



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 10, 2008

Luanne Jeram
Regulatory Affairs MPP
LanXESS Energizing Chemistry
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Subject: Product Name: PREVENTOL® A8 Preservative
EPA Reg. Number: 39967-13
Applications Date: 24-Mar-2008
Receipts Date: 26-Mar-2008

Dear Ms. Jeram:

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

Proposed label amendment:

- Revised labeling-Delete claim for paint use

General comment:

A copy of the stamped labeling is enclosed for your record.

Other comments:

The Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label:
http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub. If you have questions concerning electronic labeling, a list of contacts is available at the following site:
<http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts>.

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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 Stacey Grigsby by telephone at (703) 305-6440 or by email at grigsby.stacey@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,



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

Enclosure: (Stamped labeling)

Preventol[®] A8 Preservative

FUNGICIDE: FOR THE PRESERVATION OF WOOD-BASED COMPOSITE PRODUCTS, WOOD PRODUCTS INTENDED FOR ABOVE GROUND AND IN-GROUND CONTACT, PLASTICS, PAPER COATINGS FOR INDOOR, NON-FOOD CONTACT USES, GLUES, ADHESIVES, SEALANTS, AND METALWORKING FLUIDS AGAINST BIODETERIORATION.

ACTIVE INGREDIENT: TEBUCONAZOLE, α -[2-(4-Chlorophenyl)ethyl]- α -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol-----97%
INERT INGREDIENTS -----3%
TOTAL -----100.0%

KEEP OUT OF REACH OF CHILDREN WARNING!

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING! May be fatal if inhaled. Harmful if swallowed. Causes eye irritation. Do not breathe dust and avoid contact with eyes or clothing. Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID

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 SWALLOWED: Call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: No specific antidote is available. Treat symptomatically.

The LANXESS Pittsburgh Emergency Response Telephone Number is 800-410-3063

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. Protective clothing should be laundered separately following application.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to estuarine invertebrates. 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 Reg. No.: 39967-13

EPA Est. No.:

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.

Labeling directions, precautionary statements and restrictions for any other products recommended must be followed.

FOR DETAILED DIRECTIONS FOR USE, PLEASE REFER TO THE LANXESS CORPORATION LABEL SUPPLEMENT. Read these entire Directions before using Preventol A8 Preservative.

NOTE: This product is not for use in sealants or paper coatings in the state of California.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

PESTICIDE DISPOSAL: 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 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 DISPOSAL: Do not use container in connection with food, feed, or drinking water. Completely empty container into the processing equipment. Then dispose of empty container in a sanitary landfill, by incineration or, if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

When the water-soluble bags have been removed, dispose of corrugated box in a sanitary landfill, by incineration or, if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

RESTRICTIONS: Do not package Preventol A8 Preservative in metal containers.

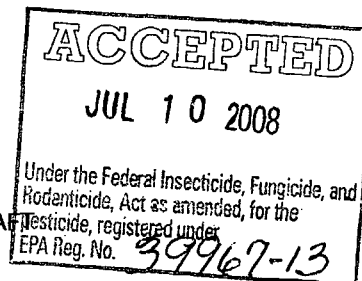
Preventol is a registered trademark of LANXESS Corporation.

INTERNATIONAL 703-527-3887

Net Contents:

Lot No.:

LABEL TEXT DATE: DRA

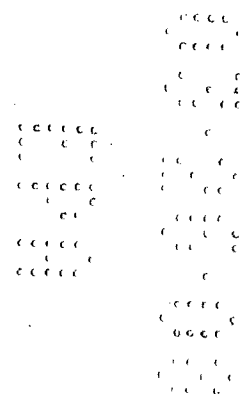


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LANXESS

Energizing Chemistry

Product Information



Preventol A8 Preservative FUNGICIDE

EPA Registration Number 39967-13
CAS Number [107534-96-3]

ACCEPTED
JUL 10 2008
Under the Federal Insecticide, Fungicide, and
Rodenticide Act as amended, for the
pesticide, registered under
EPA Reg. No. 39967-13

FOR THE PRESERVATION OF WOOD-BASED COMPOSITE PRODUCTS, WOOD PRODUCTS INTENDED FOR ABOVE GROUND AND IN-GROUND CONTACT, PLASTICS, GLUES, ADHESIVES, SEALANTS, AND METALWORKING FLUIDS AGAINST BIODETERIORATION

