

84683-2

07/20/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 20 2011

Dr. J. Michael Kelley, Ph.D
Representative for OhSo Clean, Inc.
P.O. Box 363
7140 Heritage Village Plaza
Gainesville, VA 20156

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Benefect® Biocide AD
EPA Registration No.: 84683-2
Application Date: 05/23/2011
Receipt Date: 05/23/2011

Dear Dr. Kelley:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions.

Proposed Amendment

- Optional "CleanWell™ Inside" logo

Conditions

Revise the label as follows:

1. As per PR Notice 2000-5, Mandatory Labeling, delete the terms "should" and "recommended" and rephrase or state "must" or "required."
2. Delete the terms "botanically-derived" in the first sentence on page 2. This is false and misleading when describing that the biocide is botanically-derived whereas the formulation is not certified or proven to be botanical.
3. Clarify the second sentence in parentheses on page 6.

General Comments

A stamped label with conditions is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

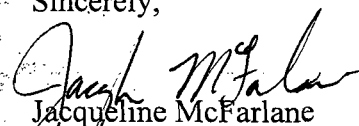
CONCURRENCES

SYMBOL								
SURNAME								
DATE								

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov.

When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Jacqueline McFarlane
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

{All text in brackets [xxx] is optional & may or may not be included on a final label.}
{All text in braces {xxx} is administrative & will not appear on a final label.}

Benefect® Biocide A.D.

Fungistat
Mildewstat
Bacteriostat

Biocide for Air Ducts

Controls & inhibits odor causing bacteria, fungi & other odor causing organisms in air duct surfaces.

Controls Odors

Deodorizer

Botanically-Derived Active Ingredient

Lemon [Lemongrass] [& Clove] [Spice] Scent

Ready To Use

[Caution]

Keep Out of the Reach of Children

Active Ingredient:

Thymol (present as a component of Thyme Oil)	0.23%
Inert Ingredients:	99.77%
Total.....	100%

EPA Reg. No.: 84683-2 EPA Est. Number 075840-CAN-001
Net Contents: 1.0 Gal. (3.78 L.)

DIRECTIONS FOR USE ON AIR DUCTS ARE CONTAINED IN THE ATTACHED BOOKLET & MUST BE READ COMPLETELY PRIOR TO USING THIS PRODUCT. IF THE BOOKLET IS MISSING, RETURN THIS PRODUCT TO THE PLACE OF PURCHASE & OBTAIN A REPLACEMENT PACKAGE.

FOR COMMERCIAL USE ONLY BY PROFESSIONAL, TRAINED APPLICATORS.

Patented Internationally
OhSo Clean, Inc.
315 Pacific Avenue
San Francisco, CA 94111
www.CleanWellToday.com
TerraChoice.com

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

JUL 2 9 2011

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **84683-2**

4/11

Benefect® Biocide AD is ~~the first botanically derived biocide~~ for use in air ducts. The patented technology is a proven bacteriostat, fungistat (mold & mildew), mildewstat & deodorizer. It controls & inhibits odor causing bacteria, fungi & other odor causing organisms in air duct surfaces.

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

Pesticide Storage: Store airtight at room temperature.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinse into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state, and local authorities, by burning. If burned, stay out of smoke.

- For Air Duct Applications:

PERSONAL PROTECTION EQUIPMENT:

Applicators & other handlers must wear chemical-resistant gloves and eyewear (goggles/face shield).

SPECIAL INSTRUCTIONS FOR APPLICATORS:

Applicators treating the inside of an air duct system must ensure the ductwork is ventilated with airflow of approximately 50 CFM per square foot of duct cross section as a safety precaution against pre-existing contaminants. If this is not possible, OSHA confined space regulations must be followed that and the requirements for a permit required space apply. These requirements include testing the atmospheric conditions (e.g. pre-existing hazardous or flammable contaminants, dust & oxygen levels etc.) and use of adequate respirator protection. If the level of contamination cannot be determined, then maximum respiratory protection (SCBA or airline with an escape bottle) must be used. If needed, the full-face respirator must also be equipped with a spray mist pre-filter in addition to the charcoal filters.

