EPA Reg. No. 84368-1

Volume 1

Material to be added to an e-Jacket/Jacket

Reg. No. 84368-1

Description: _____

1. ☐ **Placement within the e-Jacket/jacket:**
   - ☐ **Default: (chronological, top = newest)**
   - ☐ **File Location: (PDF page number, i.e., "before page 45")**

2. ☒ **Send to Data Extraction contractors this material:**
   - ☒ **Newly stamped accepted label**
   - ☐ **Notification**
   - ☐ **New CSF**
   - ☐ **Other:** _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Jacqueline Campbell-McFarlane

Phone: _____ **Division:** _____

Date: 2/3/2011

Created August 14, 2008

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

FEB - 3 2011

Mr. Olav Messerschidt
Urth Tech LLC
30777 Morthwestern Hwy, Ste 300
Farmington Hills, MI 48334

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: UrthProTM Cleaner, Disinfectant, and Fungicide
EPA Registration No.: 84368-1
Submission Dated: September 9, 2010
EPA Receipt Date: September 13, 2010

Dear Mr. Messerschidt,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with conditions.

Proposed Amendment

Change primary eye irritation toxicity category

Conditions
Revise the label as follows:

1.) Delete the 6th claim in the left column on page 3.

2.) Revise the 17th claim in the left column on page 3 by deleting the terms, ingredients or chemicals.

3.) Revise the 6th claim in the right column on page 4 to by removing the brackets from the terms, allergens, dust mite matter, and pet dander such that the claims reads "*Reduces dust mite matter and pet dander allergens*."

4.) Revise the 11th claim in the right column by qualifying the "kills germs" claim by stating "kills *household/bathroom/household* germs" since your product does not meet the Agency's criteria for an unqualified germs claim by not supporting data against a non-envelop virus.

5.) Since this product does not support efficacy data as a food contact sanitizer, you must delete all indirect food contact sites on page 5 such as kitchen tools, knives, and silverware. You must indicate that appliances being disinfected must be qualified as non food contact surfaces by stating "exterior surfaces of" beverage bars, freezers, grills, stovetops, and toasters.

SYMBOL							
SURNAME							
DATE							

6.) You must qualify tile and stone are hard nonporous surfaces on page 5 by stating "glazed" tile and "sealed" stone.

7.) Revise the "4.2.3.1 and 4.4.1 Hard, Smooth surface (Glass, Metal)" directions on page 10 by deleting the "mist" application method. The mist application method is not an option to supporting disinfection claims on hard, smooth surfaces, and thereby must be deleted from these sections of directions. The fogging application is an adjunct to normal disinfection procedures and the proposed labeling is misleading to the users.

Data Summary

Data Requirement	Means of Support	Status
Primary Eye Study in Rabbits	Submitted study, MRID 482230-01	Acceptable, Category III

General comments

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

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact me by telephone at (703) 308-6416 or email at: campbell-mcfarlane.jacqueline@epa.gov or Chris Jiang by telephone at (703) 305-0545 or email at: jiang.chris@epa.gov.

Sincerely,

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

Enclosure: Stamped Label
Acute Toxicity Data Evaluation

	CONCURRENCES						
SYMBOL							
SURNAME							
DATE							

Master Label:

UrthPRO™ Cleaner, Disinfectant and Fungicide

Kills Mold, Fungi, Viruses and Bacteria

ACTIVE INGREDIENT

Ethyl alcohol	29.4%
OTHER INGREDIENTS	70.6%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

See side/back panel for First Aid
Directions for Use must be read completely prior to using this product.
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted con detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Net Contents: [24 oz., 1 quart, 1 gallon, 5 gallon, or 55 gallon]

EPA Reg. No. 84368 – 1

EPA Est. No. XXXX - YY

URTH Tech LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

ACCEPTED
with COMMENTS
In EPA Letter Dated:

FEB - 3 2011

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

84368 - 1

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

GENERAL CLAIMS:

- Controls fungi, including Trichophyton mentagrophytes, and bacteria including *Salmonella enterica, Staphylococcus aureus* and *Pseudomonas aeruginosa* on hard, non-porous surfaces
- Contains no bleach or acid
- Kills fungi, viruses and bacteria
- Eliminates musty odors
- Colorless
- Mold Control on hard, non-porous surfaces
- Mildew stain remover
- Bacterial disinfectant
- General disinfectant
- URTH's patented technology kills [destroys] mold and fungi, including *Trichophyton mentagrophytes*, bacteria, including *Salmonella enterica, Staphylococcus aureus* and *Pseudomonas aeruginosa* in 5 minutes, and all influenza A viruses [including Pandemic 2009 H1N1 influenza A virus].
- Works in hard to clean places (sealed tile grout, caulking and corners) without scrubbing.
- Kills fungi, viruses and bacteria in hard to clean places including:
    - Basements
    - Bathrooms
    - Vacation homes
    - Boat interiors
    - Areas under construction
- For use in homes, businesses, institutions, hospitals
- Colorless
- No fumes
- Fungicide
- Effective against [fungi] and [bacteria]
- Controls odor causing mold and fungi on hard, non-porous surfaces
- Deodorizer
- URTHPRO CLEANER, DISINFECTANT AND FUNGICIDE is [specially formulated] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold, mildew and bacteria.
- Use all around the [kitchen] [home] [house]
- [lightly] cleans [and disinfects]
- Great for [daycare] [restroom] [restaurant] [office] [school] use!
- Great for [all around] [everywhere in] [the] [house] [home] [kitchen] [bathroom]
- Just spray [and] [wipe] [walk away]
- Latest in [antimicrobial] [disinfectant] technology
- Leaves a streak-free shine
- Leaves no residue
- Leaves surfaces [shiny] [clean]
- Leaves your [kitchen] [home] [house] [bathroom] [smelling] clean
- Makes your job easier
- No [harsh fumes] [accidental whitening]
- No measuring
- No mixing
- Non-abrasive [formula]
- Cleaning and disinfecting
- Cleaner and disinfectant
- Patent pending [formula]
- Perfect size for [bathrooms] [kitchens] [your purse] [your pocket] [use all around the house]
- Pocket-sized
- Globetrotter
- On the spot disinfectant
- Proper dilution every time
- Quick – or – easy – or – fast – or – convenient – or – versatile
- Ready-to-use – or – RTU
- Use on any washable surface including (list any surface from list 2 or 3)
- Use for a [fresh] [home] [house]
- Eliminates potential for mixing errors
- Eliminates the need to test ppm level
- Food [contact] [surface] [service] disinfectant
- For [daily] [everyday] [light-duty] [kitchen] [bathroom] [hospital] disinfection –or – cleaning
- For [daily] [everyday] use
- For a cleaner, fresher [bathroom] [kitchen] [home] [house]
- For use on both white and colored surface and on any washable surface

• Controls mold [leaving a fresh clean scent] [leaving rooms clean and fresh smelling]. • Eliminates musty odors [caused by mold on hard, non-porous surfaces]. • URTHPRO disinfects in 5 minutes • A way to [clean] [and] [disinfect] • A [smarter] way to clean • ~~A new technology that is enough to use around your family…on the surfaces they touch most~~ • Multi purpose [antibacterial] kitchen [cleaner] [mist] [spray] [disinfectant] • Antibacterial [daily] kitchen [cleaner] [mist] [disinfectant] [spray] • Disinfectant that can be used anywhere • Check [out] our website at [www.cleanurth.com] [www.URTHPRO Cleaner, Disinfectant and Fungicide.com] [www.urthtech.com] [for more information] • [Clean] [light] [airy] [fresh] fragrance – or – scent • [Clear] [colorless] formula • [Urth™] everywhere • Color fast • [Color fast] will not whiten or bleach [surfaces] [or] [clothes] • Contains no [abrasives] [or] [bleach] [or] [[harsh] acids] • Contains no [artificial – or - [fragrances] [or] [dyes] [or] [~~ingredients~~] [or] [~~chemicals~~] • [Controls] [prevents] [stops] the growth of odor-causing [bacteria] [and] [mold] [and] [fungi]. • [Daily] [everyday] kitchen [cleaner] [mist] [disinfectant] [spray] • Deodorizer • Deodorizes sponges • [Easy] [quick] [convenient] to use • [Easy] [quick] [convenient] way to disinfect • [Economy] [institutional] [refill] [value] size – or – pack • [Economy] [value] refill • Eliminates buckets and rags for [cleaning] [and] [disinfecting] • Eliminates labor required to mix solution	including (list any surface(s) from list 2 or 3) • [Worry free] spray [that you can use all around the house] • All-in-one [cleaner] [and] [disinfectant] [and] [fungicide] • Use [daily] [everyday] • Use for wiping [bathroom] [kitchen] counters • Works quickly • [Free of] [No] bleach -or- harmful chemicals • Degreaser [Degreases]

DISINFECTANT/FUNGICIDE CLAIMS	
• Antibacterial • Can help reduce the risk of cross-contamination • Can reduce the cross contamination of [kitchen] bacteria [on [hard non porous] • Eliminates food odors like garlic and onion left behind on kitchen surfaces after cooking • Eliminates odors caused by [bacteria] [and] [mold] [and] [fungi] • [lightly] cleans and [kills] [eliminates] [destroys] [removes] [the most common] [kitchen] [bacteria] [and] [fungi] • Kills [fungi] [bacteria] in 5 minutes • Kills household germs [such as] [bacteria] [viruses] [and] [fungi] • Kills the [bacteria] [fungi] commonly found in kitchens and bathrooms • Kills [the] bacteria you can't see • [Kills] [eliminates] [destroys] [removes] [all] [bacteria [and/or] fungi] [all] around your [bathroom] [kitchen] [home] [house] • [Kills] [eliminates] [destroys] [removes] [bacteria [and/or] fungi] all around your [kitchen] [bathroom] [including] [like] Salmonella [enterica] [and] Staph [Staphylococcus aureus] [and] Pseudomonas [aeruginosa] [and] Athletes foot fungus [Trichophyton mentagrophytes] • [Kills] [eliminates] [destroys] [removes] [bacteria [and/or] mold [and/or] mildew [and/or] fungi] without leaving a harmful residue • [Kills] [eliminates] [destroys] [removes] [bacteria [and/or] fungi] on commonly touched surfaces that can be transfer points for bacteria [such as doorknobs, telephones, keyboards, and lightswitches]	• [Kills] [eliminates] [destroys] [removes] [bacteria] [and/or] fungi] on: (list any surface from list 2 or 3) • [Kills] [eliminates] [destroys] [removes] [bacteria] [and/or] fungi] [on hard, nonporous surfaces] • [Kills] [eliminates] [destroys] [removes] common household [bacteria] [and/or] fungi] • Kills odor causing [bacteria [and/or] mold [and/or] mildew [and/or] fungi] • Leaves household surfaces [sanitary] [disinfected] [free from germs] • Reduces [allergens] [dust mite matter] [pet dander] • Disinfects • Specially designed for use on: (list any surface from list 3) • Tough on [bacteria [and/or] mold [and/or] mildew [and/or] fungi], [Urth™] [the solution] is easy to both hands and surfaces • [Cleaner] [and] [Disinfectant] [and] [Fungicide] • Cleans as it [disinfects] [kills germs] [kills common household bacteria] • A[n] [quick] [and] easy way to [kill] [eliminate] [destroy] [remove] bacteria [and] [fungi]

USE SITES (LIST 3)			
• Around toilet areas • [Around] toilets • Automobiles • [Bath]tubs • Bathroom [Counter]tops • Bathroom [Surfaces] • Beverage Bars • Blinds • Boat Interiors • Booster Chairs • Cabinet Handles • Cabinets • Cafeteria[s] • Can Openers • Cars • Children's [Kids'] [Wading] Pool • Children's [Kids'] Table • [Computer] Keyboards • Counter(s) -or- Countertop(s) • Cupboards • Dairy Cases	• Dining Room Tables • Dish Racks • Dishwashers • Door Handles • Doorknobs • Doors • Drainboards • Dryers • [Empty] Clothes Hampers • [Empty] Garbage Cans [Bins] • Faucets • Floors • Freezers • Grills • Grocery Carts • [Grocery] Checkout Areas • Handrails • High Chair Trays • High Chairs • Inside Dishwasher[s] [Interiors] • Kid's [Children's] Playroom [Toys]	• [Kitchen] [Bathroom] Sinks • [Kitchen] [dining room] Tables • Kitchen Surface • ~~Kitchen Tools~~ • ~~Knives~~ • Laundry Rooms • Light Switches • Litter Boxes • Outdoor[s] [Areas] • Oven Doors • Ovens • Pet Bowls [Areas] • Piano Keys • Patio Furniture • Playpens • Potty-Chair[s] [Seats] • Range Hoods • Recycling Bins • Restrooms • Shower [Faucets] [Doors] [Handles] [Fixtures] [Walls] [Floors]	• ~~Silverware~~ • Sink [Faucets] [Fixtures] [Handles] • Soap Dispensers • Storage Areas • Stovetops • Stroller [Handles] [Trays] • Tables • Telephones • Toasters • Toilet [[Flushing] Handles] [Seats] [Surfaces] [Exteriors] • Towel [Tissue] Dispensers • Under Sinks • Urinals • Vanities • Vanity Tables • [Vinyl] Shower Curtains • Walls • Washing Machines • Windowsills
USE SURFACES (LIST 4)			
• Basements and crawl spaces • Cabinets and counter tops • Sealed cement • Glazed Ceramic Tile	• Sealed Hardwood [floors] • Chrome • Corian • Floor surfaces • Formica • Glass	• Sealed granite • Linoleum • Marble • Metal • Painted wallboard •	• Glazed porcelain • Stainless Steel • Tile • Vinyl • Sealed Wood • Stone

{Optional text}
URTHPRO Cleaner, Disinfectant and Fungicide is an effective disinfectant against *Salmonella enterica (ATCC #10708), Staphylococcus aureus (ATCC #6538)* and *Pseudomonas aeruginosa ATCC #15442) on hard, non-porous surfaces in the presence of 5% organic soil for a 5-minute contact time*

URTHPRO Cleaner, Disinfectant and Fungicide is effective against fungi, including *Trichophyton mentagrophytes (ATCC #9533.*

URTHPRO Cleaner, Disinfectant and Fungicide kills influenza A viruses (H1N1) within a 1-minute contact time.

