

08/08/2006

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 8, 2006

Ann M. Cozad
Scientific & Regulatory Consultants, Inc.
Agent for
Siamons International, Inc.
P.O. Box 1014
Columbia City, IN 46725

Subject: Notification Application Per PR Notice 98-10
Concrobium
EPA Registration No. 82552-1
Application Date: July 11, 2006
Receipt Date: July 14, 2006

Dear Ms. Tackema:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification:

- Additional marketing text to the master labeling


General Comment:

Based on a review of the material submitted, the notification is acceptable.

A copy of the notification has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or by email at heyward.adam@epa.gov or Lisa McKelvin at (703) 308-7496 or by email at mckelvin.lisa@epa.gov.

Sincerely,


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

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SRC
Scientific & Regulatory
Consultants, Inc.

July 11, 2006

Mr. Adam Heyward, PM 34
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: NOTIFICATION
Concrobium
EPA Reg. No.: 82552-1

Dear Adam,

On behalf of our client, Siamons International, Inc., enclosed is a notification to add marketing text to the Master Label for Concrobium (EPA Reg. No. 82552-1).

Note: Text that appears to be new is highlighted in red. A draft of the revised label along with the most recent accepted label (Notification submitted 11/22/05, accepted 12/5/05) is enclosed.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Thank you for your assistance on this matter. If you have any questions please contact me at (260) 244-6270 or by e-mail at acozad@srconsultants.com.

Sincerely,



Ann M. Cozad
Agent for Siamons International, Inc.

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82552-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Concrobium	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Siamons International, Inc. 36 Meteor Drive Toronto, Ontario Canada M9W 1A4 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of text additions through PR Notice 98-10.
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

For contact Ann Cozad at acozad@srconsultants.com or at 260-244-6273 (fax) with any questions.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	If "Yes" Unit Packaging wgt. No. per container		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Package wgt No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 660mL, 946mL, 3.8L, 4L, 20L, 208.175L		5. Location of Label Directions <input type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Cozad	Title Agent for Siamons International, Inc.	Telephone No (Include Area Code) (260) 244-6270
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		C. Date Application Received (Stamped)
Signature 	3. Title Agent for Siamons International, Inc.	
4. Typed Name Ann M. Cozad	5. Date July 11, 2006	

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CONCROBIUM

ACTIVE INGREDIENT

Sodium Carbonate.....0.95%
OTHER INGREDIENTS.....99.05%
TOTAL.....100.00%

NOTIFICATION
Date Reviewed: 8-01-06
Reviewed By: R. Whiteaker

KEEP OUT OF REACH OF CHILDREN

Net Contents 22 oz (660ml)
1 quart (946 ml)
1 gallon (3.8 L)
1 gallon 7 oz. (4 L)
5 gallon 1 quart 4 oz. (20 L)
55 gallon (208.175 L)

EPA Reg. No. 82552-1

EPA Est. No. XXXXX-XX-XX

Sold by Siamons International Inc.
36 Meteor Drive, Toronto, ON M9W 1A4
Toronto, Canada