ENGINEERING CONTROLS: During ULV, mist or spray application, the duct system interior must be maintained under slight negative pressure (0.015 to 0.025 In. WG) with an outdoor exhaust or using a negative air machine equipped with HEPA filter. Avoid higher pressure differentials that would be likely to disrupt the coverage pattern.

RECEIVED
STATEMENTS
EPA Office Denver

APPROVED FOR RELEASE
DATE 10/10/2011
BY 60322/UC/STP

DIRECTIONS FOR USE FOR AIR DUCTS:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELLING. THE PERSON APPLYING THIS PRODUCT IS RESPONSIBLE FOR FOLLOWING THESE DIRECTIONS UNDER BOTH STATE AND FEDERAL LAWS. FOR COMMERCIAL USE ONLY BY PROFESSIONAL, TRAINED APPLICATORS.

1.0 General

BENEFECT® BIOCIDE AD is designed to be used one component of a comprehensive HVAC & duct maintenance program. The purpose of such a program is to assure that the HVAC system & ducts function in the manner they were designed to, remain free from mold & other microbial growth & other contamination, & continue in that condition. This product must only be used in only those cases where visible microbial growth has been detected in the system & then only after removing that growth & identifying & correcting the conditions that led to that growth. If you need help in understanding any part of these instructions or have additional questions after reading these instructions, DO NOT APPLY THIS PRODUCT until you have received the answers for all of your questions.

2.0 Inspection

Prior to inspecting, cleaning, treating, repairing or otherwise working on a duct section, turn off the HVAC system or the section under repair physically isolated from sections in active use.

Prior to any application of BENEFECT® BIOCIDE AD the system must be inspected for cleanliness & mechanical condition. When initiating any measures to repair, clean or treat ducts & associated HVAC system components, industry standards from the National Air Duct Cleaners Association (NADCA) & other organizations must be followed.

Inspect the HVAC systems routinely for cleanliness by visual means. The NADCA Standard, *Assessment, Cleaning and Restoration of HVAC Systems* (ACR 2002 or the latest revision), provides minimum recommended inspection frequency schedules for ducts & other system components. More information on NADCA standards can be obtained from the NADCA web site at www.nadca.com.

2.1 Cleanliness Inspection

According to NADCA Standards, HVAC system cleaning must be performed when any of the following conditions are found in the cleanliness inspection. If any of these deficiencies are found during inspection, cleaning in accordance with industry standards must be performed prior to the application of BENEFECT® BIOCIDE AD:

2.1.1 Contamination

- Operate the HVAC systems in a clean condition. If significant accumulations of contaminants or debris are visually observed within the HVAC system, then cleaning is necessary. Likewise, if evidence of microbial growth is visually observed or confirmed by analytical methods, then cleaning is required.
- If the HVAC system discharges visible particulate into the occupied space, or a significant contribution of airborne particulates from the HVAC system into the indoor ambient air is confirmed, then cleaning is necessary.

- Heat exchange coils, cooling coils, air flow control devices, filtration devices, and air-handling equipment determined to have restrictions, blockages, or contamination deposits that may cause system performance inefficiencies, air flow degradation, or that may significantly affect the design of the HVAC system, require cleaning.
- Drain pans must be free from slime and sludge or other condition. Badly rusted or corroded drain pans must be repaired or replaced.
- Fans & fan housings must be free from accumulations of microbial growth & particulate matter.

If you need help in understanding existing industry standards, consult a qualified professional [or contact CleanWell Company at 877-401-6031] for guidance and further direction or consult the information at www.epa.gov (search on "air ducts"). In addition, consult the associations and society Internet sites for information on standards and guidelines they have developed:

- ACCA – www.acca.org
- ASHRAE – www.ashrae.org
- NADCA – www.nadca.com
- NAIMA – www.naima.org
- SMACNA – www.smacna.org

2.2 Mechanical Inspection

BENEFECT® BIOCIDE AD must be used only on ducts & other HVAC system components in sound mechanical condition as defined in 2.2.1 and 2.2.2 (below). The HVAC system components must be designed and installed in conformance with industry standards and guidelines. Prior to using the product, inspect the ducts & assure that they are in sound mechanical condition. The following general guidelines, supplemented by industry standards from SMACNA, NAIMA, ASHRAE, ACCA and other organizations must be followed:

2.2.1 Air Leaks and Mechanical Defects

The ducts must be free from air leaks and other mechanical defects. Air leaks will promote condensation of water that causes microbial growth and will lead to failure of BENEFECT® BIOCIDE AD to protect the system adequately.