DIRECTIONS FOR USE

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

The person applying this product is responsible for following these directions under both state and federal laws.

1.0 General

URTHPRO Cleaner, Disinfectant and Fungicide liquid formula kills and eliminates bacteria, including *Salmonella enterica*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*, mold and fungi, including *Trichophyton mentagrophytes*, in 5 minutes, and influenza A viruses in 1 minute. URTHPRO Cleaner, Disinfectant and Fungicidedestroys odor, stain causing or other damage causing organisms including mold and mildew on hard, non-porous surfaces including floors, walls, contents and other interior building surfaces until such time as the cause of such growth can be identified and corrected. It is also used as [one component] [part of an all-in-one] [part of a one-step] mold remediation or water damage restoration program. The purpose of such a program is to minimize damage from growth of mold and other odor, stain and damaging organisms, and help building interiors continue in that condition. This product must only be used in those cases where visible microbial growth has been detected and then only as part of a program that removes that growth and identifies and corrects the conditions that led to that growth. If you need help understanding these instructions or have additional questions after reading these instructions, DO NOT APPLY THIS PROUCT until you received answers for all of your questions.

2.0 Causes of Microbial Growth

Microbial (including bacteria, mold, mildew, and other fungi) growth is present at all times both outdoors and in building interiors. Normally the natural balance of the environment limits such growth to acceptable levels. Under certain conditions, growth can reach problem levels and if not controlled, will cause foul odors, stain and damage furnishings and valuables, and may even destroy structural components of the building. Normally fungal spores, live organisms and food sources are plentiful in building interiors. Elevated water from the following can lead to growth:

2.1 Floods

If water floods the interior of a building it brings a massive load of organic matter, bacteria and fungal spores. If the water and excessive organic load is not cleaned quickly, substantial growth will result. Floods can result from rising water and plumbing failures.

2.2 Leaks

Leaks release lesser amounts of water, often over extended time periods. Thus, they can lead to high levels of growth in wall cavities and other spaces where they are not visible until considerable damage has been done. Leaks can be both from plumbing, roof, wall or other structural failures.

2.3 Humidity

Microorganisms grow in moisture that form on surfaces and within porous materials. This is known as water activity of the maternal or surface. High levels of humidity can lead to sufficient surface water activity to support accelerated growth if that elevated level is maintained for as little as 24 hours. Accelerated growth takes place with some fungi within 24 hours at humidity levels between 66% - 70%.

3.0 Indications for Use and Guidelines

Homeowners and building managers must survey their buildings at least monthly for any of the following conditions. When they are found, they must be corrected according to the guidelines.

3.1 Visible Growth

Areas of visible growth of less than 32 square feet (the area of a single wall panel) can normally be remediated without elaborate procedures. When these areas are identified, mist (see application instruction below) lightly with URTHPRO Cleaner, Disinfectant and Fungicide to completely kill and eliminate bacteria, mold and fungi 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:

- Clean contaminated area to remove surface soil. For best results, and to avoid possible interference from other chemicals, use URTHPRO Cleaner, Disinfectant and Fungicide 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.
- Apply URTHPRO Cleaner, Disinfectant and Fungicide on cleaned area until evenly wet and let it stand for 5 minutes.
- Allow treated surfaces to dry completely.
- Wipe with wet sponge or cloth if cosmetically necessary.

Aras larger than 32 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 Association (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 URTHPRO Cleaner, Disinfectant and Fungicide in mitigation of large projects, you must be knowledgeable of one or more of these guidelines and follow them when using this product.

3.2 Water Damage

Evidence of possible water damage includes water stains on ceilings and walls, persistent wet spots or actual flowing water whether from plumbing failure or outside sources. 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 must be removed. Detailed guidance on proper removal on 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 are wet with URTHPRO Cleaner, Disinfectant and Fungicide will kill any potential bacteria, fungi or mold that might have grown on the surfaces 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 URTHPRO Cleaner, Disinfectant and Fungicide, provides for the user and occupant safety documentation and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, IICRC S500 contains excellent guidance. In the context of such a plan, URTHPRO Cleaner, Disinfectant and Fungicide can be used on materials to be removed and disposed of and in other applications where an Antimicrobial use is indicated.

4.0 General Directions for Using URTHPRO Cleaner, Disinfectant and Fungicide

URTHPRO Cleaner, Disinfectant and Fungicide's patented technology completely destroys [kills] [and] [eliminates] household and residential bacteria, including *Salmonella enterica, Staphylococcus aureus* and *Pseudomonas aeruginosa*, mold and fungi, including *Trichophyton mentagrophytes*, in 5 minutes, and influenza A viruses in 1 minute. URTHPRO Cleaner, Disinfectant and Fungicide also effectively eliminates stain and odor causing bacteria, mold and fungi, or damage causing organisms on floors, walls, and other surfaces in residential, commercial, institutional, and industrial buildings in 5 minutes. URTHPRO Cleaner, Disinfectant and Fungicide 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 a comprehensive preventative maintenance approach.

URTHPRO Cleaner, Disinfectant and Fungicide is a bactericide and fungicide, which [destroys] [kills] [eliminates] disease causing household and residential bacteria, mold and fungi, and is a deodorizer for use in residential, commercial and industrial settings. It will not stain or bleach materials or fabrics and will not harm or damage most interior surfaces. Test on an inconspicuous area if you are unsure of the surface on which you are working.

URTHPRO Cleaner, Disinfectant and Fungicide is formulated for use on all kinds of surfaces including:

- Painted wallboard
- Structural members and supports
- Ceilings and above ceiling spaces
- Basements and crawl spaces
- Cabinets and countertops
- Case goods and other furnishings
- Floor surfaces

Follow the directions for the specific type of component being treated. The following directions must be carefully read and understood prior to using the product.

4.1 Mixing Instructions
4.1 URTHPRO Cleaner, Disinfectant and Fungicide is a ready to use product – DO NOT DILUTE. Read the label before using.

4.2 Application Equipment and Devices
Apply URTHPRO Cleaner, Disinfectant and Fungicide on the surface until thoroughly wet, let it stand for 5 minutes and wipe with wet sponge or cloth if is cosmetically necessary. URTHPRO Cleaner, Disinfectant and Fungicide must come in direct contact with bacteria, mold, fungi or other micro-organisms to be effective.

Refer to the precautionary statements and other special instructions that must be followed.

4.2.1 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. When using brush or mop application, tools and materials used must be reserved only for application of URTHPRO Cleaner, Disinfectant and Fungicide, kept clean and protected between uses and replaced when worn or visibly soiled. Natural fiber brushes are preferred although any quality brush is acceptable. Where other types of cloths are used, they must be soft enough that they absorb a sufficient quantity of liquid to provide uniform application.

During Brush, Mop or Wipe Application, the applicator must have access to the surfaces being treated. Apply to a limited area at a time. Overlap applications to assure complete coverage. Cover completely while avoiding runs or pooling.

4.2.2 ULV (Ultra Low Volume) or Mist Generating Sprayers
ULV, mist or other small particle application is preferable where surfaces are irregular or less accessible. Equipment capable of generating particles in the 15 – 60 micron range is most satisfactory. Do not use thermal type fog generators.

Generally a fog will carry and provide adequate coverage up to 8 feet from the point of application so the fog must be directed in all directions to assure coverage without over wetting. All surfaces must be cleaned and disinfected in accordance to label directions prior to fogging. Fogging is only to be used as an adjunct to surface disinfection. Personal protective equipment including HEPA filtered mask, hooded coveralls and rubber gloves must be used when applying in open space with mist generating application equipment.

Close room off so fog is confined to room to be treated. Insert nozzle or fogger through suitable opening to room. Vacate area of all personnel during fogging. Do not allow people to breathe or contact the fog or to enter the room until the fog

has completely settler or exhausted. Do not use surfaces or equipment until treatment has dried.

4.2.3 Spray Applications and Rates

4.2.3.1 Hard, Smooth surface (Glass, Metal)

Apply until surface is evenly wet. [redacted], wipe or spray coverage rate is 400 ft^2 per gallon. If this rate results in surface runoff or liquid pooling, lower the application rate until the surface is thoroughly and evenly wet without runoff or pooling.

4.2.3.2 Semi-Porous Surfaces such as Concrete or Plaster or Wallboard

Apply until surface is evenly wet. Mist coverage rate is 200 ft^2 per gallon. Wipe is not recommended. Spray coverage rate is 100 ft^2 per gallon. URTHPRO Cleaner, Disinfectant and Fungicide 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 make multiple applications at a lower application rate on some surfaces as the first application will wet the surface and facilitate penetration of following applications.

4.3 Application Techniques

URTHPRO Cleaner, Disinfectant and Fungicide must be applied evenly over 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 desired results.

4.4 Rate of Application

Users of this product must carefully follow the rate of application instructions provided below.

4.4.1 Hard, Smooth surface (Glass, Metal)

Apply until surface is evenly wet. [redacted] wipe or spray coverage rate is 400 ft^2 per gallon. If this rate results in surface runoff or liquid pooling, lower the application rate until the surface is thoroughly and evenly wet without runoff or pooling.

4.4.2 Semi-Porous Surfaces such as Concrete or Plaster or Wallboard

Apply until surface is evenly wet. Mist coverage rate is 200 ft^2 per gallon. Wipe is not recommended. Spray coverage rate is 100 ft^2 per gallon. URTHPRO Cleaner, Disinfectant and Fungicide 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 make multiple applications at a lower application rate on some surfaces as the first application will wet the surface and facilitate penetration of following applications.

4.5 Frequency of Application

URTHPRO Cleaner, Disinfectant and Fungicide is suitable for frequent reapplication, but a single application will provide effective control. If there is evidence of re-growth, investigate to determine the cause of re-growth and correct that problem prior to re-application. Also make sure the re-occurrence of microbial growth does not have another cause such as persistently high humidity, standing water or hidden leaks.

Removed components that are contaminated with mold and other microbial growth may spread contamination while being removed from the building. To prevent this, smaller items must be placed in plastic bags that must then be sealed before being removed. Larger items that cannot be safely packaged must be treated before being moved through occupied spaces.

NOTICE ON CONDITIONS OF SALE

The **Directions For Use** of this product reflects the opinion of experts based on experimental use and tests. The directions are believed to be reliable and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result, because of factors such as the presence of other materials, or use of the product in a manner inconsistent with its labeling, all of which are beyond the control of UrthTech or the Seller.

To the extent consistent with applicable law, UrthTech warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions For Use**, subject to the inherent risks, referred to above. To the extent consistent with applicable law, UrthTech makes no other express or implied warranty of fitness or merchantability or any other express or implied warranty. To the extent consistent with applicable law, in no case shall UrthTech or the Seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. To the extent consistent with applicable law, UrthTech and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing **Conditions of Sale and Warranty** which may be varied only be agreement in writing signed by a duly authorized representative of UrthTech.