Chemical and Physical Data

Common Name:	Tebuconazole	
Chemical Name:	α -[2-(4-Chlorophenyl)ethyl]- α -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol	
Minimum Purity:	min. 93%	
Nominal Concentration:	97%	
Density (20°C):	1.25	
Bulk Density:	approx. 400 kg/m ³	
Vapor Pressure (60°C):	approx. 6 x 10 ⁻⁶ hPa (pure active ingredient)	
Melting Point:	approx. 103°C	
Flash Point:	> 185°C	
Ignition Temperature:	approx. 468°C	
Solubility of Active Ingredient in % by Weight (20°C):	water	approx. 32 ppm
	ethyl glycol	approx. 27.0%
	propylene glycol monomethyl ether	approx. 25.5%
	dipropylene glycol monomethyl ether	approx. 21.5%
	Solvesso 100	approx. 2.9%
	Kristalloel 60	approx. 0.3%
	white spirit*	approx. 0.3%
	*(aromatic content 30% - calculated as xylene)	

Stability

Preventol A8 Preservative is resistant to hydrolysis in acidic up to strong alkaline formulations. Reaction in water: neutral.

Storage

If correctly stored and kept in original sealed container, the shelf life of Preventol A8 Preservative is 1 year.

Applications

Preventol A8 Preservative has a broad spectrum of activity and is particularly effective against wood-rotting Basidiomycetes strains. Preventol A8 Preservative is practically unleachable, light-stable, heat-stable and non-volatile and therefore suitable for long-term protection. It is suitable for use in solvent-based and aqueous wood preservatives. The active ingredient is compatible with the binders, pigments, dryers and auxiliaries normally used in wood preservatives as well as with a variety of blue stain fungicides in solvent based wood preservatives and with insecticides such as Cyfluthrin or permethrin.

Preventol A8 Preservative is also suitable, due to the above described properties, to protect plastics, coatings and paint systems, glues and adhesives as well as metalworking fluids against infestation by fungal organisms.

Spectrum of Activity

Preventol A8 Preservative has a broad spectrum of activity against wood-rotting fungi. Toxic values are determined in accordance with the relevant internationally recognized standards. The values obtained from samples which have been aged artificially - for example evaporative aging as specified in EN 73 or leaching as specified in EN 84 - are not substantially higher than the levels recorded in samples which have not been aged.

Toxic values (kg/m³) determined in accordance with EN 113

Test institute BAM ¹ 1990, scots pine sapwood			Test institute BRE ² 1990/1993, scots pine sapwood		
Test fungus	unaged	after evaporative aging (EN 73)	unaged	after evaporative aging (EN 73)	after leaching (EN 84)
Coniophora puteana	0.030 - 0.050	0.070 - 0.110	* - 0.052 ³	* - 0.053 ³	* - 0.054 ³
Gloeophyllum trabeum	0.012 - 0.030	0.045	* - 0.051 ³	* - 0.050 ³	* 0.051 ³
Poria placenta	0.120 - 0.180	0.280 - 0.440	0.012 - 0.153	0.150 - 0.310	0.099 - 0.152
Coriolus versicolor	test not conducted	test not conducted	0.151 - 0.299	0.155 - 0.306	0.101 - 0.150
1 BAM = Federal Office for Material Research and Testing, Berlin, Germany					
2 BRE = Building Research Establishment Timber Division, Biodeterioration Section, Garston, UK					
3 no falling concentration determined					

Soil block test AWPA E10-91 carried out by test institute MSFPL⁶

Test fungus	Wood species	Weathering	Toxic values (kg/m ³)
Coriolus versicolor	Sweetgum	without	< 0.540 ⁷
		with	< 0.546 ⁷
Irpex lacteus	Sweetgum	without	0.018 - 0.019
		with	0.019 - 0.021
Gloeophyllum trabeum	Ponderosa pine	without	0.018 - 0.0193
		with	0.026 - 0.030
Poria Placenta	Ponderosa pine	without	0.117 - 0.123
		with	0.138 - 0.144
6 MSFPL = Mississippi State Forest Products Laboratory, Mississippi State, USA			
7 no weight loss even at lowest retention of tebuconazole used; no toxic value calculated			

Soil block test ASTM D 1413 carried out by test institute MTU⁸

Retention of tebuconazole (kg/m ³ wood)	0.12	0.24	0.48	0.96
Test fungus	weight loss of the test blocks			
Coriolus versicolor (birch)	> 50	> 50	13.9	0.9
Gloeophyllum trabeum ⁹ (southern pine)	0.2	-1.6	-0.2	-1
8 MTU = Michigan Technological University, Institute of Wood Research, Houghton, USA				
9 no weight loss even at lowest retention of tebuconazole used; no toxic value calculated				

In addition, the product was tested for fungicidal effectiveness in accordance with the German quality and test regulations (*Güte und Prüfbestimmungen*) for the award of the RAL-quality mark for wood preservatives (*RAL-GZ-830*).

The results show that Preventol A8 Preservative applied in quantities of 1.3 g/m² or more is sufficient to protect the wood against decay.