2.2.2 Design and Installation

ASHRAE, SMACNA, NAIMA and other industry organizations have established guidelines and standards for the design and installation of HVAC and duct systems. Determine that the duct system you wish to treat conforms to industry practice. If you are not knowledgeable of industry guidelines and standards, consult a qualified professional [or contact CleanWell Company at 877-401-6031] for assistance.

In some situations, the inspection may reveal that the duct system or other component is badly damaged or in such poor operating condition that it cannot be corrected through cleaning and/or minor repair. In these situations, replaced or rebuild the system in conformity to the applicable industry standards prior to using BENEFECT® BIOCIDE AD. Some (but not all) of the conditions that would indicate the need for major repairs or replacement of the system include:

- Improper size of ducts – Ducts must be sized to achieve correct airflow. When air-handling equipment is changed or new inlet or outlets added, the size of all components in the system must be recalculated and replacements made as needed.

- Physical damage – Crushed or deformed air ducts will restrict airflow and may leak (especially at joint areas). Replace the damaged sections or, if there is extensive damage, replace the entire system.
- Badly corroded metal components including duct sections, housings & cabinets, coil assemblies, drain pans, fans & their housings and heat exchange surfaces.
- Loose, damaged, friable or missing insulation – Insulation is important in preventing moisture condensation and subsequent growth of mold & other organisms. If insulation (either interior or exterior) is damaged, missing or not properly fastened it must be repaired or replaced or the associated duct sections replaced. Air handling, mixer & VAV box housings are also normally insulated & this insulation must be checked for damage in a like manner.

Removed components that are contaminated with mold & other microbial growth may spread contamination while being removed from the building. To prevent this, place smaller items into sealed plastic bags before being removed. Treat the larger items that cannot be safely packaged before being moved through occupied spaces. An appropriately labelled disinfectant can be used during treatment. Care must be used during treatment to assure that fumes from the agent being used are not released into occupied spaces. Use the products according to their label directions. [Please contact CleanWell Company at 877-401-6031 for guidance on the appropriate disinfectant to use for treatment.]

3.0 General Directions for BENEFECT® BIOCIDE AD Usage

BENEFECT® BIOCIDE AD effectively controls by inhibiting growth of odor causing bacteria, fungi, and other odor, stain or damage causing organisms in air ducts in residential, commercial, institutional, and industrial buildings. BENEFECT® BIOCIDE AD also eliminates odors associated with bacteria, mold, mildew, smoke, animals, cooking, spoilage, musty and other odors and removes odor-causing organisms when used as part of such a comprehensive preventative maintenance program in air ducts and other HVAC system components.

BENEFECT® BIOCIDE AD is a Bacteriostat, Fungistat (mold & mildew), Mildewstat and deodorizer for use in residential, commercial and industrial settings. It will not stain or bleach materials or fabrics and will not harm or damage HVAC system components.

BENEFECT® BIOCIDE AD is formulated for use in all kinds of ducts and HVAC components including:

- Unlined sheet metal
- Air supply and return ducts and plenums fabricated with plywood, OSB or other wood like material
- Flexible air ducts fabricated of metal or plastic
- Air distribution components such as air handlers, mixing boxes, transfer boxes, transitions, turning vanes, dampers, fans and fan housings and associated components
- Condensate drain pans

Follow the directions below for the specific type of duct or component being treated. It is vital that the following direction be carefully read and understood prior to using the product. If you have any questions, need further information, require clarification, or do not understand any of the directions, consult a qualified professional [or call CleanWell Company at 877-401-6031] prior to use.

3.1 Application Instructions

Shake well & wet the surfaces with the spray, giving special attention to cracks and crevices (BENEFECT® BIOCIDE AD should not stain any materials not stained by water but testing for compatibility on surface of concern first is recommended). Allow ten to twenty minutes for drying. No rinsing or wiping is required. Following the elapsed drying time it is best practice to purge the system, by increasing the negative pressure through the outdoor exhaust or negative air machine or by turning on the vacuum used to pre-clean the HVAC system, while removing the duct openings seals. This will minimize the release of scent into the spaces served by the system.