URTHPRO ™ is a trademark of UrthTech, LLC

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:
CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear such as goggles or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes. Then continue rinsing eye. • Call a poison control center or doctor for treatment advice
Hot Line Number: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on URTHPRO Cleaner, Disinfectant and Fungicide, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.	

Physical or Chemical Hazards
Combustible. Do not use or store near heat or open flame.

DIRECTIONS FOR USE

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

GENERAL CLEANING: [For everyday cleaning] spray URTHPRO Cleaner, Disinfectant and Fungicide™ directly on to surface and wipe clean. Repeat this procedure for heavily soiled areas.
DISINFECTION [OF FOOD CONTACT AND NON-FOOD CONTACT SURFACES] on HARD NON-POROUS SURFACES: [To kill common household germs such bacteria, mold, viruses and fungi on hard, non-porous surfaces - or – To disinfect hard, non-porous surfaces . Clean area [with this product] to remove surface soil. Spray surface [with this product] [until thoroughly wet] and let stand for 5 minutes. [If desired], wipe with paper towel or clean towel. [Air dry] Organisms (List 1): Staphylococcus [Staphylococcus aureus] Salmonella [Salmonella enterica] Pseudomonas [Pseudomonas aeruginosa] Organisms (List 2): Trichophyton mentagrophytes Organisms (List 3): All influenza A viruses [including Pandemic 2009 H1N1 influenza A virus].
{Optional} **SPONGES:** To [prevent] [stop] [control] the growth of odor-causing bacteria in [your] sponge[s], spray sponge [with this product] until saturated and let stand 5 minutes.

[Residential - Household label]

STORAGE and DISPOSAL

Store in a cool dry place out of reach of children and pets and away from direct sunlight, windows, flames and other sources of heat or ignitions. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[Commercial, institutional and industrial]

STORAGE and DISPOSAL

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

Storage: Store in a cool, dry place inaccessible to children and pets.

Pesticide Disposal: Wastes resulting from the use of this product must 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 (or equivalent) promptly after emptying. Then 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.

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 24, 2011

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol: 84368-1
DP Barcode: D382682

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang
1/24/11

Thru: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang for KPH
1/24/11

To: Jacqueline Campbell-McFarlane PM 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Urthtech, LLC

ACTIVE INGREDIENT	% by wt.
Ethanol	29.4

BACKGROUND:

The applicant has submitted an eye irritation study (MRID 48223001) to modify the toxicity category for eye irritation. The original formulation that was tested contained an increased amount of surfactant that increased the severity of eye irritation. The registrant has discontinued the use of the original formulation. Instead, the company is declaring an alternate formulation as the basic formulation.

RECOMMENDATION:

1. The submitted eye irritation study (MRID 48223001) is acceptable.

2. The previous acute toxicity profile of 84268-1 was:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	Waiver request	IV	Waived
Acute Dermal Toxicity	Waiver request	IV	Waived
Acute Inhalation Toxicity	Waiver request	IV	Waived
Primary Eye Irritation	47320204	II	Acceptable
Primary Skin Irritation	Waiver request	III	Waived
Dermal Sensitization	Waiver request	Non-sensitizer	Waived

3. The current acute toxicity profile of 84368-1 is:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	Waiver request	IV	Waived
Acute Dermal Toxicity	Waiver request	IV	Waived
Acute Inhalation Toxicity	Waiver request	IV	Waived
Primary Eye Irritation	48223001	III	Acceptable
Primary Skin Irritation	Waiver request	III	Waived
Dermal Sensitization	Waiver request	Non-sensitizer	Waived

Labeling:

The signal word is "CAUTION".

The precautionary labeling must read,"Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear such as goggles or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

The First Aid statement must read:

If in Eyes:

Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present, after the first 5 minutes. Then continue rinsing.
Call a poison control center or doctor for treatment advice.

The statement of "then continue rinsing eye" in the first aid statement is acceptable.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

Product Manager: Jacqueline McFarlane
MRID No.: 48223001

Reviewer: Chris Jiang
Study Completion Date: July 20, 2010
Report No.: 29900

Testing Laboratory: Eurofins | Product Safety Laboratories
Author: Jennifer Durando

Quality Assurance (40 CFR §160): Quality Assurance statement and Good Laboratory Practice statement were included.

Test Material: UrthPro, lot 04-282010, a clear liquid

Dosage: 0.1 mL

Species: Three New Zealand albino rabbits
Sex: Females
Age: Young adult
Weight: Not indicated
Source: Robinson Services, Inc., Clemmons, NC

Summary:

1. **Toxicity Category**: III
2. **Classification**: Acceptable

Procedure (Deviations from Guideline 870.2400: None noted

Results:

Individual Scores for Ocular Irritation

Observations	Rabbit No. 3401 (Female)					
	Time After Treatment					
	Hours				Days	
	1	24	48	72	4	7
I. Corneal Opacity	1	1[1]	1	1[1]	1[1]	0[1]
II. Iritis	1	1	1	1	1	0
III. Conjunctivae						
A. Redness	3	3	3	3	2	0
B. Chemosis	2	3	2	2	2	0
C. Discharge	3	3	2	2	2	0
Observations	Rabbit No. 3402 (Female)					
	Time After Treatment					
	Hours				Days	
	1	24	48	72	4	7
I. Corneal Opacity	1	1[1]	1	1[1]	1[1]	0[1]
II. Iritis	1	1	1	1	1	0
III. Conjunctivae						
A. Redness	3	3	2	2	1	0
B. Chemosis	2	2	1	0	0	0
C. Discharge	3	2	1	1	1	0
Observations	Rabbit No. 3403 (Female)					
	Time After Treatment					
	Hours				Days	
	1	24	48	72	4	7
I. Corneal Opacity	1	1[1]	1	1[1]	0[1]	0
II. Iritis	1	1	1	1	0	0
III. Conjunctivae						
A. Redness	3	2	2	2	1	0
B. Chemosis	2	2	1	0	0	0
C. Discharge	3	1	1	1	1	0

[1]2% ophthalmic fluorescein sodium used to evaluate the extent or verify the absence of corneal opacity.

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[XX] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number UrthTech, LLC/ 84368-1	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) UrthTech, LLC/ DETOX	PM# 34	
5. Name and Address of Applicant *(Include ZIP Code)* UrthTech, LLC 30777 Northwestern Hwy, Suite 300 Famington Hills, MI 48334 [ ] *Check if this is a new address*	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

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

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

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Metal [XXX] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	24 oz, 1 Qt, 1, 5 and 55 Gallons	[ ]

6. Manner in Which Label is Affixed to Product [XXX] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olav Messerschmidt	Registration Agent	517-881-0106

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature Olav Messerschmidt	3. Title Registration Agent	6. Date Application Received (Stamped)
4. Typed Name Olav Messerschmidt	5. Date September 9, 2010	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number UrthTech, LLC, 30777 Northwestern Hwy, Suite 300, Farmington Hills, MI 48334	EPA Registration Number/File Symbol 84368-1
Active Ingredient(s) and/or representative test compound(s) Ethyl Alcohol	Date September 21, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor	Product Name UrthPro

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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.

Signature	Date	Typed or Printed Name and Title
Olav Messerschmidt	9/21/2010	Olav Messerschmidt

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No, 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W. WASHINGTON, D.C. 20460

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DATA MATRIX

Date	EPA Reg. No./File Symbol	Page
September 21, 2010	84368-1	2 of 3

Applicant's/Registrant Name and Address	Product
UrthTech, LLC 30777 Northwestern Hwy, Suite 300 Farmington Hills, MI 48334	UrthPro

Ingredient: Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6317	Storage Stability				1
OPPTS 830.6319	Miscibility	47377702	UrthTech	OWN	
OPPTS 830.6320	Corrosion Characteristics	47377702	UrthTech	OWN	
OPPTS 830.7000	pH	47377702	UrthTech	OWN	
OPPTS 830.7050	UV/Visible Light Absorption	47377702	UrthTech	OWN	
OPPTS 830.7100	Viscosity	47377702	UrthTech	OWN	
OPPTS 830.7200	Melting Point / Melting Range				2
OPPTS 830.7220	Boiling Point / Boiling Range				2
OPPTS 830.7300	Density, Bulk Density or Specific Gravity	47377702	UrthTech	OWN	
OPPTS 870.1100	Acute Oral Toxicity	47129702	UrthTech	OWN	
OPPTS 870.1200	Acute Dermal Toxicity	47129702	UrthTech	OWN	
OPPTS 870.1300	Acute Inhalation Toxicity	47129702	UrthTech	OWN	

Signature	Name and Title	Date
Olav Messerschmidt	Olav Messerschmidt, Registration Agent	9/21/2010

Form Approved OMB No, 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W. WASHINGTON, D.C. 20460

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DATA MATRIX

Date	EPA Reg. No./File Symbol	Page
September 21, 2010	84368-1	1 of 3

Applicant's/Registrant Name and Address	Product
UrthTech, LLC 30777 Northwestern Hwy, Suite 300 Farmington Hills, MI 48334	UrthPro

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 880.1550	Product Identity and Composition	47146301	UrthTech	OWN	
OPPTS 880.1600	Description of Materials to Produce Product	47146301	UrthTech	OWN	
OPPTS 880.1620	Description of Formulation Process	47146301	UrthTech	OWN	
OPPTS 830.1650	Discussion of the Formation of Impurities	47146301	UrthTech	OWN	
OPPTS 830.1670	Preliminary Analysis	47320202	UrthTech	OWN	
OPPTS 830.1700	Certified Limits	47146301	UrthTech	OWN	
OPPTS 830.1800	Enforcement Analytical Method	47146301	UrthTech	OWN	
OPPTS 830.6302	Color	47377702	UrthTech	OWN	
OPPTS 830.6303	Physical State	47377702	UrthTech	OWN	
OPPTS 830.6304	Odor	47377702	UrthTech	OWN	
OPPTS 830.6313	Stability at Normal and Elevated Temperatures, Metals and Metal Ions	47377702	UrthTech	OWN	
OPPTS 830.6315	Flammability	47377702	UrthTech	OWN	

Signature	Name and Title	Date
Olav Messerschmidt	Olav Messerschmidt, Registration Agent	9/21/2010

Form Approved OMB No, 2070-0060

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401 M Street, S.W. WASHINGTON, D.C. 20460

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DATA MATRIX

Date	EPA Reg. No./File Symbol	Page
September 21, 2010	84368-1	3 of 3

Applicant's/Registrant Name and Address	Product
UrthTech, LLC 30777 Northwestern Hwy, Suite 300 Farmington Hills, MI 48334	UrthPro

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 870.2400	Primary Eye Irritation	47320204	UrthTech	OWN	3
OPPTS 870.2500	Primary Dermal Irritation	47129702	UrthTech	OWN	
OPPTS 870.2600	Dermal Sensitization	47129702	UrthTech	OWN	
Efficacy of Anti-Microbial Agents					
91-2	Fungicidal Activity on T. mentagrophytes AOAC Test 955.17	47220205	UrthTech	OWN	
91-2	Bactericidal Activity AOAC Use Dilution Test	47677201	UrthTech	OWN	
91-2	Virucidal Effectiveness Test: Human Influenza Virus	48014801	UrthTech	OWN	

NOTES

1	These data are not applicable to this product
2	Not expected to affect performance, thus not required per PR Notice 92.5
3	New study included with application

Signature	Name and Title	Date
Olav Messerschmidt	Olav Messerschmidt, Registration Agent	9/21/2010

Form Approved OMB No, 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W. WASHINGTON, D.C. 20460

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DATA MATRIX

Date	EPA Reg. No./File Symbol	Page
September 21, 2010	84368-1	1 of 1

Applicant's/Registrant Name and Address	Product
UrthTech, LLC 30777 Northwestern Hwy, Suite 300 Farmington Hills, MI 48334	UrthPro

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Generic Data Requirements					1

NOTES

1	Generic data requirements not data gaps per EPA March, 1995 Registration Eligibility Document (RED) on aliphatic alcohols (C1 – C5).

