

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

April 10, 2023

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Jennifer Tillman, Agent for Intelligent Fabric Technologies NA Inc. c/o Interteck Surveying Services 16441 Space Center Blvd., Unit D-100 Houston, Texas 77058

Subject: Notification per PRN 98-10 – Addition of Indoor Non-Food Use Site; other grammatical updates Product Name: PROTX2 Self-Sanitizing Textiles EPA Registration Number: 87246-13 Received Date: 2/2/2023 Action Case Number: 00429562

Dear Jennifer Tillman:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

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) lists 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 Assurance.

If you have any questions, you may contact me via email at garvie.heather@epa.gov.

Sincerely,

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Heather A. Garvie Senior Regulatory Advisor Regulatory Management Branch 2 Antimicrobials Division Office of Pesticide Programs

## **PROTX2®** Self-Sanitizing Textiles

#### [Alternate Brand Names]

PROTX2<sup>®</sup> Continually Self-Sanitizing Textiles

# NOTIFICATION 87246-13

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/10/2023

The Master Label consists of the label that will accompany the PROTX2<sup>®</sup> Self-Sanitizing Textiles and a Fabricated Product Label that will accompany each product fabricated using the registered PROTX2<sup>®</sup> Self-Sanitizing Textiles and associated fabricated products

| PROTX2 <sup>®</sup> Self-Sanitizing Textiles  |               |  |
|---|---------------|--|
| Active Ingredients:   |               |  |
| 3-(Trimethoxysilyl) Propyldimethyloctadecyl ammonium chloride   | 0.65%         |  |
| Polyhexamethane Biguanide   | 0.26%         |  |
| Silver  | 0.18%         |  |
| Propiconazole   | 0.44%         |  |
| Other Ingredients   | <u>98.47%</u> |  |
| Total   | 100.0%        |  |
|   |               |  |
| KEEP OUT OF REACH OF CHILDREN   |               |  |
| EPA Reg. No. 87246-X  |               |  |
| NET WT: XXX   | Lot No. XXX   |  |
| *Active Ingredient is hydrolyzed to produce methanol. The final concentration of the<br>active ingredient and methanol are:<br>3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride 0.52%<br>Methanol approx. 0.1% |               |  |
| [See insert (side panel) (back panel) for Directions for Use]   |               |  |

## DIRECTIONS FOR USE:

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

Fabric is effective in reducing 99.99% *Staphylococcus aureus* ATCC 6538 and *Pseudomonas aeruginosa* ATCC 15442 if the product used for up to 24 hours and then must be washed. Product has been tested up to a total of 30 washings. Do not use bleach. Use a nonionic detergent. Rinse with citric acid to remove any residual soap or detergent if needed. Washing, drying, and ironing must not exceed 160°F. The use of this product is a supplement to and not a substitute for standard infection control practices.

User must continue to follow all current infection control practices, including regular washes and good hygiene practices.

Textile materials were tested in fabric form on visibly clean treated fabric surfaces. Antimicrobial treated textile has been shown to reduce microbial contamination but does not necessarily prevent cross contamination.

It is prohibited to incorporate this product into textiles that may come into contact with skin, such as apparel, furnishings, and household fabrics (except shower curtains and window shades).

(Note to reviewer: the following marketing claims may be used individually or group together. These claims may be used on the product label, insert labeling, and/or fabricated product label. They may also be used with the prefix "This product". If more than one claim is chosen "and" "&" "or" may be used to link them together)

# (Note to reviewer: Bracketed information is denoted as: <<directive>>, (optional text) (The term "X" is a placeholder that represents a number between 1 and 99)