3.2 Application Equipment and Devices

Refer to the precautionary statements for the Personal Protective Clothing and other special instructions that must be followed.

3.2.1 Brush, Mop or Wipe Application

Brush, Mop or Wipe Application may be specified by some facility maintenance or remediation plans. These techniques are generally more labor intensive than other methods and are normally used only when specifications require. These methods are suitable only for smooth uniform surfaces. Do not use on porous or non-uniform surfaces. [If in doubt about a given surface, consult a qualified professional [or contact CleanWell Company at 877-401-6031] before proceeding. When using brush or mop application, use tools and materials only for application of BENEFECT® BIOCIDE AD, kept clean and protected between users and replaced when worn or visibly soiled. Natural fiber brushes are preferred although any quality brush is acceptable. Use mops that leave minimal lint behind. Micro-fiber or other non-linting cloths are preferable. Where other types of cloths are used, they must be soft enough that they absorb a sufficient quantity of liquid to perform uniform application.

During Brush, Mop or Wipe Application, the applicator must have access to the surface being treated. Usually this will require entering the ducts. The applicator will then work from that point back to the entry point covering a 3 foot length of duct at a time. Apply to the top of the duct first, followed by the sides then the floor of the duct. Overlap applications to ensure complete coverage. Cover completely while avoiding runs or pooling.

3.2.2 Spray Applicators

Spray application is preferred on large surfaces that are easily accessible (such as in long runs of large diameter ducts, coil assemblies and the interior of cabinets and housings with removable access panels). The spray equipment chosen must provide a consistent fine (1-300 micron) particle size and uniform spray pattern. Powered medium pressure sprayers are preferred. However, airless sprayers are suitable.

Where airless sprayers are use, the most satisfactory spray pattern will be achieved using a 0.011" spray tip. For other brands and options consult a qualified professional [or contact CleanWell Company at 877-401-6031].

Pump up garden type sprayers can be used but care must be taken to maintain maximum pressure by pumping frequently and the spray nozzle must be adjusted for the finest spray pattern possible. During application achieve complete uniform coverage. Avoid excessive wetting and do not allow the spray to run or pool.

3.2.3 ULV or Mist Generating Sprayers

ULV or mist or other wet small particle application is preferable where surfaces are irregular or less accessible. Equipment capable of generating particles in the 15 to 60 micron range is most satisfactory. Avoid use of thermal type fog generators. [Contact CleanWell Company at 877-401-6031 for information on other devices.]

Generally a fog will carry and provide adequate coverage up to 8 feet from the point of application so adequate penetrations must be cut in the ducts to assure complete coverage without over wetting. SMACNA, NADCA and NAIMA have established standards and guidelines for making and sealing openings in ducts. Insure that the operators have training on proper application techniques as well as correct duct penetration and sealing procedures using these standards and guidelines. Operators must also carefully read and follow directions for the brand of equipment used. Consult a qualified professional [or contact CleanWell Company at 877-401-6031] for information on training for using various types of equipment. Ensure that the duct penetrations are properly closed following application, in accordance with industry standards.

3.2.4 Automated Atomizing or Spray System

There are a number of automated spray systems on the market including those that are carried by a "robot" through air ducts. These may provide an excellent option for application of BENEFECT® BIOCIDÉ AD in parts of air ducts that are difficult to access if they produce the correct spray pattern and application quantity. These devices must be visually monitored using video or other means while applying spray so proper application rate will be maintained. Please contact a qualified professional [or CleanWell Company at 877-401-6031] regarding a specific device should you have questions.

3.3 Application Techniques

BENEFECT® BIOCIDÉ AD must be applied evenly throughout duct system and over other surfaces that are being treated. Even and uniform application is essential for satisfactory results. The procedures, equipment and techniques described below have been tested and provide the desired results. Other procedures, equipment, or techniques may also achieve satisfactory results, but first discuss the specific situation and equipment with a qualified professional [or a representative of CleanWell Company at 877-401-6031].

3.3.1 Application from Exterior of the HVAC System

BENEFECT® BIOCIDÉ AD may be sprayed into openings at intervals throughout the duct system or on components that are accessible through removable panels or access doors. Spray into openings every 8 feet at a minimum. Existing supply openings can be used where they provide a clear view of the surfaces being sprayed so that uniform application can be achieved. However, additional penetrations will have to be made as needed, so enough openings will be available to achieve total and uniform coverage.