{Optional marketing claims, may be used on any panel} {General claims}

For Mold Prevention *{in box}*

- [Eliminates,] [and] [Prevents] mold [and] [mildew,] [fungi,] [staining,] [and associated staining]
- Prevents [future] mold [and mildew] [problems]
- Eliminates [and prevents] mold [growth] [problems]
- [Controls] [Prevents] [Inhibits] [fungi] [mildew] [mold] [mold and mildew]
- [Stops] [Controls] [Prevents] [Inhibits] [the growth of] [fungi] [mildew] [mold] [mold and mildew] [growth] [and their odors] [and their stains] [on hard surfaces]
- Effective against [fungi] [mildew] [mold] [mold and mildew] [mold and mildew stains]
- Eliminates mold [musty] odor [stains] [caused by mold and mildew]
- Contains no ammonia, bleach, alcohol, acid, or VOCs
- [Suitable] for [use on] most [indoor] surfaces
- [Hard Surface] Fungistat [and] [Hard Surface] Mildewstat
- Odorless [and] colorless
- Mold Control
- Concrobium's patented [breakthrough] technology prevents mold [and mildew] growth. [Treated surfaces retain a protective barrier [that [will] prevent[s] the growth of mold and mildew.]]
- Concrobium dries on surfaces to create an invisible antimicrobial shield that [eliminates mold] [and mildew] [problems], [inhibits the growth of mold] [and] [fungal spores] [fungi], [prevents new [mold] growth] [and] [eliminates] [gets rid of] [wipes out] [musty] odors. Concrobium contains no [bleach,] [ammonia,] [alcohol,] [acids,] [or] [other] [VOCs] [and is suitable for use on most surfaces.]
- Use Concrobium [to [eliminate] [mold problems] [and prevent mold] [problems] [control] mold] in [the following [vulnerable] areas] [basements,] [bathrooms,] [closets] [and] [around windows.]
- For use on [the following] [non-porous] [semi-porous] [porous] [hard] surfaces [wallboard,] [plaster,] [wood,] [metal,] [masonry,] [concrete,] [tile].
- CONCROBIUM is [specially formulated] [a unique technology] for effective [control] of [most] offensive [stains] [odors] caused by mold and mildew.
- Controls [Inhibits] mold and mildew [leaving a fresh clean scent] [leaving rooms clean and fresh smelling].
- Helps prevent mold [growth] [in] [on] [surfaces] [places vulnerable to mold], [including] *{Select from list below}*:
 - Basements
 - Bathrooms
 - Vacation homes
 - Boat interiors
 - Areas under construction
- For use in homes, businesses or institutions.
- No fumes
- Not flammable
- Deodorizer
- [Also] available in 1 [gal] [Gallon] and 20 [gal] [Gallon] sizes [for larger areas]
- Eliminates [kills] [musty] [foul] [stale] odors [from] [gym] [sports] [hockey] [football] [baseball] [basketball] [athletic] [equipment]

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- Concrobium eliminates odor-causing particles [fungi and mold], [eliminating] [getting rid of] [killing] [reducing] [the] [that] [musty] [stale] [foul] [odor] [smell].
- [For] [Use] [on] [in] [gym] [sports] [hockey] [football] [baseball] [basketball] [athletic] [equipment] [lockers]
- No mixing required.
- Ready to use
- Easy to use

IDEAL [CAN BE USED] [FOR]

- Mold prevention in homes, businesses and institutions
- Mold prevention following flooding or water damage cleanup
- Pre-treatment of building materials for mold resistance
- [DIY] [Do-it-yourself] mold prevention
- New construction protection

{Remedial related claims}

Encapsulates mold spores *{icon}*

For Mold Remediation and Prevention *{in box}*

- [Cleans,] [Removes,] [Eliminates,] [and] [Prevents] mold [and] [mildew,] [fungi,] [staining,] [and associated staining]
- [Cleans,] [Remediates] [and Prevents] mold [and mildew] [all-in-one]
- [Three] [All]-in-one [solution]
- Eliminates existing [mold] [problems] and prevents future [mold] [problems]
- Get[s] rid of mold
- Wipe[s] out mold
- Wherever mold takes hold
- [Stops] [Cleans and] [Controls] [Prevents] [Inhibits] [the growth of] [fungi] [mildew] [mold] [mold and mildew] [and their odors] [and their stains] [on hard surfaces]
- CONCROBIUM's patented [breakthrough] technology encapsulates mold and fungal spores with a microscopic coating that inhibits [and prevents] its growth. [Treated surfaces retain a protective barrier that will prevent the growth of mold and mildew.]
- Concrobium dries on surfaces to create an invisible antimicrobial shield that [encapsulates and] inhibits the growth of mold [and] [fungal spores] [fungi], prevents new [mold] growth and eliminates [musty] odors. Concrobium contains no [bleach,] [ammonia,] [alcohol,] [acids,] [or] [other] [VOCs] [and is suitable for use on most surfaces.]

IDEAL [CAN BE USED] [FOR]

- Mold remediation in homes, businesses and institutions
- [DIY] [Do-it-yourself] [Household] mold clean-up [and prevention]
- Professional mold remediation

For use [on, in] {Select from below}

[Surfaces:]

Bathroom Basins	[Glazed] Ceramic [tile]	Plastic Mattress Cover
Bathroom Surfaces	[Glazed] Porcelain	Plexiglass®
Bathroom Tile	Hard [non-porous] surfaces	Portable Toilet
[Fiberglass] Bathtub [Tub]	Hard [Plastic] surfaces	Recycle Bin
Bed Frames	Laminated Surfaces	Resilient Flooring
Bed Springs	Lamps	Shower [Stall] [Area]
Bidet	Linoleum	Shower [plastic] [liner]
Cabinets	Lockers	[Under] Sink [Basin]
Cat Litter Box	Louvers	[Sealed] granite
Chairs	Marble [Cultured]	Slate
Desks	Marble [Synthetic]	Sports Equipment
Diaper Pails	Marlite	Stainless Steel
Dorm	Metal Blinds	Toilet / Urinal exteriors
Enamel	Mirrors	[around] Toilet Areas
Fixtures	No wax floors	Vinyl [tile]
Garage Surface	Parquet	[Washable] Walls
Garbage Can [Pail]	Plastic Laundry [basket] hamper	Windows
	Plastic Laminate	Windowsill [non-wood]

