK Preservative and mixed until homogeneous. The

JOINT CEMENTS: **EFFECTIVE CONCENTRATION**

Other joint cement materials	Protein based	Vinyl latex based
0.075 - 0.20%	0.075 - 0.20%	0.075 - 0.20%

following the initial addition of water or other liquid components sufficient to disperse the cement formulation. The preservative must be incorporated into the joint cement formulation just The weight of PREVENTOL CMK Preservative to be used is based on the total weight of the joint To ensure homogeneous distribution, good stirring is needed

POLYMER DISPERSIONS: AND EMULSIONS	EFFECTIVE CONCENTRATION
Acrylic	0 05 - 0 20%

Other Polymer emulsions Styrene Butadiene (SBR Latex) Polyvinylacetate (PVA) 0.05 -0.05 - 0.20% 0.05 - 0.20% 0.05 - 0.20% 0.20%

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

EFFECTIVE CONCENTRATION

LEATHER:

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

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.

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. applied in the drum simultaneously. Finished vegetable-tanned leathers and chrome leathers may The oil-soluble PREVENTOL CMK Preservative can also be dissolved in the fat liquor and

MINERAL OIL BASED PRODUCTS:	EFFECTIVE CONCENTRATION
Straight oils (Mineral-oil based)	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) (ready for use)	1.00 - 6.00% 0.05 - 0.30%
Synthetic (solutions) (concentrates) (ready for use)	1.00 - 6.00% 0.05 - 0.30%
(ready for use)	0.05 - 0.30%

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 completely dissolved (the compatibility of the fluid to be preserved and the preservative must 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 must be mixed at a point in the system under conditions which ensure good circulation. maximum distribution within the ready-to-use dilution of the metalworking fluid, the preservative metalworking fluids by adding the solid preservative under stirring until the preservative is PREVENTOL CMK Preservative can be incorporated into the original concentrate

Fount solutions	Inks	PRINTING INDUSTRY:	MATERIALS IN THE
0.05 - 0.20%	0.05 - 0.20%		EFFECTIVE CONCENTRATION

Printing pastes

Other printing materials and auxiliaries

0.05 - 0.30% 0.20 - 0.30%

solutions, which are added to the products 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 needed to achieve homogeneous distribution of the preservative. PREVENTOL CMK Preservative is incorporated preferably after pre-dissolution in suitable Stirring is needed to achieve

MATERIALS IN THE BUILDING INDUSTRY:

EFFECTIVE CONCENTRATION

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

alkaline pH-value. The additive solution must 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 1,2way that preservative is homogeneously distributed throughout the product. PREVENTOL CMK Preservative can easily be incorporated into the concrete additives in such a propanediol or by converting it to a water dilutable alkaline concentrate. In this pre-dissolved form PREVENTOL CMK Preservative can be added directly to concrete additive solutions having an

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%

evaluated before conducting lab trials. throughout the paint material. Depending on the ingredients, discoloration may occur and must be water during the grind. For best results, the preservative must be dispersed homogeneously 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

MATERIALS IN THE PAPER INDUSTRY:

EFFECTIVE CONCENTRATION

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

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

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

MATERIALS IN THE Spinning Preparations TEXTILE INDUSTRY: **EFFECTIVE CONCENTRATION** 0.15%

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

Printing thickeners (solid)
Printing thickeners (liquid)
Other materials and auxiliaries

0.10 - 0.15% 0.05 - 0.10% 0.05 - 2.00% 0.10 - 0.15% 0.05 - 0.20%

Sizes and finishing agents

Yarn humidifiers

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 distribution of the preservative, stirring is needed prepared and then added to the thickener solutions to be preserved. For fast and homogeneous

MATERIALS IN THE PHOTO INDUSTRY:	EFFECTIVE CONCENTRATION
Gelatin Other materials and auxiliaries	0.05 - 0.20% 0.05 - 0.20%

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

Biopolymers, solid	
(xanthan, starch, galactomannan, etc.) Biopolymers, liquid	0.50 - 2.00%

MATERIALS IN THE

EFFECTIVE CONCENTRATION

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

Other materials and auxiliaries

0.05 - 0.20% 0.05 - 0.20%

(drilling muds)

prepared and then added to the thickener solutions to be preserved. For fast and homogeneous distribution of the preservative, stirring is needed. solvents such as ethanol or 1,2-propanediol, or an aqueous caustic soda stock solution is 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

ADDITIONAL MATERIALS: **EFFECTIVE CONCENTRATION**

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

systems such as ethanol or 1,2-propanediol, or by preparation of water dilutable alkaline solutions 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 production stage. water at the beginning of the production and/or generally by stirring at every appropriate preservative must be achieved for example, by incorporation of the preservative into the make-up The concentration of PREVENTOL CMK Preservative as indicated is based on total weight of the in caustic soda). Independent of the method chosen, for satisfactory results,

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

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.