

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 30, 2014

Dr. Matthew Brooks, Director Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124

Subject:

Label Amendment – Additional Sub-Label (Supersedes 11/25/14 Letter)

Product Name: Cupron Anti-Fungal Fibers and Fabrics II

EPA Registration Number: 84542-10 Application Date: August 19, 2014

Decision Number: 498637 (Supersedes Decision Number 494954)

Dear Dr. Brooks:

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

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with FIFRA section 6. If you have any questions, please contact Stacey Grigsby by phone at (703) 305-6440, or via email at grigsby.stacey@epa.gov.

Sincerely,

Julie Chao, Acting Product Manager 34 Regulatory Management Branch II Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure

**Master Label containing** 

**Sublabel 1. Athlete's Foot Label** 

**Sublabel 3. Athlete's Foot Label- no washings** 

Sublabel 2. Jock Itch Label

[Sublabel 1: Athlete's Foot Label]

## **CUPRON ANTI-FUNGAL FIBERS AND FABRICS II**

[Additional Brand Name: Cupron AntiFungal Pro Fibers]

\*\*\*\*

Active Ingredient

Copper (I) Oxide 2.6 %
Other Ingredients (Garment) 97.4 %
Total 100.0 %

EPA Registration No. 84542- 10 EPA Establishment No \*\*\*\*\*

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by\*\*\*\*\*\*\*

Net Contents\*\*\*\*\*\*

## ACCEPTED

12/30/2014

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 0.4540, 40

84542-10

Cupron Anti Fungal Fibers and Fabrics II

# **Cupron Anti Fungal Fibers and Fabrics II**

[When Additional Brand Name is used the statement <u>Cupron enhanced fibers/fabric</u> shown below is replaced with Cupron AntiFungal Pro Fibers]

# -THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T.mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the [sock, bathmat, shoe inserts].

Cupron enhanced fibers/fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, fungus that causes athlete's foot on the sock.

#### THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

Cupron Anti Fungal Fibers and Fabrics II

#### **DIRECTIONS FOR USE**

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

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics II may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE SOCKS, FOOTWEAR, SHOE INSERTS AND BATHMATS.

#### STORAGE AND DISPOSAL

**Disposal:** Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

Cupron Anti Fungal Fibers and Fabrics II



### **ABN: Cupron AntiFungal Pro Fibers**

Cupron Antifungal Pro Fibers Kill 99.9% of T. mentagrophytes (athlete's foot fungus) after 12 hours of contact with socks.

#### **Active Ingredient**

Copper (I) Oxide 2.6%

Other Ingredients (Garment) 97.4%

Total 100%

EPA Registration No 84542-10 EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for

Cupron Inc

Suite 123, 800 East Leigh Street, Richmond, VA 23219

#### **DIRECTIONS FOR USE**

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

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner: Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners Do not dry clean.

#### Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

**Master Label containing** 

Sublabel 1. Athlete's Foot Label Sublabel 3. Athlete's Foot Label- no washings

Sublabel 2. Jock Itch Label

[Sublabel 2: Jock Itch Label]

### **CUPRON ANTI-FUNGAL FIBERS AND FABRICS II**

[Additional Brand Name: Cupron AntiFungal Pro Fibers]

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Active Ingredient

Copper (I) oxide 2.6%
Other Ingredients (Garment) 97.4%
Total: 100.00%

EPA Registration No. 84542- 10 EPA Establishment No \*\*\*\*\*

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by\*\*\*\*\*\*

Net Contents\*\*\*\*\*\*

Cupron Anti Fungal Fibers and Fabrics II

# **Cupron AntiFungal Fibers and Fabrics II**

# -THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

- Cupron enhanced fibers / fabric will assist in reducing the spread of *T. mentagrophytes* (jock itch fungus)
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (jock itch fungus) after 12 hours of contact with the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on [USE SITE]
- Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (jock itch fungus) on the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the growth of *T. mentagrophytes*, jock itch fungus, on [USE SITE]
- Cupron enhanced fibers / fabric reduce(s) the spread of *T. mentagrophytes*, jock itch fungus, on the surface of the [USE SITE]
- Cupron enhanced fibers / fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, the fungus that causes jock itch on the[USE SITE]

#### THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

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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.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

**TEXTILES ARE TO BE USED TO MAKE:**-underwear, studio apparel (pants, capris, shorts, leggings, tights), yoga apparel (pants, capris, shorts, leggings, tights), run apparel (pants, capris, shorts, leggings, tights), training apparel (pants, capris, shorts, leggings, tights), team sports apparel (pants, capris, shorts, leggings, tights), team sports uniforms (pants, capris, shorts, leggings, tights), baselayer (pants, capris, shorts, leggings, tights), compression products (pants, capris, shorts, leggings, tights), warmth layers (pants, capris, shorts, leggings, tights), leg sleeves.

#### STORAGE AND DISPOSAL

**Disposal:** Discard in trash when fibers/fabric are worn out after 20 washings. Do not reuse clothing for other purposes than as sold.

Cupron Anti Fungal Fibers and Fabrics II



### **ABN: Cupron AntiFungal Pro Fibers**

Cupron Antifungal Pro Fibers Kill 99.9% of T. mentagrophytes (jock itch fungus) after 12 hours of contact with (INSERT USE SITE).

#### **Active Ingredient**

Copper (I) Oxide 2.6%

Other Ingredients (Garment) 97.4%

Total 100%

EPA Registration No 84542-10 EPA Establishment No

Manufactured for

**Cupron Inc** 

Suite 123, 800 East Leigh Street, Richmond, VA 23219

#### **DIRECTIONS FOR USE**

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

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners Do not dry clean.

#### Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

Cupron Anti Fungal Fibers and Fabrics II

**Master Label containing** 

Sublabel 1. Athlete's Foot Label Sublabel Sublabel 3. Athlete's Foot Label –no washings

Sublabel 2. Jock Itch Label

[Sublabel 3: Athlete's Foot Label –no washings]

## **CUPRON ANTI-FUNGAL FIBERS AND FABRICS II**

[Additional Brand Name: Cupron AntiFungal Pro Fibers]

\*\*\*\*

Active Ingredient

Copper (I) Oxide 2.6% Other Ingredients (Garment) 97.4% Total 100.0%

EPA Registration No. 84542- 10 EPA Establishment No \*\*\*\*\*

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by\*\*\*\*\*\*\*

Net Contents\*\*\*\*\*\*

## **Cupron Anti Fungal Fibers and Fabrics II**

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# -THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T.mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the [sock, bathmat, shoe inserts].

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The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

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Cupron Anti Fungal Fibers and Fabrics II

#### **DIRECTIONS FOR USE**

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

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

Do not wash or dry clean.

[Cupron Anti Fungal Fibers and Fabrics II may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

#### TEXTILES ARE TO BE USED TO MAKE FOOTWEAR AND SHOE INSERTS.

#### STORAGE AND DISPOSAL

**Disposal:** Discard in trash when fibers/fabric are worn out. Do not reuse clothing for other purposes than as sold.



### **ABN: Cupron AntiFungal Fibers**

Cupron Antifungal Pro Fibers Kill 99.9% of T. mentagrophytes (athlete's foot fungus) after 12 hours of contact with socks.

#### **Active Ingredient**

Copper (I) Oxide 2.6 %

Other Ingredients (Garment) 97.4%

Total 100%

EPA Registration No 84542-10 EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for

Cupron Inc

Suite 123, 800 East Leigh Street, Richmond, VA 23219

#### **DIRECTIONS FOR USE**

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

Do not wash.

Do not dry clean.

#### Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.