Signature	Name and Title	Date
	Olav Messerschmidt, Registration Agent	9/21/2010

September 9, 2010

Ms. Jacqueline Campbell-MacFarlane
Product Manager (34)
Antimicrobials Division (7510P)
Document Processing Desk **(AMEND)**
Antimicrobial Division (AD)
Office of Pesticide Programs
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: UrthPRO (EPA Reg. No.: 84368 – 1)
Label Amendment - Proposed Change in Toxicity Category, Signal Word

Dear Ms. Carlisle:

This application proposes to amend the subject label in the following ways:

1. The label is updated per your letter dated July 19, 2010 (copy attached)
2. The signal word and precautionary statements have been changed to reflect a Toxicity Category III product

In May 5, 2010, UrthTech submitted an alternate formulation which substantially reduced the amount of [redacted] in the formulation. This alternate CSF was approved on August 6, 2010. The basic formulation of UrthPro had higher levels of [redacted] ts eye irritation study still had eye irritation effects on Day 7 and was thus a Toxicity Category II product.

A new eye irritation study was conducted by Eurofins PSL with the alternate formulation approved on August 6. All signs of irritation cleared before Day 7 with the new formula; with the new formula UrthPro is now a Toxicity Category III for ocular irritation effects. Since the only acute toxicity effects for UrthPro are eye irritation, the appropriate Signal Word for UrthPro is now CAUTION with the appropriate precautionary statement for potential eye irritation in Toxicity Category III.

In support of this request, attached are the following documents:

- Application for Pesticide Registration (EPA Form 8570-1)
- A revised CSF which now labels the CSF approved on August 6, 2010 as the Basic Formulation – no changes are made in the formulation.
- A copy of the July 19, 2010 which requested the additional label changes
- One copy of the label with all proposed changes highlighted
- 5 copies of the draft label
- 48223001 Volume 1 of 1: Primary Eye Irritation Study in Rabbits by Eurofins PSL (July 20, 2010)

Inert ingredient information may be entitled to confidential treatment

Ph: 517-881-0106 ** Fax: 517-336-9788 ** email: omesserschmidt@comcast.net

During my meeting with you on August 11, 2010, we had discussed the possibility of splitting off the homeowner use directions so that the NOP logo and NOP statements could appear on the professional label. After further consideration by UrthTech, they have decided to leave the label as is with no NOP statement and the homeowner sub-label remains.

If you have any questions, please don't hesitate to contact me at 517-881-0106 or by email at omesserschmidt@comcast.net

Sincerely,

Olav Messerschmidt
Registration Agent for UrthTech, LLC

9/23 9/28

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 9-13-10

Experts In-Processing Signature: MF Harrington Date 9-15-10 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes _____ Date _____

EPA Reg. Number: 84368-1	EPA Receipt Date: 9-13-10

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels **)**			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

* CSF is approved.
* Data Package is approved.
* Jacket is approved.

MRID 482230

* N/A – Not Applicable

IK
(6955)

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

RE: EPA Product Update for Urth Pro.
Olav
to:
Wilkinson Unugboji
09/21/2010 03:38 PM
Show Details

Dear Mr. Unugboji,

Per our phone conversation, attached are EPA Form 8570-34 and the confidential and non-confidential pages of the Data Matrix (8570-35). These are for the recently submitted registration amendment application on UrthPro (EPA Reg. No. 84368-1).

Best regards,

Olav Messerschmidt
OMC AG Consulting
828 Tanglewood Lane
East Lansing, MI 48823
Phone: 1-517-881-0106
Fax: 1-517-336-9788
Email: omesserschmidt@comcast.net

-----Original Message-----
From: Unugboji.Wilkinson@epamail.epa.gov [mailto:Unugboji.Wilkinson@epamail.epa.gov]
Sent: Tuesday, September 21, 2010 9:27 AM
To: Omesserschmidt@Comcast.net
Subject: EPA Product Update for Urth Pro.

Hi Mr. Messerschmidt,

Please consider this as a follow up email to our conversation concerning the deficiencies associated with your recent submission that is in support of the registration of Urth Pro (84368-1). Per our conversation, please email to me a copy of the Certification with Respect to Citation of Data (form 8570-34) and Data Matrix (8570-35). If you have any further questions regarding the deficiencies, please, don't hesitate to ask.

Regards,

Unugboji Wilkinson
Data Analyst - MacFadden/EPA Contractor
One Potomic Yard
2777 S.Crystal Drive, S-6921
Arlington, VA 22202
Tel:(703).347.8518
Fax:(703)305.5060
EPA mail: unugboji.wilkinson@epa.gov

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

September 15, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-439759
EPA File Symbol or Registration Number: 84368-1
Product Name: URTH PRO
EPA Receipt Date: 13-Sep-2010
EPA Company Number: 84368
Company Name: URTHTECH, LLC

MR. OLAV MESSERSCHMIDT
OMC AG CONSULTING
URTHTECH, LLC
828 TANGLEWOOD LANE
EAST LANSING, MI 48823-

SUBJECT: Receipt of Amendment and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your amendment, 75% small business waiver request, and certification of payment. If you submitted data with this action, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,
Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{881996d~

This package includes the following

- ○ New Registration
- ⊙ Amendment

☑ Studies? ☑ Fee Waiver?

☐ volpay % Reduction: 75

for Division

- ⊙ AD
- ○ BPPD
- ○ RD

Risk Mgr. 34

Receipt No. S-	881996
EPA File Symbol/Reg. No.	84368-1
Pin-Punch Date:	9/13/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A570

Granted: A570

Amount Due: $ 5,308.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Leary Date: 9/14/10

Remarks:

Online Payment

Step 3: Confirm Payment 1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 251ESHOT
Agency Tracking ID: 74137356062
Transaction Date and Time: 09/10/2010 11:38 EDT

Payment Summary

Address Information

Account Holder Name: Robert T George
30777
Billing Address: Northwestern Hwy
Billing Address 2: Suite 300
City: Farmington Hills
State / Province: MI
Zip / Postal Code: 48334
Country: USA

Account Information

Card Type: American Express
Card Number: **********3005
Decision Number:
Registration Number: 84368-1
Company Name: UrthTech LLC
Company Number: 84368
Action Code: A570

Payment Information

Payment Amount: $827.00
Transaction Date and Time: 09/10/2010 11:38 EDT

FW: Pay.Gov Payment Confirmation
Olav
to:
downs.teresa
09/14/2010 01:55 PM
Show Details

Hello Ms Downs,

Attached and below are the confirmations of pay.gov payment for the following label amendment action

Product: UrthPRO (EPA Reg. No: 84368 – 1)
Action: Label Amendment
PRIA Code: A570

Also attached is a small business certification form for a pesticide fee reduction. A 75% fee waiver was accepted by the EPA for this registrant earlier this year.

Thank you for your help on this matter.

Olav Messerschmidt
OMC AG Consulting
828 Tanglewood Lane
East Lansing, MI 48823
Phone: 1-517-881-0106
Fax: 1-517-336-9788
Email: omesserschmidt@comcast.net

-----Original Message-----
From: paygovadmin@mail.doc.twai.gov [mailto:paygovadmin@mail.doc.twai.gov]
Sent: Friday, September 10, 2010 11:39 AM
To: omesserschmidt@comcast.net
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 251ESHOT
Agency Tracking ID: 74137356062

Account Holder Name: Robert T George
Transaction Type: Sale
Transaction Amount: $827.00
Billing Address: 30777 Northwestern Hwy
Billing Address 2: Suite 300
City: Farmington Hills
State/Province: MI
Zip/Postal Code: 48334
Country: USA
Card Type: American Express
Card Number: **********3005
Transaction Date: Sep 10, 2010 11:38:32 AM

Decision Number:
Registration Number: 84368-1
Company Name: UrthTech LLC
Company Number: 84368
Action Code: A570

Material to be added to an e-Jacket/Jacket

Reg. No. 84368-1

1. ☐ Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top/newest)
   - ☐ Description: (PDF page number, i.e., "before page 45")

_____

_____

2. ☒ Send to Data Extraction contractors this material:
   - ☐ Newly stamped accepted label
   - ☐ Notification
   - ☒ New CSF
   - ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Killian Swift

Phone: _____ Division: AD

Date: 7/28/09

Created July 21/2

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager

PRODUCT REVIEWER: Killian Swift	**RMB** II **TEAM** 34
Description of Action: Alternate CSF	**EPA File Symbol/Reg No.** 84368-1

Decision No. 409635	**Submission No.** 849491	**Fee for Service Action Code:**
FQPA Action Code: 362	**Non-FQPA Action Code:**	**PRIA FEE AMOUNT: $**

	MONTH	DAY	YEAR
APPLICATION DATE	4	28	2009
EPA PIN DATE	5	1	2009
DATE PM RECEIVED FROM FRONT END			2009
Date sent to Reviewer			2009
DATE SENT TO SCIENCE [VIVIAN COMPLETES]			2009
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			**DATE DUE OUT OF AGENCY**

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue
	✓						

COMMENTS: Karen: Please review alternate formula. Thanks

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

DATE FEE PAID:	**RESPONSE CODE:** 1155 **RESPONSE DATE:** 7/28/09

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Olav Messerschmidt, Registration Agent
Urth Tech, LLC
30777 Northwestern Hwy., Suite 300
Farmington Hills, MI 48334

JUL 28 2009

Subject: Detox™
EPA Registration Number: 84368-1
Application Date: April 28, 2009
Receipt Date: May 1, 2009

Dear Mr. Messerschmidt:

This acknowledges receipt of your amendment, submitted under the provisions of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

Proposed Amendment:

Confidential Statement of Formula (CSF) submitted to create an alternate formulation for this end-use product.

Comments:

The amendment is acceptable. The alternate CSF, dated May 15, 2009, has been inserted in your file for future reference.

At your next label amendment, please make the following revisions:

1.) On Pages 1 and 2, delete "ammonia" and "synthetic ingredients." You must not state, contains no ammonia or synthetic ingredients as per 40 CFR 156.10(a) (5) (i) and 40 CFR 156.10 (a) (5) (viii) as this is considered a misleading claim.
2.) As per PR Notice 2000-5, revise all advisory language on the label to mandatory language.
3.) Delete all references to contains no ammonia from the label as per #1.
4.) On Page 4 in1.0 General in the eighth line down, replace "This product should only be used in those cases... Replace the word "should" with the word "must" as per PR Notice 2000-5.
5.) On Page 5 in 3.0 Indications for Use and Guidelines, delete the word "should" and replace it with "must" as per PR Notice 2000-5.
6.) On Page 7 in 4.1 Mixing Instructions, Revise the sentence "Read the label before suing." to read, "Read the label before using."
7.) On Page 7 in 4.2.1 Brush, Mop or Wipe Application, the phrase "kept clean

8.) and protected between sues" must revised to read "kept clean and protected between uses."

9.) On Page 7 in 4.2.2 Spray Applications, In the sentence "The spray equipment chosen should provide a consistent fine (1-300 micron) particle size and uniform spray pattern, revise the word "should" to read "must" as per PR Notice 2000-5.

10.) On Page 9 in the first paragraph, In the sentence "Care must be used during treatment to assure that fumes from the agent being sued are not released into occupied spaces." Replace the word "sued" with the word "used."

Include these label revisions at the time of your next label amendment. Go to The Office of Air site on mold remediation at http://www.epa.gov/mold/mold_remediation.html and consult Tables 1 and 2 in order to obtain vital information on mold remediation to include in your product labeling before you submit this label to the Agency again for review and approval. Revise your label to include directions that no more than 10 sq. ft. of area is to be treated unless applicator wears appropriate PPE and containment measures are taken.

Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6415 or by e-mail at lantz.tracy@epa.gov or Killian Swift of my staff by telephone at (703) 308-6346 email address at: swift.killian@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely yours,

Tracy Lantz

Tracy Lantz
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

OMC Ag Consulting

April 28, 2009

Ms. Tracy Lantz
Herbicide Product Manager (PM-34)
Regulatory Branch II
Document Processing Desk (AMEND)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: DETOX™ (EPA Reg. No. 84368 – 1)
Alternate CSF

Dear Ms. Lantz:

Attached is an application for an alternate Confidential Statement of Formula for the subject UrthTech product. Specifically, the addition of another solvent is requested.

Since this is not a PRIA action, we presume that a PRIA fee is not required. In support of this request attached are completed EPA Forms 8570-1 and 8570-4 (CSF).

A Certification with Respect to the Citation of Data (EPA Form 8570-29) is not attached since this request is exempted from that requirement under 40 CFR 152.81(b)(4).

If you have any questions, please don't hesitate to contact me directly at 517-881-0106.

