

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

December 5, 2005

Bob MacDonald Scientific & Regulatory Consultants, Inc. Agent for **Siamons International, Inc.** P.O. Box 1014 Columbia City, IN 46725

Subject:

Notification in Accordance with PR Notice 98-10

Concrobium

EPA Registration Number 82552-1 Application: November 22, 2005 Receipt Date: November 25, 2005

Dear Mr. MacDonald:

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

Proposed Notification:

- Add minor text to labeling

- Additional Brand Name:

Concrobium Mold Control

General Comment:

Based on a review of the material submitted, the following comment apply.

The notification application is acceptable. A copy has been inserted in the file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

Adam Heyward

Product Manager 34

Regulatory Management Branch II Antimicrobials Division (7510C)

Please read instructions on reverse before completing form.

	Registration
	Amendment
✓	Other

Form Approved, OMB No. 2070-0060.

OPP Identifier Number

Environmental Protection Agency Washington, DC 20460			Amendme Other	nt		
Applica	ation for Pesti	cide - Section	1			
1. Company/Product Number 82552-1	t t	2. EPA Product Manager Adam Heyward		3. Proposed Classification		
4. Company/Product (Name) Concrobium	PM# 34	PM#				
5. Name and Address of Applicant (Include ZIP Code) Siamons International, Inc. 36 Meteor Drive Toronto, Ontario Canada M9W 1A4 Check if this is a new address	(b)(i) to: EPA	6. Expedited Reveiw. 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						
Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below. Explanation: Use additional page(s) if necessary. (For seconds)	Table 1 and Section II	Final printed labels in repsonse to Agency letter dated "Me Too" Application. Other - Explain below.				
Notification of minor text additions and rearrangement through PR Notice This notification is consistent with the provisions of PR Notice 98-10 and statement of formula of this product. I understand that it is a violation of not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, th sections 12 and 14 of FIFRA.	e 98-10. EPA regulations at 40 C	FR 152.46, and no other rillfully make any false station of FIFRA and I may	atement to EPA. I fur	ther understand that if this notification is		
1. Material This Product Will Be Packaged In:	Occion		***			
Child-Resistant Packaging Yes No No If "Yes" Unit Packaging Who is a second of the contained of the con	Water Soluble Yes No If "Yes" Package wgt	No. per container	PI G Pi	etainer letal lastic lass lass aper ther (Specify)		
3. Location of Net Contents Information 4. Size(s)	Retail Container	ner 5. Location of Label Directions				
Label Container		- on label				
6. Manner in Which Label is Affixed to Product Lithograph Paper glued Stenciled Control Control						
	: Section -	IV				
1. Contact Point (Complete items directly below for identific	ation of individual to	be contacted, if nec	essary, to proces	ss this application.)		
Name Bob MacDonald	Title Agent for Siam	Title Telephone No. (Include Area Code) Agent for Siamons International, Inc. (260) 244-6270.				
Certify I certify that the statements I have made on this form if acknowledge that any knowlingly false or misleading both under applicable law.						
2. Signature	3. Title	3. Title				
You Markald	Agent for Siamo	Agent for Siamons International, Inc.				
4. Typed Name Bob MacDonald	5. Date ///2	5. Date 11/22/05				



November 22, 2005

Mr. Adam Heyward, PM 34
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202-4501

SUBJECT:

NOTIFICATION

Concrobium

EPA Reg. No.: 82552-1

Dear Adam,

On behalf of our client Siamons International, Inc. ("Siamons") enclosed is a notification for the above mentioned product.

As noted in our e-mailed correspondence to you (11/16/05) we have been working with our client on their labeling and they desire to rearrange certain text and add some minor language to clarify their labeling. In most cases the text proposed is either existing text taken from paragraph form and placed in bullet form or paragraph text pulled together from existing bullets. As you are most likely aware we sometimes have difficulty in certain states when they have to "search" for the text when it is not readily apparent. Therefore to address this situation we are supplying you with this notification for the following text additions in their labeling:

Note: Text that appears to be totally new is highlighted in blue

NEW GROUPING OF BULLETS

For Mold remediation and Prevention

Mold remediation in homes, businesses and institutions

Pre-treatment of building materials for mold resistance

Concrobium dries on surfaces to create an invisible antimicrobial shield that encapsulates and inhibits the growth of mold and fungal spores, prevents new growth and eliminates musty odors. Concrobium contains no bleach, ammonia, alcohol or other VOC's and is suitable for use on cost surfaces.

Use Concrobium to control mold in vulnerable areas such as basements, bathrooms, closets and around windows. For use on hard surfaces such as wallboard, [plaster], wood, metal, masonry, ... concrete and tile.