## Marketing Claims: - all claims to be optional

- PROTX2<sup>®</sup> Self-Disinfecting Textiles^
- Continuous Self-Disinfectant^
- Continuous (disinfecting) (self-disinfecting) ^
- Durable design for long-lasting continuous performance^
- PROTX2<sup>®</sup> Treated Textiles Kills 99.99% of bacteria in 10 mins with nonstop disinfection for 24 hours^
- Continuous Self-Disinfection^
- Self-disinfecting textiles^
- Continually self-disinfecting^
- Continuous bacteria-killing textiles^
- 100% PROTX2<sup>®</sup> Self-Sanitizing Textiles
- Odor (protection) (protector)
- Controls odors
- Reduce odors
- Long-lasting freshness
- Stay odor free
- Odor-resistant
- Odor control that doesn't wash out
- No bacteria, No odor
- Odor (-) free confidence
- Inhibits the growth of odor [on the fabric] caused by bacteria
- Kills pathogenic bacteria (\*)^
- Self-cleaning of bacteria\*^
- Destroys (bacteria), (harmful bacteria)
- <u>dD</u>isinfectant for (textile) (fabric)^
- Effectively Eliminates 99.99% Germs\*^
- Fabric maintains freshness (even after 30 industrial washes)
- Self-Disinfecting
- Effective wash after wash^
- (kills) (destroys) (eliminates) (disinfects) (self-disinfects) (stops) 99.99% of bacteria
- [Great] [Designed] for -[carpet backings] [rug backings]
- Ten (10) minute bacteria kill
- Kills bacteria within Ten (10) minutes
- Kills 99.99% of bacteria non-stop for 24 hours

- Kills 99.99% of bacteria
- Kills 99.99% of bacteria
- Has a 5-log kill rate in 10 minutes
- Kills 99.99% of bacteria in 10 minutes
- Continuously disinfects bacteria after 24 hours of continuous use without washing
- Self-disinfecting, bacteriostatic, and hypoallergenic^
- •\_\_\_\_
- Self-cleaning (fabric) ^
- A fabric that's always (hygienically) (fresh) clean
- (Clean) (fresh) fabric
- Reduces 99.99% of bacteria growth
- Kills 99.99% of gram-negative and gram-positive bacteria\* in 10 minutes
- Kills 99.99% both gram-negative and gram-positive bacteria\*
- Continuously kills 99.99% gram-negative and gram-positive bacteria\*
- Inhibits the growth of bacteria^
- A fabric that self-cleans from bacteria ^
- Continuous anti-bacterial performance^
- Durable performance up to 30 industrial washes
- Reduces 99.99% of bacteria on fabric surface.
- Self-disinfecting
- Effective up to 30 industrial washes
- Non-leaching
- Kills 99.99% of bacteria in 10 mins with nonstop disinfection for 24 hours^

## \*Staphylococcus aureus and Pseudomonas aeruginosa ^ (for) up to 30 washes

(Note to reviewer: the following marketing claims may be used individually or group together. These claims may be used on the product label, insert labelling, and/or fabricated product label. They may also be used with the prefix "This product". If more than one claims is chosen "and" "&" "or" may be used to link them together)

Public Health Claims: - all claims to be optional

- Kills 99.99% of bacteria such as *Staphylococcus aureus* and *Pseudomonas aeruginosa*.
- Reduces risk of cross-contamination from bacteria between treated surfaces.
- Being bacteriostatic, provides continued protection for on the textile in 24 hours, providing continued protection

•----

• Effective against 99.99% Gram-Negative and Gram-Positive Bacteria.

(Product label is to be affixed or as an insert)

#### Product Label

This product is effective in reducing 99.99% *Staphylococcus aureus* ATCC 6538 and *Pseudomonas aeruginosa* ATCC 15442 if the product used for up to 24 hours and then must be washed. Product has been tested up to a total of 30 washings. Do not use bleach. Use a non-ionic detergent. Rinse with citric acid to remove any residual soap or detergent if needed.

Washing, drying, and ironing must not exceed 160°F. The use of this product is a supplement to and not a substitute for standard infection control practices: user must continue to follow all current infection control practices, including regular washes and good hygiene practices. Textile materials were tested in fabric form. Antimicrobial treated textile has been shown to reduce microbial contamination but does not necessarily prevent cross contamination.

Washed \_\_\_\_\_ Times

## Locations and Surfaces

(Note to reviewer: the following locations and surfaces can be used individually or group together. If more than one location or surfaces is chosen "and" "&" "or" may be used to link together)

It is prohibited to incorporate this product into textiles that may come into contact with skin, such as apparel, furnishings, and household fabrics (except shower curtains and window shades).

## [In Hospitality] [Cruise Ships]

[-<u>sS</u>hower curtains, <u>window shades</u>, carpet backing, inner layer and backing for flooring, and mats (backing only)]

## [In Food Processing], [Food Handling] [Food Handling and Packaging]-

[Ceonveyor belts, carpet backing, inner layer and backing for flooring, matting, cart covers, and canvas]

## [Other]-:

[-Shower curtains, <u>window shades</u>, carpet backing, inner layer and backing for flooring, rug backings, and mat backings

## STORAGE AND DISPOSAL:

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

Pesticide Storage: Store in a cool dry area.