Sincerely,

Olav Messerschmidt
Registration Agent for UrthTech LLC

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[XX] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number UrthTech, LLC/ 84368-1	2. EPA Product Manager Tracy Lantz	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) UrthTech, LLC/ DETOX	PM# 32	
5. Name and Address of Applicant *(Include ZIP Code)* UrthTech, LLC 30777 Northwestern Hwy, Suite 300 Famington Hills, MI 48334 [ ] *Check if this is a new address*	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

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

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

Alternate CSF

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [XX] No * *Certification must be submitted*	[ ] Yes [XX] No If "Yes" Unit Packaging wgt. / No. per container	[ ] Yes [XX] No If "Yes" Package wgt / No. per container	[ ] Metal [XXX] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	24 oz, 1 Qt, 1, 5 and 55 Gallons	[ ]

6. Manner in Which Label is Affixed to Product [XXX] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olav Messerschmidt	Registration Agent	517-881-0106

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Olav Messerschmidt	Registration Agent	Olav Messerschmidt	April 28, 2009

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

May 15, 2009

DP BARCODE:		D364883
MRID:		N/A
SUBJECT:		Detox
REG. NO. OR FILE SYMBOL:		84368-1
DOCUMENT TYPE:		Product Chemistry Review
Manufacturing-use [ ]	OR	End-use Product [X]
INGREDIENTS (PC Codes):		001501
CAS Number:		64-17-5
TEST LAB:		N/A
SUBMITTER:		Mandala Technologies
GUIDELINE:		N/A
COMMODITIES:		Formulation
REVIEWER:		Chris Jiang CJ
ORGANIZATION:		AD
APPROVER:		Karen P. Hicks
APPROVED DATE:		5/15/09
COMMENT:		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

May 15. 2009

MEMORANDUM

Subject: Review for 84368-1

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang for KPH

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Tracy Lantz PM 34\Killian Swift
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies

Formulation from Label

Active Ingredient(s)	% by wt.
Ethyl alcohol	29.4 %
Other Ingredients	70.6 %
Total	100.0 %

BACKGROUND:

The registrant has submitted a Confidential Statement of Formula (CSF) to create an alternate formulation of this end-use product. The registrant has also submitted a product specification sheet for the active ingredient and a label for the source of the active ingredient. This reviewer has added a label for the end-use product to this package.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated 5/15/2009) is consistent with the label declaration. This CSF supersedes all previous CSFs for the respective formulation.

2. All ingredients are cleared for use in pesticidal formulations.

3. All certified limits are **acceptable**.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the submission for 84368-1 to be acceptable.

OMC Ag Consulting

April 28, 2009

Ms. Tracy Lantz
Herbicide Product Manager (PM-34)
Regulatory Branch II
Document Processing Desk (AMEND)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: DETOX™ (EPA Reg. No. 84368 – 1)
Alternate CSF

Dear Ms. Lantz:

Attached is an application for an alternate Confidential Statement of Formula for the subject UrthTech product. Specifically, the addition of another solvent is requested.

Since this is not a PRIA action, we presume that a PRIA fee is not required. In support of this request attached are completed EPA Forms 8570-1 and 8570-4 (CSF).

A Certification with Respect to the Citation of Data (EPA Form 8570-29) is not attached since this request is exempted from that requirement under 40 CFR 152.81(b)(4).

If you have any questions, please don't hesitate to contact me directly at 517-881-0106.

Sincerely,

Olav Messerschmidt
Registration Agent for UrthTech LLC

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

Pie instructions on reverse before pleting form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[XX] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number UrthTech, LLC/ 84368-1	2. EPA Product Manager Tracy Lantz	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) UrthTech, LLC/ DETOX	PM# 32	
5. Name and Address of Applicant *(Include ZIP Code)* UrthTech, LLC 30777 Northwestern Hwy, Suite 300 Famington Hills, MI 48334 [ ] *Check if this is a new address*	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

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

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

Alternate CSF

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Metal [XXX] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information [X] Label [ ] Container	4. Size(s) Retail Container 24 oz, 1 Qt, 1, 5 and 55 Gallons	5. Location of Label Directions [ ]
6. Manner in Which Label is Affixed to Product	[XXX] Lithograph [ ] Paper glued [ ] Stenciled	[ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olav Messerschmidt	Registration Agent	517-881-0106

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature Olav Messerschmidt	3. Title Registration Agent
4. Typed Name Olav Messerschmidt	5. Date April 28, 2009

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Product ingredient source information may be entitled to confidential treatment

[redacted]

Product ingredient source information may be entitled to confidential treatment

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

May 5, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OLAV MESSERSCHMIDT
MANDALA TECHNOLOGIES
30777 NORTHWESTERN HWY, SUITE 330
FARMINGTON HILLS, MI 48334-

PRODUCT NAME: DETOX
COMPANY NAME: MANDALA TECHNOLOGIES
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 84368-1
EPA RECEIPT DATE: 05/01/09

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at (703) 308-6422.

Sincerely,

P. K. Moore
Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

pem {849491B~

This package includes the following

- ○ New Registration
- ⊙ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ⊙ AD
- ○ BPPD
- ○ RD

Risk Mgr. 34

Receipt No. S-	849491
EPA File Symbol/Reg. No.	84368-1
Pin-Punch Date:	5/1/2009

☑ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: $ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Team 1 Date: 5/4/09

Remarks:

Receipt for Section 3

S: 849491

Resubmission: Yes No

Regulatory Type: Product Registration - Section 3

Fee For Service: Yes No

Application Type: Amendment

Billable: Yes No

Company: 84368 MANDALA TECHNOLOGIES

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 84368-1 Product Name: DETOX

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 28-Apr-2009 OPP Rec'vd Date: 01-May-2009

Front End Date: 04-May-2009 Risk Manager Send Date: 05-May-2009

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
CSF	

View/Edit

Fast Track: New Ingredient:

Receipt Description:

CSF amendment

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

Material to be added to an e-Jacket/Jacket

Reg. No. 84368-1

1. ☑ **Placement within the e-Jacket/jacket:**
   - ☐ **Default: (chronological, top/newest)**
   - ☐ **Description: (PDF page number, i.e., "before page 45")**

_____

_____

2. ☐ **Send to Data Extraction contractors this material:**
   - ☑ **Newly stamped accepted label**
   - ☐ **Notification**
   - ☐ **New CSF**
   - ☐ **Other:** _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Lisa McKelvin

Phone: 308 7496 **Division:** AD

Date: 10/7/08

Created July 21/2008

ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

PRODUCT REVIEWER: LISA MCKELVIN	RMB II TEAM 34
Related/Me-Too Product:	EPA File Symbol/Reg No. 84368-1

Decision No. D: 397481	Submission No. ~~836171~~ 837261	PRIA CODE:
FQPA Action Code: 302	Non-FQPA Action Code:	PRIA FEE AMOUNT:

	DAY	MONTH	YEAR
APPLICATION DATE	24	SEPT	2008
EPA PIN DATE	29	SEPT	2008
DATE RISK MANAGER RECEIVED FROM FRONT END	01	OCT	2008
21-DAYS START DATE			
21-DAYS END DATE			2008
PM DUE DATE			

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

Comments:

ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS

B	For Arctic Slope Contract Only	
	Contract No.: 0052	*ARCTIC SLOPE*/MANAGER
	Final Task: Signature _____	_____ (Total hrs)
C	Reviewer Comments: 1155	

DATE FEE PAID:	RESPONSE CODE: RESPONSE DATE: 10/7/08

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 7, 2008

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject: **DETOX™**
EPA Registration Number: 84368-1
Application Dated: September 24, 2008
Receipt Date: September 29, 2008

Dear Mr. Messerschmidt:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment

- Revised label

General Comment

Thank you for submitting this amendment as an electronic application. Please continue to submit your application(s) electronically. Refer to the following website for guidance on electronic submissions, including label: http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub. If you have questions concerning electronic labeling, a list of contacts is available at the following site: http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts

Other Comments

Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epamail.epa.gov or Lisa McKelvin by telephone at (703) 308-7496 or by email at mckelvin.lisa@epa.gov during the hours of 8:00 am to 4:00 pm EST.

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

Sincerely,

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

DETOX™

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

- Controls fungi, molds and fungi, including *Trichophyton mentagrophytes*, on hard, non-porous surfaces
- For Mold Remediation
- Contains no ammonia, bleach, acid or synthetic ingredients
- Kills mold and fungi
- Eliminates musty odors
- Colorless
- Mold Control
- Mildew stains remover

ACTIVE INGREDIENT
Ethyl alcohol.....29.4%
OTHER INGREDIENTS.....70.6%
TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN
WARNING

See side/back panel for First Aid
Directions for Use must be read completely prior to using this product.
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted con detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Net Contents: [24 oz., 1 quart, 1 gallon, 5 gallon, or 55 gallon]

EPA Reg. No. 84368 – 1 EPA Est. No.

Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

ACCEPTED
OCT 7 2008
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 84368-1

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

- DETOX 's patented technology kills [destroys] mold and fungi, including *Trichophyton mentagrophytes*, within 5 minutes.
- DETOX works in hard to clean places (tile grout, caulking and corners) without scrubbing.
- Kills mold in places vulnerable to mold and hard to clean places including:
    - Basements
    - Bathrooms
    - Vacation homes
    - Boat interiors
    - Areas under construction

- For use in homes, businesses or institutions.
- Contains no bleach, ammonia, acid, or synthetic ingredients
- Colorless
- No fumes
- Fungicide
- Effective against [fungi][mold]
- [Controls] [fungi][mold]
- Deodorizer
- DETOX is [specially formulated] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold and mildew
- Controls mold [leaving a fresh clean scent] [leaving rooms clean and fresh smelling].
- Eliminates musty odors [caused by mold].

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear such as goggles or safety glasses. Wash thoroughly with water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes. Then continue rinsing eye. • Call a poison control center or doctor for treatment advice
Hot Line Number: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on DETOX, call the **National Pesticides Information Center** at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.	

Physical or Chemical Hazards

Combustible. Do not use or store near hear or open flame.

DETOX contains no bleach, ammonia, and is suitable for use on most surfaces to eliminate musty odor.

DETOX liquid formula kills and eliminates mold and fungi, including *Trichophyton mentagrophytes*, within 5 minutes. DETOX contains no bleach, ammonia, and is suitable for use on most surfaces to eliminate musty odor.

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

DIRECTIONS FOR USE

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

The person applying this product is responsible for following these directions under both state and federal laws.

1.0 General

DETOX liquid formula kills and eliminates mold and fungi, including *Trichophyton mentagrophytes*, within 5 minutes. DETOX destroysodor, stain causing or other damage causing organisms including mold and mildew on floors, walls, contents and other interior building surfaces until such time as the cause of such growth can be identified and corrected. It is also used as one component mold remediation or water damage restoration program. The purpose of such a program is to minimize damage from growth of mold and other odor, stain and damaging organisms, and help building interiors continue in that condition. This product should only be used in those cases where visible microbial growth has been detected and then only as part of a program that removes that growth and identifies and corrects the conditions that led to that growth. If you need help understanding these instructions or have additional questions after reading these instructions, DO NOT APPLY THIS PROUCT until you received answers for all of your questions.

2.0 Causes of Microbial Growth

Microbial (including bacteria, mold, mildew, and other fungi) growth is present at all times both outdoors and in building interiors. Normally the natural balance of the environment limits such growth to acceptable levels. Under certain conditions, growth can reach problem levels and if not controlled, will cause foul odors, stain and damage furnishings and valuables, and may even destroy structural components of the building. Normally fungal spores, live organisms and food sources are plentiful in building interiors without uncontrolled growth taking place. Elevated water from the following can lead to growth:

2.1 Floods

If water floods the interior of a building it brings a massive load of organic matter, bacteria and fungal spores. If the water and excessive organic load is not cleaned quickly, massive growth will result. Floods can result from rising water and massive plumbing failures.

2.2 Leaks

Leaks release lesser amounts of water and often over extended time periods. Thus, they can lead to high levels of growth in wall cavities and other spaces where they are not visible until considerable damage has been done. Leaks can be both from plumbing and roof, wall or other structural failures.

2.3 Humidity

Microorganisms grow in moisture that form on surfaces and within porous materials. This is known as water activity of the maternal or surface. High levels of humidity can lead to sufficient surface water activity to support accelerated growth if that elevated level is maintained for as little as 24 hours. Accelerated growth takes place with some fungi within 24 hours at humidity levels between 66% - 70%.

3.0 Indications for Use and Guidelines

Homeowners and building managers should survey their buildings at least monthly for any of the following conditions. When they are found, they should be corrected according to the guidelines.

3.1 Visible Growth

Areas of visible growth of less than 32 square feet (the area of a single wall panel) can normally be remediated without elaborate procedures. When these areas are identified, mist (see application instruction below) lightly with DETOX to completely kill and eliminate mold and fungi 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:

- Clean contaminated area to remove surface soil. For best results, and to avoid possible interference from other chemicals, use DETOX 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.
- Apply DETOX on cleaned area until evenly wet and let it stand for 5 minutes.
- Allow treated surfaces to dry completely.
- Wipe with wet sponge or cloth if cosmetically necessary.