Ideal for {followed by previously accepted bullets}

P.O. Box 1014 Columbia City, IN 46725

{

Phone: 260-244-6270 Fax: 260-244-6273

NEW BULLET

Mold prevention following flooding or water damage cleanup

CORRECTIONS/CLARIFICATIONS

Adam - while the following does not change the directions it clarifies them:

Referral statement - Originally said "Refer to the precautionary statements for the appropriate PPE to wear."

Would like to revise to "Refer to the Personal Protective Equipment Requirements for Applicators section for appropriate PPE to wear." also since this section may be on another panel would like to include [This section along with additional directions for use are contained on [inside] [fold out] ["other appropriate reference"] portion of labeling.]

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.

Alternate language for (approximately 400 square feet per gallon) - [(approximately one gallon of product should treat a 400 sq. ft. room in a fogger)]

Concrobium must come in direct contact with mold to be effective.

Add the word "comprehensive" to the statement "...as part of a comprehensive program that removes the growth and identifies and corrects the conditions that led to the growth."

ADDITIONAL BRAND NAME

Concrobium Mold Control

We also wish to notify you of additional package sizes although we understand these may be done by non-notification: 1 quart (946 ml), 1 gallon 7 oz. (4 L), 5 gallon 1 quart 4 oz. (20 L), 55 gallon (208.175 L)

We have attached both a draft of the revised labeling, with the above items highlighted, along with the most recent stamped label. I believe the attached label with its highlights makes the items covered in this notification clearer. We have additionally enclosed a 2nd copy of the revised labeling if you can stamp it for pursuing State registrations otherwise we will just provide them a copy of our correspondence to you and your official response to our notification.

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 bmacdonald@srcconsultants.com.

Sincerely

Bob MacDonald

At Mersald

Agent for Siamons International, Inc.

cc: E. Green

CONCROBIUM

{Front panel; marketing claims may be used on any panel}

Encapsulates mold spores (icon)

For Mold Remediation and Prevention (in box)

- Prevents mold and mildew
- Eliminates mold odor
- Contains no ammonia, bleach, alcohol or acid
- Suitable for use on most surfaces
- Fungistat and Mildewstat
- Prevents and inhibits mold and fungi
- Eliminates musty odors
- Contains no ammonia, bleach, alcohol or VOCs
- Odorless and colorless
- Mold Control

ACTIVE INGREDIENT

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

KEEP OUT OF REACH OF CHILDREN

Directions for Use must be read completely prior to using this product.

Net Contents 25.4 oz./800 ml 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. Toronto, Canada

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

- CONCROB!UM's patented technology encapsulates mold and fugal spores with a microscopic coating that inhibits its growth. Treated surfaces retain a protective barrier that will prevent the growth of mold and mildew.
- For use on most indoor surfaces.

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

- Helps prevent mold growth in places vulnerable to mold, including:
 - o Basements
 - o Bathrooms
 - Vacation homes
 - Boat interiors
 - Areas under construction
- For use in homes, businesses or institutions.
- Contains no volatile organic compounds (VOC's)
- Contains no bleach, ammonia, alcohol or acid
- Odorless and colorless
- No fumes
- Not flammable
- Fungistat
- [Hard Surface] Fungistat
- Mildewstat
- [Hard Surface] Mildewstat
- [Cleans and][Controls][Prevents][Inhibits] the growth of [fungi][mildew][mold][mold and mildew] [and their odors] on [hard surfaces]
- Effective against [fungi][mildew][mold][mold and mildew]
- [Controls][Prevents][Inhibits] [fungi][mildew][mold][mold and mildew]
- Deodorizer
- CONCROBIUM is [specially formulated] [a unique technology] for effective [control] [elimination] 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].
- Eliminates musty odors [caused by mold and mildew].

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CONCROBIUM EPA Reg No. 82552-1

[1G Pro - Back Panel]

Concrobium dries on surfaces to create an invisible antimicrobial shield that encapsulates and inhibits the growth of mold and fungal spores, prevents new growth and eliminates musty odors. Concrobium contains no bleach, ammonia, alcohol or other VOCs and is suitable for use on most surfaces.

Use Concrobium to control mold in vulnerable areas such as basements, bathrooms, closets and around windows. For use on hard surfaces such as wallboard, [plaster], wood, metal, masonry, concrete and tile.

IDEAL FOR

- >Mold remediation in homes, businesses and institutions
- >Mold prevention following flooding or water damage cleanup
- >Pre-treatment of building materials for mold resistance

DIRECTIONS FOR USE

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.

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

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 contaminates until the area can be

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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.

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.

TM 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)]*

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

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

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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.

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{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