Pesticide Disposal: Place product in trash or in a sanitary landfill.

Container Handling: Non-refillable container. Do not reuse or refill this container. If empty: place in trash or offer for recycling if available.

#### WARRANTY STATEMENT:

Buyer/User assumes the responsibility to handle, use and store this product in accordance with the safety instructions and use directions contained on the label. Buyer/User purchases this product subject to the foregoing Conditions of Sale and Limited Warranty, which, subject to applicable law, may be varied only by a written agreement signed by a duly authorized representative of Intelligent Fabric Technologies (North America), Inc.

Intelligent Fabric Technologies (North America), Inc. 525 Denison Street, Unit 2 Markham, Ontario, Canada L3R 1B8

EPA Reg No. 87246-X

EPA Establishment No. XXX-XXX

#### PROTX2<sup>®</sup> Self-Sanitizing Textiles – Fabricated Products

The PROTX2<sup>®</sup> Self-Sanitizing Textiles Products listed above maybe sold and distributed under EPA Registration Number 87246-X. Products fabricated with PROTX2<sup>®</sup> Self-Sanitizing Textiles must bear the EPA approved product label, below with one or more of the listed claims

#### **PROTX2® Self-Sanitizing Textiles**

#### **Fabricated Product Label**

#### FRONT LABEL:

| PROTX2 <sup>®</sup> Self-Sanitizing Textiles   |   |  |
|--|---|--|
| Active Ingredients:  |   |  |
| 3-(Trimethoxysilyl) Propyldimethyloctadecyl ammonium chloride<br>Polyhexamethane Biguanide<br>Silver<br>Propiconazole<br>Other Ingredients<br>Total  | 0.65%<br>0.26%<br>0.18%<br>0.44%<br><u>98.47%</u><br>100.0% |  |
| KEEP OUT OF REACH OF CHILDREN<br>EPA Reg. No. 87246-X  |   |  |
| EPA Est. No. XXX-XXX   |   |  |
| NET WT: XXX  | Lot No. XXX   |  |
| *Active Ingredient is hydrolyzed to produce methanol. The final concentration of the active ingredient and methanol are:<br>3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride 0.52%<br>Methanol approx. 0.1% |   |  |
| [See insert (side panel) (back panel) for Directions for Use]  |   |  |

## **BACK PANEL / INSERT:**

Laboratory testing has shown that the technology: [Marketing Claims] (Note to reviewer: The marketing and public health claims are optional and may be used individually or group together. The claims located in the label may be used on the product label, insert labeling, and/or fabricated product label. They may also be used with the prefix "This product". If more than one claims is chosen "and" "&" "or" may be used to link them together. Products that bear the EPA approved fabricated product label, must list one or more of the claims

#### **DIRECTIONS FOR USE:**

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This product is effective in reducing 99.99% *Staphylococcus aureus* ATCC 6538 and *Pseudomonas aeruginosa* ATCC 15442 if the product used for up to 24 hours and then must be washed. Product has been tested up to a total of 30 washings. Do not use bleach. Use a nonionic detergent. Rinse with citric acid to remove any residual soap or detergent if needed. Washing, drying, and ironing must not exceed 160°F. The use of this product is a supplement to and not a substitute for standard infection control practices. User must continue to follow all current infection control practices, including regular washes and good hygiene practices. Textile materials were tested in fabric form. Antimicrobial treated textile has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination

#### STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage or disposal. Pesticide Storage: Store in a cool dry area. Pesticide Disposal: Place product in trash or in a sanitary landfill. Container Handling: Non-refillable container. Do not reuse or refill this container. If empty: place in trash or offer for recycling if available.

#### WARRANTY STATEMENT:

Buyer/User assumes the responsibility to handle, use and store this product in accordance with the safety instructions and use directions contained on the label. Buyer/User purchases this product subject to the foregoing Conditions of Sale and Limited Warranty, which, subject to applicable law, may be varied only by a written agreement signed by a duly authorized representative of Intelligent Fabric Technologies (North America), Inc.

Intelligent Fabric Technologies (North America), Inc. 525 Denison Street, Unit 2 Markham, Ontario, Canada L3R 1B8

EPA Reg No. 87246-X EPA Establishment No. XXX-XXX <<(Optional Graphics/ Company Logo)>>