Aras larger than 32 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 Association (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 DETOX in mitigation of large projects, you should be knowledgeable of one or more of these guidelines and follow them when using DETOX.

3.2 Water Damage

Evidence of possible water damage includes water stains on ceilings or walls, persistent wet spots or actual flowing water whether from plumbing failure or outside sources. 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 on 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 are wet with DETOX will kill any potential fungi or mold that might have grown on the surfaces 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 DETOX, provides for the user and occupant safety and documentation and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, IICRC S500 contains excellent guidance. In the context of such a plan, DETOX can be used on materials to be removed and disposed of and in other applications where an Antimicrobial use is indicated. The Standard must be followed exactly and all growth and contaminated organic materials removed prior to using DETOX.

4.0 General Directions for Using DETOX

DETOX's patented technology completely destroys [100% killing] of household and residential mold, including *Trichophyton mentagrophytes*, within 5 minutes. DETOX also effectively eliminates stain and odor causing bacteria, mold and fungi, or damage causing organisms on floors, walls, and other surfaces in residential, commercial, institutional, and industrial buildings within 5 minutes.. DETOX 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 a comprehensive preventative maintenance approach.

DETOX is a fungicide, destroys disease causing household and residential mold, and is a deodorizer for use in residential, commercial and industrial settings. It will not stain or bleach materials or fabrics and will not harm or damage most interior surfaces. Test on an inconspicuous area if you are unsure of the surface on which you are working.

DETOX is formulated for use on all kinds of surfaces including:

- Painted wallboard
- Structural members and supports
- Ceilings and above ceiling spaces
- Basements and crawl spaces
- Cabinets and countertops
- Case goods and other furnishings
- Floor surfaces

Follow the directions for the specific type of component being treated. The following directions must be carefully read and understood prior to using the product.

4.1 Mixing Instructions
DETOX is a ready to use product – DO NOT DILUTE. Read the label before suing. DETOX must come in direct contact with the mold or other micro-organisms to be effective.

4.2 Application Equipment and Devices
Apply DETOX on the surface until thoroughly wet, let it stand for 5 minutes and wipe with wet sponge or cloth if is cosmetically necessary. DETOX must come in direct contact with mold to be effective.

Refer to the precautionary statements and other special instructions that must be followed.

4.2.1 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. When using brush or mop application, tools and materials used should be reserved only for application of DETOX, kept clean and protected between sues and replaced when worn or visibly soiled. Natural fiber brushes are preferred although any quality brush is acceptable. Where other types of cloths are used, they must be soft enough that they absorb a sufficient quantity of liquid to provide uniform application.

During Brush, Mop or Wipe Application, the applicator must have access to the surfaces being treated. Apply to a limited area at a time. Overlap applications to assure complete coverage. Cover completely while avoiding runs or pooling.

4.2.2 Spray Applications
Spray application is preferred on large surfaces that are easily accessible and uniformly shaped. The spray equipment chosen should provide a consistent fine (1 – 300 micron) particle size and uniform spray pattern. Powered medium pressure sprayers are preferred. However, airless sprayers are suitable.

Pump-up garden type sprayers can be used with 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 applications achieve complete uniform coverage. Avoid excessive wetting and do not allow the spray to run or pool.

4.2.3 ULV (Ultra Low Volume) or Mist Generating Sprayers

ULV, mist or other small particle application is preferable where surfaces are irregular or less accessible. Equipment capable of generating particles in the 15 – 60 micron range is most satisfactory. Do not use thermal type fog generators.

Generally a fog will carry and provide adequate coverage up to 8 feet from the point of application so the fog must be directed in all directions to assure coverage without over wetting. Fogging is only to be used as an adjunct to surface disinfection. Personal protective equipment including HEPA filtered mask, hooded coveralls and rubber gloves must be used when applying in open space with mist generating application equipment.

4.3 Application Techniques

DETOX must be applied evenly over 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 desired results.

4.4 Rate of Application

DETOX is a ready to use product – DO NOT DILUTE. Users of this product must carefully follow the rate of application instructions provided below.

4.4.1 Hard, Smooth surface (Glass, Metal)

Apply until surface is evenly wet. Mist, wipe or spray coverage rate is 400 ft^2 per gallon. If this rate results in surface runoff or liquid pooling, lower the application rate until the surface is thoroughly and evenly wet without runoff or pooling.

4.4.2 Semi-Porous Surfaces such as Concrete or Plaster or Wallboard

Apply until surface is evenly wet. Mist coverage rate is 200 ft^2 per gallon. Wipe is not recommended. Spray coverage rate is 100 ft^2 per gallon. DETOX 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 make multiple applications at a lower application rate on some surfaces as the first application will wet the surface and facilitate penetration of following applications.

4.5 Frequency of Application

Normally, infrequent application (once a year or less) will provide effective control. Do not apply more often than monthly and then only if there is evidence of re-growth. Prior to re-application in such cases, investigate to determine the cause of re-growth and correct that problem prior to re-application. Also make sure the re-occurrence of microbial growth does not have another cause such as persistently high humidity, standing water or hidden leaks.

Removed components that are contaminated with mold and other microbial growth may spread contamination while being removed from the building. To prevent this, smaller items should be placed in plastic bags that should then be sealed before being removed. Larger items that cannot be safely packaged should be treated before being moved through occupied spaces. An appropriately labeled disinfectant can be used for treatment. Care must be used during treatment to assure that fumes from the agent being sued are not released into occupied spaces. Products should be used according to their label directions.

STORAGE and DISPOSAL

Storage: Store in a cool, dry place inaccessible to children and pets.
Pesticide Disposal: If empty: Do not reuse this container. Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.
Do not contaminate water, food or feed by storage and disposal.

NOTICE ON CONDITIONS OF SALE

The **Directions For Use** of this product reflects the opinion of experts based on experimental use and tests. The directions are believed to be reliable and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result, because of factors such as the presence of other materials, or use of the product in a manner inconsistent with its labeling, all of which are beyond the control of Mandala Technologies or the Seller. All such risks are assumed by the Buyer.

To the extent consistent with applicable law, Mandala Technologies warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions For Use**, subject to the inherent risks, referred to above. To the extent consistent with applicable law, Mandala Technologies makes no other express or implied warranty of fitness or merchantability or any other express or implied warranty. To the extent consistent with applicable law, in no case shall Mandala Technologies or the Seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. To the extent consistent with applicable law, Mandala Technologies and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing **Conditions of Sale and Warranty** which may be varied only be agreement in writing signed by a duly authorized representative of Mandala Technologies.

DETOX™ is a trademark of Mandala Technologies, LLC

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

October 1, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OLAV MESSERSCHMIDT
MANDALA TECHNOLOGIES
30777 NORTHWESTERN HWY, SUITE 330
FARMINGTON HILLS, MI 48334-

PRODUCT NAME: DETOX
COMPANY NAME: MANDALA TECHNOLOGIES
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 84368-1
EPA RECEIPT DATE: 09/29/08

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at (703) 308-6422.

Sincerely,

PK Moore
Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

OMC Ag Consulting

September 24, 2008

Mr. Adam Heyward
Herbicide Product Manager (PM-34)
Regulatory Branch II
Document Processing Desk (AMEND?)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: DETOX™
EPA File Symbol: 84368 – 1
FQPA label amendment

Dear Mr. Heyward:

Attached is a revised label per our FQPA submission of July 8, 2008. All changes have been incorporated per our recent emails. This label was approved by Lisa McKelvin per her September 23, 2008 email.

The attachments are:

- EPA Form 8570-1
- A CD with a pdf copy of the revised Detox label.
- Five (5) copies of revised labeling

If you have any questions, please don't hesitate to contact me directly at 517-881-0106.

Sincerely,

Olav Messerschmidt
Registration Agent for Mandala Technologies, Inc.

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[XX] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Mandala Technologies LLC/ 84368-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) Mandala Technologies LLC/ DETOX	PM# 32	
5. Name and Address of Applicant *(Include ZIP Code)* Mandala Technologies LLC 30777 Northwestern Hwy, Suite 300 Famington Hills, MI 48334 [ ] *Check if this is a new address*	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

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated September 6, 2007
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

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

Final label revisions per August 28, 2008 letter from Adam Heyward.
Electronic label copy enclosed.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [XX] No *** Certification must be submitted**	[ ] Yes [XX] No If "Yes" Unit Packaging wgt. / No. per container	[ ] Yes [XX] No If "Yes" Package wgt / No. per container	[ ] Metal [XXX] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	24 oz, 1 Qt, 1, 5 and 55 Gallons	[ ]

6. Manner in Which Label is Affixed to Product [XXX] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olav Messerschmidt	Registration Agent	

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Olav Messerschmidt	3. Title: Registration Agent
4. Typed Name: Olav Messerschmidt	5. Date: September 24, 2008

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

MATERIAL TO BE ADDED TO JACKET

REG # 84368-1

Description: please add to file

check all that apply		
☐	new stamped accepted label	Send to CSC
☐	new CSF	
☑	notification	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's Name: Stacey Grigsby Date: 9/18/08

Phone: 305-6440 Division: AD

ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

PRODUCT REVIEWER: Stacey Grigsby	**RMB** II **TEAM** 34
Description of Action:	**EPA File Symbol/Reg No.** 84368-1

Decision No. 398764	**Submission No.** 833920	**Fee for Service Action Code:**
FQPA Action Code:	**Non-FQPA Action Code:**	**PRIA FEE AMOUNT:**

	DAY	MONTH	YEAR
APPLICATION DATE	30	7	08
EPA PIN DATE	7	8	08
DATE RISK MANAGER RECEIVED FROM FRONT END	11	8	08
PRIA DUE DATE			
EXPECTED DATE FROM CTT			
PM DUE DATE			

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

Comments:

ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS

B	For Arctic Slope Contract Only	
	Contract No.: 0052	*ARCTIC SLOPE/MANAGER*
	Final Task: Signature _____	_____ (Total hrs)
C	Reviewer Comments:	

DATE FEE PAID:	**RESPONSE CODE:** 1155	**RESPONSE DATE:** 9/16/08

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 16, 2008

Olav Messerschmidt
Mandala Technologies LLC
30777 Northwestern Hwy
Suite 300
Famington Hills, MI 48334

Subject:

DETOX™
EPA Registration No. 84368-1
Application Date: July 30, 2008
Receipt Date: August 7, 2008

Dear Mr. Messerschmidt:

The following amendments, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amendment, is acceptable.

Proposed Amendment:

- Alternate Confidential Statement of Formula (CSF). See revised alternate CSF dated 7/29/08

General Comment:

A copy of the alternate confidential statement of formula dated 7/29/2008 has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me via electronic mail: heyward.adam@epa.gov or by telephone (703) 308-6422 or Stacey Grigsby via electronic mail at grigsby.stacey@epa.gov or by telephone at (703)305-6440 during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Stacey Grigsby

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

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

August 29, 2008

DP BARCODE:		D355543
MRID:		N/A
SUBJECT:		Detox
REG. NO. OR FILE SYMBOL:		84368-1
DOCUMENT TYPE:		Product Chemistry Review
Manufacturing-use [ ]	OR	End-use Product [X]
INGREDIENTS (PC Codes):		001501
CAS Number:		64-17-5
TEST LAB:		N/A
SUBMITTER:		Mandala Technologies
GUIDELINE:		N/A
COMMODITIES:		Formulation
REVIEWER:		Chris Jiang CJ
ORGANIZATION:		AD
APPROVER:		Karen P. Hicks
APPROVED DATE:		8/29/08
COMMENT:		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

August 29, 2008

MEMORANDUM

Subject: Review for 84368-1

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)
Chris Jiang

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)
Chris Jiang for KPH 8/29/08

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM 34\Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies

Formulation from Label

Active Ingredient(s)	% by wt.
Ethyl alcohol	29.4 %
Other Ingredients	70.6 %
Total	100.0 %

BACKGROUND:

The registrant has submitted a Confidential Statement of Formula (CSF) to create an alternate formulation of this end-use product. This reviewer has added a label to this package.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated 7/29/2008) is consistent with the label declaration.

2. All ingredients are cleared for use in pesticidal formulations.

3. All certified limits are **acceptable**.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the submission for 84368-1 to be acceptable.