[Household Use Sites]

Attic	Dining Room	Laundry Room	RV's
Basement	Dorm	Living Room	[damp] Storage Area [Room]
Bathroom	Family Room	Mobile Home	Storage Building
Bedroom	Farmhouse	Mud Room	Summer Cottage
Boat Interior	Garage	Nursery	Sunroom
Camper Interior	Home / House	Other Household Areas	Tool Shed
Closet	Home Workshop	Pet Areas	Trailer
Den / Study	Household [Areas]	Playroom	Vacation Home
			Workshop

[Professional Use Sites]

Airplane Interior	Industrial Building	Public Factory
Airports	Institution	[Public] [Restroom]
Attic	[Institutional] [Bathroom] [restroom]	Public telephone booth
Bowling Alley	[Institutional] [Laundromat]	Recreational Center [facility]
Business [building]	Kennel	School [College]
Closet	Laboratory	Shelter
Commercial Building	Manufacturing Plant	Storage Area [Room]
Day Care Center	Military Installation	Tack Shops
Dressing rooms	Office [Building]	Toll Booth
Factory	Pet areas	Train Interior
Gymnasium	Pet Shops	Utility Rooms
Health Care Facility	Pharmacy	Waiting Room
Health Club	Public Facility	Warehouse Club
Hotel / Motel		

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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.

MOLD AND MILDEW CONTROL IN WOOD, WALLBOARD, CONCRETE AND MASONRY (CINDER) BLOCK CONSTRUCTION MATERIALS IN BUILDINGS

Concrobium is used to treat wood, wallboard, concrete and masonry (cinder) block building materials to inhibit or prevent the growth of mold organisms when the materials are subjected to moist or wet environments. Before applying this product, visible mold growth must be removed and conditions favorable to mold growth must be identified and corrected.

READ LABEL BEFORE USING PREVENTATIVE TREATMENT

To inhibit the growth of mold and mildew on surfaces:

- 1) Apply Concrobium on area until evenly wet.
- 2) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness.
- 3) Allow treated surfaces to dry completely.

REMEDIAL TREATMENT

SMALL AREAS – TOTAL SURFACE AREA AFFECTED LESS THAN 30 SQUARE FEET

Areas of visible growth of less than 30 square feet (the area of a single wall panel) can normally be remediated without elaborate procedures. When these areas are identified, apply Concrobium to retard growth and spread of fungal spores and other contaminants until the area can be thoroughly cleaned and remediated. If growth is on ceiling tiles or other such easily removable items of nominal value, remove them and seal them in a plastic bag and dispose with normal trash. If the surface is not easily replaceable:

- 1) *Clean contaminated area to remove surface soil. For best results, and to avoid possible interference from other chemicals, use Concrobium for initial cleaning. Use a cloth, cleaning pad or brush suitable to the durability of the surface being cleaned. Remove as much dirt and visible mold as possible.*
- 2) Apply Concrobium on cleaned area until evenly wet.
- 3) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness.
- 4) Allow treated surfaces to dry completely.

Refer to the Personal Protection Equipment Requirements for Applicators section for the appropriate PPE to wear. [This section along with additional directions for use are contained on [inside] [fold out] [other appropriate reference] portion of labeling.]

Concrobium is suitable for use on most surfaces. If in doubt, perform a test on a small, inconspicuous section. Materials vulnerable to water marks should be wiped immediately after contact with Concrobium. Over-application may in some cases result in residue formation, which can be easily wiped away with a Concrobium-dampened cloth.

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Concrobium can be applied by hand-spray, paintbrush, roller, immersion, airless sprayer or pressure fogger [(approximately 400 square feet per gallon)] [approximately one gallon of product should treat a 400 sq. ft. room in a fogger)] To maintain protection against re-growth, do not rinse or wash surfaces after treatment. Reapplication of Concrobium may be required if surfaces are washed or painted or are otherwise directly exposed to water.

Ready to use – do not dilute. Concrobium must come in direct contact with mold to be effective.

STORAGE/DISPOSAL: Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container in areas inaccessible to small children. Keep securely closed.