INFORMATION ABOUT SAFETY AND HANDLING AND ON ECOLOGICAL AND TOXICOLOGICAL BEHAVIOR IS GIVEN IN OUR MATERIAL SAFETY DATA SHEET.

DIRECTIONS FOR USE

IMPORTANT: Labeling directions, precautionary statements and restrictions for all other products recommended in this bulletin must be followed.

Wood-based Composite Products

GENERAL: Preventol A8 Preservative is recommended to preserve wood-based composite products, such as waferboard, fiberboard, particleboard, plywood and oriented-strand board to prevent the growth of mildew, blue stain and wood destroying fungi on the composite product. These composites are used in the following applications: millwork, including door and window frames; exterior siding; construction lumber; and exterior wood. Composite wood treated with Preventol A8 Preservative does not change in appearance and may be painted when dry.

Preventol A8 Preservative may be applied into a wood composite through a number of methods, including:

- a) Metering Preventol A8 Preservative onto the dried wood flakes, fibers, etc. immediately before the blender. The Preventol A8 Preservative is then mixed with flakes in the blender.
- b) Mixing Preventol A8 Preservative with the wood flakes in the blender.
- c) Mixing Preventol A8 Preservative with the adhesive or wax which is subsequently applied to the flakes in the blender.

The method of incorporation of Preventol A8 Preservative will depend on the specific manufacturing process and wood species used for the composite.

The suggested use level is 0.01 to 0.03 lbs. Preventol A8 Preservative per cubic foot of wood, or 0.025 to 0.075% Preventol A8 Preservative, based on dry board weight.

ALL OF THE ABOVE USES ARE NON-SOIL CONTACT NON-FUMIGATION TREATMENTS

Wood Products Intended for Above Ground and In-Ground Contact

GENERAL: Preventol A8 Preservative is recommended for the preservation of wood intended for above-ground and/or in-ground contact, such as Ponderosa pine, Scots pine, Southern yellow pine, beech, oak, birch, and other wood species susceptible to decay by rotting fungi. Such uses include railway sleepers, fence posts, poles, horticultural posts, etc. Wood preserved with Preventol A8 Preservative alone does not change in appearance and may be painted when dry.

Preventol A8 Preservative may be applied to wood by dissolving in a suitable solvent and adding auxiliaries such as: water and/or organic solvents, emulsifiers, fixating agents, paraffin wax or resins, additional active ingredients (to protect against fungi and/or insects, including termites), dyestuffs, pigments, penetration improvers and other auxiliaries.

The method of incorporation of Preventol A8 Preservative will depend on the specific treating process and wood species to be treated and intended use of the treated wood.

Preventol A8 Preservative may be applied by dip, double vacuum or pressure treatment methods. Solution uptake and treatment conditions for each method should result in a 0.003 to 0.05 pcf (lbs/ft³) retention of active ingredient in the treated article. Wood for in-ground contact generally needs the highest treatment retention.

Dip: For dip treatment, wood should be used only for above-ground uses that are continually protected from direct exposure to weather. Immerse wood completely until enough solution has been absorbed to meet the retention requirements given above. Use dip treatment procedures consistent with the equipment being used and standard treatment practices. In general, an immersion time of 3 minutes in a 0.5% solution of Preventol A8 Preservative will be sufficient.

Double Vacuum: For double vacuum treatment, stack the wood in the treatment vessel so that it will remain submerged. In general, a treating solution concentration of 0.5% of Preventol A8 Preservative will be sufficient. Pull vacuum of -10 inches for five minutes. Fill the vessel, allow the pressure to return to atmospheric and discharge preservative solution. Pull a vacuum of -20 inches and maintain for twenty minutes. Return to atmospheric pressure and drain preservative.

Pressure Treatment: For pressure treatment follow the general requirements of the American Wood Protection Association Standard T1 Processing and Treatment Standard.

The suggested use level is 0.003 - 0.03 lbs. Preventol A8 Preservative per cubic foot of wood.

ALL OF THE ABOVE USES ARE NON-FUMIGATION TREATMENTS

Plastics Preservation

GENERAL: Preventol A8 Preservative is recommended for use as a fungicide (mildewcide) in PVC, polyurethane, and other polymers used for the production of shower curtains, tarpaulins, sun umbrellas and other plastics products.

Preventol A8 Preservative should be used at an application rate of 0.3 - 1.2% of Preventol A8 Preservative based on the weight of the finished formulation. To insure uniform distribution in the end product it is recommended that Preventol A8 Preservative be pre-blended with plasticizer or other liquid ingredient of the finished formulation before the final production step. The treatment is recommended up to a temperature of 350°F and is limited only by decomposition of the substance.

Other use recommendations include the following: the maximum level of protection is achieved if Preventol A8 Preservative is combined with a second fungicide, e.g. N-octyl isothiazolinone. Recommended concentrations for a combination of Preventol A8 Preservative and this active substance are in the ratio 2:1 - 4:1 (in plastics this calculates as 0.3 - 0.8% active ingredient).