Spray application is not an acceptable technique where openings are greater than 8 feet apart, additional openings cannot be made and properly sealed, and/or the duct geometry does not allow for uniform coverage. In such cases, application from within the HVAC system is necessary (see 3.3.2 below).

3.3.2 Application from Within the HVAC System

When BENEFECT® BIOCIDE AD cannot be sprayed into openings at intervals throughout the duct system, you must gain entry into the system and spray the product onto interior duct and other surfaces until they are thoroughly and uniformly covered using hand or powered spray equipment. This is the most frequently used technique and is the technique of choice for air handlers, other components with access panels or doors and large diameter (generally 20" x 20" minimum) ducts where direct access can be gained to surfaces being treated. Please refer to Special Instructions for Applicators above for additional instructions.

3.4 Rate of Application

The rate of application for BENEFECT® BIOCIDE AD varies depending on the surface being treated. Users of this product must carefully follow the rate of application instructions provided below:

3.4.1 Bare Metal and Flexible Ducts

Apply until surface is evenly wet. Mist or wipe coverage 1,000 ft² per gallon. Spray coverage 500 ft² per gallon. If the above application rates result in surface runoff or liquid pooling on the bottom of the duct, lower the application rate until the surface is thoroughly and evenly wet without runoff or pooling. The exception to this is when treating coil assemblies. In this case, apply the spray generously until there is runoff into the drain pan so as to penetrate the coil assembly to the greatest possible depth.

3.4.2 Semi Porous Surfaces such as Concrete or Plaster

Apply until surface is evenly wet. Mist coverage 500 ft² per gallon. Do not use wipe. Spray coverage 250 ft² per gallon. BENEFECT® BIOCIDE AD must penetrate into surface crevices and irregularities or it will not be effective. Inspect and assure that penetration is satisfactory. It may be helpful to apply half of the quantity needed for full coverage spraying from side to side then repeat the application moving the spray from top to bottom.

3.5 Frequency of Application

Normally, infrequent application (6 months to every two years) will provide effective control. Some critical applications such as duct systems serving critical health care spaces or clean rooms where it is essential to minimize the generation of particulate matter that may be released as a by-product or microbial growth may require more frequent treatment. Do not apply more often than monthly and then only if there is evidence of re-growth. This product must only be used in those cases where visible growth has been detected in the system and then only after removing that growth and identifying and correcting the conditions that led to that growth. Prior to reapplication in such cases, investigate to determine the cause of re-growth and correct that problem prior to re-application. Before embarking on a program of frequent application (more frequently than every 6 months) consult a qualified professional [or contact CleanWell Company at 877-401-6031] and discuss the specific application and situation. Also make sure the reoccurrence of microbial growth does not have another cause such as persistently high humidity, standing water or hidden leaks.

Prior to reapplication, the interior of the ducts and other surfaces must be inspected and found to be free of accumulated soil. If soil or growth is found, the cause should be determined and corrected and then the ducts cleaned in accordance with accepted industry practice.

If microbial growth persists following application re-inspect for duct leaks, carryover of water from cooling coils or humidifiers and other sources of moisture promoting growth. Eliminate such sources of moisture before retreating.

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3.6 Returning the System to Operation following Application

Fans and blowers in the section of duct being treated must be turned off during application of BENEFECT® BIOCIDE AD. If the system cannot be shut down, the section of duct being treated must be isolated until treatment is complete. This will prevent the spray of fog from being blown away from the surface that is being treated.

Do not attempt to use the system fan or blower to carry BENEFECT® BIOCIDE AD to the surfaces in the duct system. Such a practice will not result in uniform application of the product to the surfaces being treated and will lead to ineffective control. Do not attempt this.

The system can be returned to full operation as soon as treatment is completed or at any time following completion of treatment. BENEFECT® BIOCIDE AD will dry within 15 minutes following application. Extended drying time does not have an impact on effectiveness of treatment. When the above directions are followed properly, there will not be significant concentrations of BENEFECT® BIOCIDE AD released to the spaces served by a system being treated. There is no need to have occupants leave the building during application.

CleanWell™ Inside