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 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: Triple rinse (or equivalent). Then recycle or recondition, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

Made in Canada

Questions or Comments? Contact: Customer Service, Siamons International Inc.,
36 Meteor Drive, Toronto, ON M9W 1A4. 1.866.811.4148 or at www.concrobium.com.

™ Concrobium is a trademark of Siamons International Inc. Toronto, Canada

[1G Pro - Inside panel]

DIRECTIONS FOR USE (cont.)

REMEDIAL TREATMENT (cont./Large Areas)

Concrobium is designed to be used to prevent and inhibit the growth of mold, fungus and mildew on floors, walls, interior building surfaces, and other hard non-porous surfaces until such time as the cause of such growth can be identified and corrected. This product should be used in those cases where visible microbial growth has been detected (or conditions are likely to immediately result in such growth) as part of a comprehensive program that removes that growth and identifies and corrects the conditions that led to that growth, including:

- Periodic monitoring and inspection of conditions favorable to mold growth such as moisture ingress and high relative humidity
- Effecting repairs as necessary to eliminate conditions favorable to mold growth
- Drying of affected areas to below 20% moisture content

[**] [The following associations and Internet sites should be consulted for information on standards and guidelines for remedial treatment of mold and mildew:

- IAQA – Indoor Air Quality Association (www.iaqa.org)
- EPA – Environmental Protection Agency (www.epa.gov)
- DOH – New York City Department of Health
(www.ci.nyc.ny.us/html/doh/html/epi/moldrpt1.html)
- IICRC – Institute of Inspection, Cleaning and Restoration Certification (www.iicrc.org)]*

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**{Either the bulleted statement above or the references in the "Large Areas" to the guidelines are to be included in the labeling}*

LARGE AREAS – TOTAL SURFACE AREA AFFECTED GREATER THAN 30 SQUARE FEET

Areas larger than 30 square feet require special procedures and individuals trained in remediation. Guidelines for remediation of large areas of contamination have been established[**.] [by the Indoor Air Quality Associations (www.iaqa.org) and the US Environmental Protection Agency (www.epa.gov). Many in the field also refer to the New York City Department of Health, "Guidelines on Assessment and Remediation of Fungi in Indoor Environments."]* Before using Concrobium in mitigation of large projects, you should be knowledgeable of one or more of these guidelines and follow them when using the product. More information can be obtained from Concrobium's web site (www.concrobium.com)

When water damage is suspected, the first priority is to find the source of water and cut it off. Once that has been accomplished, excess water should be removed. Detailed guidance on proper removal of excess levels of water is contained in, "Standard and Reference Guide for Professional Water Damage Restoration" (IICRC S500) published by the Institute of Inspection, Cleaning and Restoration Certification [(www.iicrc.org)]*. If excess water has been removed completely in 24 hours or less, spraying surfaces that were wet with Concrobium will inhibit growth and no other steps should be necessary.

Where structural members and/or contents have been exposed to water in excess of 24 hours, there is a possibility of extensive microbial growth that may be visible or hidden. In that case a complete assessment and remediation plan must be prepared that properly incorporates the use of Concrobium, provides for user and occupant safety and documentation and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, contact Concrobium Customer Service at (866) 811-4148 for assistance. IICRC S500 contains excellent guidance. In the context of such a plan, Concrobium can be used on materials to be removed and disposed of and in other applications where an anti-microbial use is indicated.

Refer to the Personal Protection Equipment Requirements for Applicators section for the appropriate PPE to wear.

REAPPLICATION

Repeat application weekly or when growth or odor reappears. Prior to reapplication determine the cause of re-growth and correct that problem prior to re-application. Reapplication of Concrobium may be required if surfaces are washed or painted or are otherwise directly exposed to water.

PERSONAL PROTECTION EQUIPMENT REQUIREMENTS FOR APPLICATORS

For areas less than 30 sq. feet, an N-95 respirator, gloves and goggles/eye protection are recommended to avoid exposure to mold or mold spores. For areas greater than 30 sq. feet, an N-95 respirator or half-face respirator with HEPA filter, disposable overalls, gloves and goggles/eye protection.



{Secondary container label for use if contents of 1 gallon label are placed in smaller containers}

CONCROBIUM
(Filled by user)

[Secondary Container Label]

Follow directions for use, storage and disposal from the [3.8L] [800 mL] [original]
[CONCROBIUM] [container] label.

ACTIVE INGREDIENT

Sodium Carbonate.....0.95%

OTHER INGREDIENTS.....99.05%

TOTAL.....100.00%

EPA Reg. No. 82552-1