Product ingredient source information may be entitled to confidential treatment

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

August 11, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OLAV MESSERSCHMIDT
MANDALA TECHNOLOGIES
30777 NORTHWESTERN HWY, SUITE 330
FARMINGTON HILLS, MI 48334-

PRODUCT NAME: DETOX
COMPANY NAME: MANDALA TECHNOLOGIES
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 84368-1
EPA RECEIPT DATE: 08/07/08

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at (703) 308-6422.

Sincerely,

P. H. Moore

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

OMC Ag Consulting

July 30, 2008

Mr. Adam Heyward
Herbicide Product Manager (PM-34)
Regulatory Branch II
Document Processing Desk (AMEND)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: DETOX™ (EPA Reg. No. 84368 – 1)
Alternate CSF

Dear Mr. Heyward:

Attached is an application for an alternate Confidential Statement of Formula for the subject Mandala product. Specifically, an alternate pH adjusting agent is requested.

Since this is not a PRIA action, we presume that a PRIA fee is not required. In support of this request attached are completed EPA Forms 8570-1 and 8570-4 (CSF).

A Certification with Respect to the Citation of Data (EPA Form 8570-29) is not attached since this request is exempted from that requirement under 40 CFR 152.81(b)(4).

If you have any questions, please don't hesitate to contact me directly at 517-881-0106.

Sincerely,

Olav Messerschmidt
Registration Agent for Mandala Technologies, Inc.

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

Please read instructions on reverse before com[illegible]g form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[XX] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Mandala Technologies LLC/ 84368-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) Mandala Technologies LLC/ DETOX	PM# 32	
5. Name and Address of Applicant *(Include ZIP Code)* Mandala Technologies LLC 30777 Northwestern Hwy, Suite 300 Famington Hills, MI 48334 [ ] *Check if this is a new address*	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

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

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

Alternate CSF

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Metal [XXX] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	24 oz, 1 Qt, 1, 5 and 55 Gallons	[ ]

6. Manner in Which Label is Affixed to Product [XXX] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olav Messerschmidt	Registration Agent	517-881-0106

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Olav Messerschmidt	3. Title: Registration Agent
4. Typed Name: Olav Messerschmidt	5. Date: July 30, 2008

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

PRODUCT REVIEWER: Aster Grahn	RMB II TEAM 34
Related Submission:	EPA File Symbol/Reg No. ~~6836-253~~ 84368-1

Decision No. 397481	Submission No. 832367	Fee for Service Action Code:
FQPA Action Code: 302	Non-FQPA Action Code:	PRIA FEE AMOUNT:

	DAY	MONTH	YEAR
APPLICATION DATE	11	JULY	2008
EPA PIN DATE	14	JULY	2008
DATE RISK MANAGER RECEIVED FROM FRONT END	16	JULY	2008
21-DAYS START DATE			
21-DAYS END DATE			2008
PM DUE DATE			

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

Comments:
Label is not acceptable. See both letters from EPA to company. Pull the file and read the history.

ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS

B	For Arctic Slope Contract Only	
	Contract No.: 0052	*ARCTIC SLOPE*/MANAGER
	Final Task: Signature [signature]	3 (Total hrs)
C	Reviewer Comments: 1135	

DATE FEE PAID:	RESPONSE CODE: RESPONSE DATE: 8/27/08

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 27, 2008

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject:	Product Name:	DETOX
	EPA Reg. Number:	84368-1
	Application Date:	08-Jul-2008
	EPA Receipt Date:	10-Jul-2008

Dear Mr. Messerschmidt:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable for the following reasons:.

Proposed amendment:

- Label amendment per notice of registration dated 6/09/08

Labeling comments:

Based on the instructions listed in the notice of registration dated June 9, 2008, the following labeling corrections were requested and must be before the subject label amendment can be acceptable:

1. On the front panel of the draft master labeling, delete the following claims:

   - 100% killing of household and residential mold,
   - 100% killing [elimination] of disease causing household and residential mold and their spores (*where ever it appears on the label*),
   - Kills [eliminates][destroy] tough mold,
   - Attacks mold at its roots,
   - Gets into and completely destroys [eliminates] common household molds,

- penetrates to kill and completely destroy disease causing household and residential mold at its roots,
- penetrates to remove mildew stains at its source,
- completely kills [destroy], spraying, etc….,
- most indoor and outdoor surfaces,
- all kinds of surfaces,
- a unique technology.

2. Add directions for deodorizing use.

Note that these labeling corrections were requested in the EPA letter dated May 10, 2008. Please refer the May 10 2008 for detailed information.

General comments:

Submit three (3) copies of the labeling bearing the above reasons. A copy will be stamped and return for your record. The Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label: http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub. If you have questions concerning electronic labeling, a list of contacts is available at the following site: http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts.

If you have further questions concerning this letter, please contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

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

DETOX™

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

- Controls fungi, molds and fungi, including *Trichophyton mentagrophytes*, on hard, non-porous surfaces
- 100% killing of household and residential mold
- 100% killing [elimination] of disease causing household and residential mold.
- Kills [eliminates] [destroys] tough mold
- Attacks mold at its roots
- Gets into and completely destroys [eliminates] common household molds
- For Mold Remediation
- Contains no ammonia, bleach, acid or synthetic ingredients
- Kills mold and fungi
- Eliminates musty odors
- Colorless
- Mold Control
- Mildew stains remover

ACTIVE INGREDIENT
Ethyl alcohol.....29.4%
OTHER INGREDIENTS.....70.6%
TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN
WARNING

See side/back panel for First Aid
Directions for Use must be read completely prior to using this product.
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted con detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Net Contents: [24 oz., 1 quart, 1 gallon, 5 gallon, or 55 gallon]

EPA Reg. No. 84368 – 1 EPA Est. No.

Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

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

- DETOX 's patented technology kills [destroys] mold and fungi, including *Trichophyton mentagrophytes*, within 5 minutes.
- DETOX's patented technology completely destroys [100% killing] of disease causing household and residential mold within 5 minutes.
- DETOX penetrates to kill and completely destroy disease causing household and residential mold at its roots.
- DETOX penetrates to remove mildew stains at its source
- DETOX completely kills [destroys] mold in hard to clean places (tile grout, caulking and corners) without scrubbing.
- DETOX completely destroys [100% killing] of disease causing household and residential mold by just spraying; no scrubbing is required.
- For use on most indoor and outdoor surfaces.
- Kills mold in places vulnerable to mold and hard to clean places including:
    - Basements
    - Bathrooms
    - Vacation homes
    - Boat interiors
    - Areas under construction

- For use in homes, businesses or institutions.
- Contains no bleach, ammonia, acid, or synthetic ingredients
- Colorless
- No fumes
- Fungicide
- Effective against [fungi][mold]
- [Controls] [Eliminates] [kills] [fungi][mold]
- Deodorizer
- DETOX is [specially formulated] [a unique technology] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold and mildew
- Controls mold [leaving a fresh clean scent] [leaving rooms clean and fresh smelling].
- Eliminates musty odors [caused by mold].

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear such as goggles or safety glasses. Wash thoroughly with water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes. Then continue rinsing eye. • Call a poison control center or doctor for treatment advice
Hot Line Number: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on DETOX, call the **National Pesticides Information Center** at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.	

Physical or Chemical Hazards

Combustible. Do not use or store near hear or open flame.

DETOX contains no bleach, ammonia, and is suitable for use on most surfaces to eliminate musty odor.

DETOX liquid formula kills and eliminates mold and fungi, including *Trichophyton mentagrophytes*, within 5 minutes. DETOX contains no bleach, ammonia, and is suitable for use on most surfaces to eliminate musty odor.

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

DIRECTIONS FOR USE

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

The person applying this product is responsible for following these directions under both state and federal laws.

1.0 General

DETOX liquid formula kills and eliminates mold and fungi, including *Trichophyton mentagrophytes*, within 5 minutes. DETOX destroys [100% killing]odor, stain causing or other damage causing organisms including mold and mildew on floors, walls, contents and other interior building surfaces until such time as the cause of such growth can be identified and corrected. It is also used as one component mold remediation or water damage restoration program. The purpose of such a program is to minimize damage from growth of mold and other odor, stain and damaging organisms, and help building interiors continue in that condition. This product should only be used in those cases where visible microbial growth has been detected and then only as part of a program that removes that growth and identifies and corrects the conditions that led to that growth. If you need help understanding these instructions or have additional questions after reading these instructions, DO NOT APPLY THIS PROUCT until you received answers for all of your questions.

2.0 Causes of Microbial Growth

Microbial (including bacteria, mold, mildew, and other fungi) growth is present at all times both outdoors and in building interiors. Normally the natural balance of the environment limits such growth to acceptable levels. Under certain conditions, growth can reach problem levels and if not controlled, will cause foul odors, stain and damage furnishings and valuables, and may even destroy structural components of the building. Normally fungal spores, live organisms and food sources are plentiful in building interiors without uncontrolled growth taking place. Elevated water from the following can lead to growth:

2.1 Floods

If water floods the interior of a building it brings a massive load of organic matter, bacteria and fungal spores. If the water and excessive organic load is not cleaned quickly, massive growth will result. Floods can result from rising water and massive plumbing failures.

2.2 Leaks

Leaks release lesser amounts of water and often over extended time periods. Thus, they can lead to high levels of growth in wall cavities and other spaces where they are not visible until considerable damage has been done. Leaks can be both from plumbing and roof, wall or other structural failures.

2.3 Humidity

Microorganisms grow in moisture that form on surfaces and within porous materials. This is known as water activity of the maternal or surface. High levels of humidity can lead to sufficient surface water activity to support accelerated growth if that elevated level is maintained for as little as 24 hours. Accelerated growth takes place with some fungi within 24 hours at humidity levels between 66% - 70%.

3.0 Indications for Use and Guidelines

Homeowners and building managers should survey their buildings at least monthly for any of the following conditions. When they are found, they should be corrected according to the guidelines.

3.1 Visible Growth

Areas of visible growth of less than 32 square feet (the area of a single wall panel) can normally be remediated without elaborate procedures. When these areas are identified, mist (see application instruction below) lightly with DETOX to completely kill and eliminate mold and fungi 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:

- Clean contaminated area to remove surface soil. For best results, and to avoid possible interference from other chemicals, use DETOX 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.
- Apply DETOX on cleaned area until evenly wet and let it stand for 5 minutes.
- Allow treated surfaces to dry completely.
- Wipe with wet sponge or cloth if cosmetically necessary.

Aras larger than 32 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 Association (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 DETOX in mitigation of large projects, you should be knowledgeable of one or more of these guidelines and follow them when using DETOX.

3.2 Water Damage

Evidence of possible water damage includes water stains on ceilings of walls, persistent wet spots or actual flowing water whether from plumbing failure or outside sources. 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 on 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 are wet with DETOX will kill any potential fungi or mold that might have grown on the surfaces 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 DETOX, provides for the user and occupant safety and documentation and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, IICRC S500 contains excellent guidance. In the context of such a plan, DETOX can be used on materials to be removed and disposed of and in other applications where an Antimicrobial use is indicated. The Standard must be followed exactly and all growth and contaminated organic materials removed prior to using DETOX.

4.0 General Directions for Using DETOX

DETOX's patented technology completely destroys [100% killing] of disease causing household and residential mold, including *Trichophyton mentagrophytes*, within 5 minutes. DETOX also effectively eliminates stain and odor causing bacteria, mold and fungi, or damage causing organisms on floors, walls, and other surfaces in residential, commercial, institutional, and industrial buildings within 5 minutes.. DETOX 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 a comprehensive preventative maintenance approach.

DETOX is a fungicide, destroys disease causing household and residential mold, and is a deodorizer for use in residential, commercial and industrial settings. It will not stain or bleach materials or fabrics and will not harm or damage most interior surfaces. Test on an inconspicuous area if you are unsure of the surface on which you are working.

DETOX is formulated for use on all kinds of surfaces including:

- Painted wallboard
- Structural members and supports
- Ceilings and above ceiling spaces
- Basements and crawl spaces
- Cabinets and countertops
- Case goods and other furnishings
- Floor surfaces

Follow the directions for the specific type of component being treated. The following directions must be carefully read and understood prior to using the product.

4.1 Mixing Instructions
DETOX is a ready to use product – DO NOT DILUTE. Read the label before suing. DETOX must come in direct contact with the mold or other micro-organisms to be effective.

4.2 Application Equipment and Devices
Apply DETOX on the surface until thoroughly wet, let it stand for 5 minutes and wipe with wet sponge or cloth if is cosmetically necessary. DETOX must come in direct contact with mold to be effective.