Paper Coatings for Indoor, Non-food Contact Uses

Preventol A8 Preservative is effective against a wide variety of mold fungi for the preservation of coating films. The exact concentration of Preventol A8 Preservative will vary with the composition of the coating to be protected and with the risk of infestation. To reach optimum effectiveness, preliminary testing with the ranges provided below is recommended to determine the most appropriate amount of Preventol A8 Preservative to be used.

Recommended concentration of Preventol A8 Preservative in coatings for paper and paperboard (paper coatings for indoor, non-food contact uses):

- 0.1 - 2.0% (calculated on coating applied to paper/paperboard)

Glues and Adhesives

GENERAL: Preventol A8 Preservative can be used as an additive to glues and adhesive formulations to prevent infestation by a wide variety of fungal organisms. With the use of Preventol A8 Preservative, it is possible to protect both the post-application, wet stage and the dry film of such products against fungal attack. A long-lasting effect is secured, as Preventol A8 Preservative is practically non-volatile and insoluble in water.

Recommended uses include, but are not limited to the following:

- casein containing adhesives, such as that used for labeling and books;

- starch-based glues typically used in wallpaper;
- dextrin adhesives;
- synthetic polymer-based adhesives, such as acrylic, styrene butadiene, and polyvinyl alcohol ; and
- animal glues, such as bone, skin and gelatin-based glues

Recommended levels are 0.75 - 2.0% active ingredient based on the total weight of product to be protected. The powdered preservative should be mixed thoroughly with the glue powder. Additions depend on the composition of the glue, the conditions in which it is to be used, and the degree of protection required. Preventol A8 Preservative can also be added to liquid formulations, however, good stirring is required to achieve even distribution throughout the adhesive formulation. Also, Preventol A8 Preservative may be dissolved in suitable solvents prior to addition to the adhesive formulation. To reach optimum effectiveness, preliminary testing with the ranges provided is recommended to determine the most appropriate amount of Preventol A8 Preservative to be used.

Enhanced protection is achieved if Preventol A8 Preservative is combined with a second mildewcide, e.g. 3-iodo-2-propinylbutyl carbamate [IPBC], or N-octyl isothiazolinone.

Recommended concentration for a combination of Preventol A8 Preservative and 3-iodo-2-propinylbutyl carbamate [IPBC] (2:1) in glues and adhesives for fungicidal protection:

- 0.3 - 0.8% of the combination (calculated on total formula weight)

Recommended concentration for a combination of Preventol A8 Preservative and N-octylisothiazolinone (2:1) in glues and adhesives for fungicidal protection:

- 0.3 - 0.8% of the combination (calculated on total formula weight)

Note: Adhesives formulated for food packaging applications may require approval by the Food and Drug Administration.

Sealants

Preventol A8 should be incorporated into the sealant formulation to inhibit any microbial growth on the sealant. Preventol A8 is practically non volatile and insoluble in water.

Recommended levels are 0,25 - 1% active ingredient based on the total weight of product to be protected. Additions depend on the composition of the sealant, the conditions in which it is to be used, and the degree of protection required. The powdered preservative should be mixed thoroughly with the sealant formulation or pre-blended with a compatible component of the formulation. It is also possible to add Preventol A8 to liquid formulations.

Metalworking/Cutting Fluids

Preventol A8 Preservative may be used in aqueous-based metalworking, cutting cooling and lubricating fluids to prevent fungal growth. It can be incorporated into the original concentrate of metalworking fluids by adding the preservative under stirring until the preservative is completely dissolved. Depending on the metalworking fluid type, it may be advantageous to pre-dissolve Preventol A8 Preservative in a suitable solvent. Lab trials to check the compatibility of the fluid to be preserved with the preservative are strongly recommended. Preventol A8 Preservative should be added to the metalworking fluid concentrate in amounts sufficient to yield the desired concentration of active ingredient in the diluted composition. If Preventol A8 Preservative is to be added directly to the diluted metalworking fluid, it should first be dissolved in a suitable solvent. For a homogeneous mixture of substrate and preservative, add the preservative at a point in the system where good circulation is assured. Preventol A8 Preservative prevents growth of mold-fungi. If supplementary protection against bacterial growth is required, LANXESS Corporation recommends combination with a suitable bactericide.

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Recommended Concentrations:

Metalworking fluids - Mineral Oil Based

Metalworking fluids (concentrates): 2.0 - 4.0%
Metalworking fluids (ready to use): 0.1 - 0.2%

Metalworking fluids - Non-Mineral Oil Based

Metalworking fluids (concentrates): 2.0 - 4.0%
Metalworking fluids (ready to use): 0.1 - 0.2%

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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.