Refer to the precautionary statements and other special instructions that must be followed.

4.2.1 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. When using brush or mop application, tools and materials used should be reserved only for application of DETOX, kept clean and protected between sues and replaced when worn or visibly soiled. Natural fiber brushes are preferred although any quality brush is acceptable. Where other types of cloths are used, they must be soft enough that they absorb a sufficient quantity of liquid to provide uniform application.

During Brush, Mop or Wipe Application, the applicator must have access to the surfaces being treated. Apply to a limited area at a time. Overlap applications to assure complete coverage. Cover completely while avoiding runs or pooling.

4.2.2 Spray Applications
Spray application is preferred on large surfaces that are easily accessible and uniformly shaped. The spray equipment chosen should provide a consistent fine (1 – 300 micron) particle size and uniform spray pattern. Powered medium pressure sprayers are preferred. However, airless sprayers are suitable.

Pump-up garden type sprayers can be used with 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 applications achieve complete uniform coverage. Avoid excessive wetting and do not allow the spray to run or pool.

4.2.3 ULV (Ultra Low Volume) or Mist Generating Sprayers

ULV, mist or other small particle application is preferable where surfaces are irregular or less accessible. Equipment capable of generating particles in the 15 – 60 micron range is most satisfactory. Do not use thermal type fog generators.

Generally a fog will carry and provide adequate coverage up to 8 feet from the point of application so the fog must be directed in all directions to assure coverage without over wetting. Fogging is only to be used as an adjunct to surface disinfection. Personal protective equipment including HEPA filtered mask, hooded coveralls and rubber gloves must be used when applying in open space with mist generating application equipment.

4.3 Application Techniques

DETOX must be applied evenly over 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 desired results.

4.4 Rate of Application

DETOX is a ready to use product – DO NOT DILUTE. Users of this product must carefully follow the rate of application instructions provided below.

4.4.1 Hard, Smooth surface (Glass, Metal)

Apply until surface is evenly wet. Mist, wipe or spray coverage rate is 400 ft^2 per gallon. If this rate results in surface runoff or liquid pooling, lower the application rate until the surface is thoroughly and evenly wet without runoff or pooling.

4.4.2 Semi-Porous Surfaces such as Concrete or Plaster or Wallboard

Apply until surface is evenly wet. Mist coverage rate is 200 ft^2 per gallon. Wipe is not recommended. Spray coverage rate is 100 ft^2 per gallon. DETOX 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 make multiple applications at a lower application rate on some surfaces as the first application will wet the surface and facilitate penetration of following applications.

4.5 Frequency of Application

Normally, infrequent application (once a year or less) will provide effective control. Do not apply more often than monthly and then only if there is evidence of re-growth. Prior to re-application in such cases, investigate to determine the cause of re-growth and correct that problem prior to re-application. Also make sure the re-occurrence of microbial growth does not have another cause such as persistently high humidity, standing water or hidden leaks.

Removed components that are contaminated with mold and other microbial growth may spread contamination while being removed from the building. To prevent this, smaller items should be placed in plastic bags that should then be sealed before being removed. Larger items that cannot be safely packaged should be treated before being moved through occupied spaces. An appropriately labeled disinfectant can be used for treatment. Care must be used during treatment to assure that fumes from the agent being sued are not released into occupied spaces. Products should be used according to their label directions.

STORAGE and DISPOSAL

Storage: Store in a cool, dry place inaccessible to children and pets.
Pesticide Disposal: If empty: Do not reuse this container. Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.
Do not contaminate water, food or feed by storage and disposal.

NOTICE ON CONDITIONS OF SALE

The **Directions For Use** of this product reflects the opinion of experts based on experimental use and tests. The directions are believed to be reliable and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result, because of factors such as the presence of other materials, or use of the product in a manner inconsistent with its labeling, all of which are beyond the control of Mandala Technologies or the Seller. All such risks are assumed by the Buyer.

To the extent consistent with applicable law, Mandala Technologies warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions For Use**, subject to the inherent risks, referred to above. To the extent consistent with applicable law, Mandala Technologies makes no other express or implied warranty of fitness or merchantability or any other express or implied warranty. To the extent consistent with applicable law, in no case shall Mandala Technologies or the Seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. To the extent consistent with applicable law, Mandala Technologies and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing **Conditions of Sale and Warranty** which may be varied only be agreement in writing signed by a duly authorized representative of Mandala Technologies.

DETOX™ is a trademark of Mandala Technologies, LLC

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

July 15, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OLAV MESSERSCHMIDT
MANDALA TECHNOLOGIES
30777 NORTHWESTERN HWY, SUITE 330
FARMINGTON HILLS, MI 48334-

PRODUCT NAME: DETOX
COMPANY NAME: MANDALA TECHNOLOGIES
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 84368-1
EPA RECEIPT DATE: 07/10/08

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at (703) 308-6422.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

OMC Ag Consulting

July 8, 2008

Mr. Adam Heyward
Herbicide Product Manager (PM-34)
Regulatory Branch II
Document Processing Desk (AMEND?)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: DETOX™ (Active Ingredient: Ethyl Alcohol 29.4%)
EPA File Symbol: 84368 – 1
FQPA label amendment

Dear Mr. Heyward:

On June 16, 2008, Marcie Tidd, Microbiologist in the Product Science Brach in AD approved the revised study on *Trichophyton mentagrophytes* (ATCC 9533) submitted by Mandala (MRID # 473202-05). Your subsequent correspondence agreed that the amendments requested on March 13, 2008 proposed label for the subject product would be acceptable as a FQPA submission. Thus, the subject label has been revised to reflect the use of DETOX as a fungicide against *Trichophyton mentagrophytes*.

All label revisions (excludes use of the *Trichophyton mentagrophytes* study which has now been accepted) requested in your letters dated May 20, 2008 and September 6, 2007 have been incorporated with one exception. The September letter states that "skin irritation may be modestly affected by the presence of the surfactant and the pH adjustor, so the product is placed in Toxicity Category III for skin irritation." The pH modifier adjusts the pH to 7.4, only slightly above neutral. Also, the eye irritation study, a more sensitive test, had only a moderately irritating response. We request that the First Aid language regarding skin irritation not be required; that language is not on this proposed label.

Since this is not a PRIA action, we presume that a PRIA fee is not required. The attachments in support of this request are:

- EPA Form 8570-1 and
- Five (5) copies of proposed labeling

If you have any questions, please don't hesitate to contact me directly at 517-881-0106.

Sincerely,

Olav Messerschmidt
Registration Agent for Mandala Technologies, Inc.

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

Please read instructions on reverse before c[illegible]eting form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[XX] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
Mandala Technologies LLC/ EPA Reg. No. 84368-1

2. EPA Product Manager
Adam Heyward

3. Proposed Classification
[X] None [ ] Restricted

4. Company/Product (Name)
Mandala Technologies LLC/ DETOX

PM#
32

5. Name and Address of Applicant *(Include ZIP Code)*
Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Famington Hills, MI 48334

[ ] *Check if this is a new address*

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

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

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

Adding fungicidal claims against Trichophyton mentagrophytes per AD review of June 23, 2008

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes	[ ] Yes	[ ] Yes	[ ] Metal
[XX] No	[XX] No	[XX] No	[XXX] Plastic
			[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information
[X] Label [ ] Container

4. Size(s) Retail Container
24 oz, 1 Qt, 1, 5 and 55 Gallons

5. Location of Label Directions
[ ]

6. Manner in Which Label is Affixed to Product
[xxx] Lithograph
[ ] Paper glued
[ ] Stenciled
[ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olav Messerschmidt	Registration Agent	

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature
Olav Messerschmidt

3. Title
Registration Agent

4. Typed Name
Olav Messerschmidt

5. Date
July 8, 2008

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

White - EPA File Copy (original) Yellow - Applicant Copy

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 26, 2008

OPP Decision Number: D-379192

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject:	Product Name:	DETOX
	EPA Reg. Number:	84368-1
	Application Date:	10-May-2007
	EPA Receipt Date:	14-May-2007

Dear Mr. Messerschmidt:

The submitted data (MRID473202-05) ***now support*** the use of the product, DETOX, as a fungicide against *Trichophyton mentagrophytes* at full strength at room temperature on with a contact time of 5 minutes. The test employed represents a deviation from AOAC method 955.17. In both test and neutralization tubes, loopfuls of test agent or test agent/ organism mixture were added to 20 mL of neutralization media, not 10 mL as specified in the AOAC Fungicidal Test Method. However, subsequent discussions with the testing laboratory and OPP microbiologists have determined that, although the testing laboratory should have explicitly stated the alteration to the AOAC method along with approved rationale, the alteration does not significantly affect the integrity of the results and is acceptable in this instance.

In addition, AOAC Method 955.17 states that Conidia of required resistance survive 10 min exposure at 20C to phenol dilution of 1:70 but not to 1:60. Subsequent phenol resistance testing did not fit these parameters, however since ATCC stain 9533 was used (as specified in the method) and phenol resistance is no longer required, this is acceptable in this circumstance.

Labeling comments:

- The proposed label claims that the product, DETOX, is an effective fungicide against *Trichophyton mentagrophytes* at full strength with a 5 minute contact time on non-porous surfaces are now acceptable.

For detailed information and considerations, please refer to the attached EPA/AD Product Science Branch efficacy memorandum dated April 23, 2007 (Amended June 16, 2008).

If you have further questions concerning this letter, please contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epa.gov or Lisa Mckelvin by telephone at (703) 308-(703) 308-7496 or by email at mckelvin.lisa@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

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

Enclosure: PSB Efficacy review

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 23, 2008
Amended June 16, 2008

MEMORANDUM

Subject: Efficacy Review for Detox;
EPA Reg. No. 84368-R; DP Barcode: D348870

From: Marcie Tidd, Microbiologist Marcie Tidd 6/26/08
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Team Leader 6/26/08
Product Science Branch
Antimicrobials Division (7510P)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM 34 / Lisa McKelvin
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

Formulation from the Label:

Active Ingredient(s)	% by wt.
Ethyl alcohol	29.4%
Other Ingredients	70.6%
Total	100.0%

I. BACKGROUND

The product, Detox, is a new product which is intended for use as a fungicide and moldcide. Previously, the product was proposed as a fungicide solely against *Stachybotrys chartarum* (black mold) [see DP340591]. At that time, the applicant submitted data conducted under an experimental protocol that was not previously submitted to the Agency for review, and was determined to be unacceptable to satisfy Agency guidelines. The applicant is now data for *Trichophyton mentagrophytes.* The study was conducted by Microchem Laboratory located at 1107-C S. Airport Circle in Euless Texas.

The data package contained a letter from the applicant's representative to the Agency (dated January 8, "2007" which should read 2008), the Confidential Statement of Formula, the proposed label (dated January 2008), and one study (MRID 473202-05) with Statements of No Data Confidentiality and Good Laboratory Practice.

The original efficacy review for the submitted data was completed April 23, 2008. At that time it was determined that the applicant had deviated from the standard AOAC protocol during testing without documentation or prior approval. Upon receipt of the review, the applicant addressed the alteration and a senior science advisor from OPP's microbiology laboratory was consulted on the matter. This review is an amended version of the original to reflect the resulting recommendations.

II. USE DIRECTIONS

The product is intended for use against "fungi, molds, and fungal spores" in residential / household, business, or institutional settings. The product claims that it will kill mold, fungi and their spores on "most indoor and outdoor surfaces" (specifying porous and nonporous surfaces) such as glazed ceramic tiles, grout, cements, shower doors, vinyl curtains, countertops, windowsills, refrigerator seals, wood, carpets, papers, wallboard, concrete, masonry block building materials, and under the sink. The proposed label also mentions that the product will control mold in basements, bathrooms, closets, and around windows on hard surfaces such as wallboard, plaster, wood, metal, masonry, concrete, and tile.

The proposed label lists the following use directions for killing household molds. Clean contaminated area to remove surface soil. 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. Apply Detox on cleaned area until evenly wet and let it stand for 5 minutes. Allow treated surfaces to dry completely. Wipe with wet sponge or cloth if cosmetically necessary.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Supplemental Efficacy- Disinfectant Use on Pathogenic Fungi

Effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 samples representing 2 different batches using the AOAC Fungicidal Test. Performance requirements for this test: the highest dilution

that kills all fungal spores is the minimum effective concentration. Alternatively, the AOAC Use Dilution Method, modified to conform with appropriate elements in the AOAC Fungicidal Test, may be employed. If the product is intended for use as a spray, the AOAC Germicidal Spray Products Test must be employed. The inoculum in the above tests must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 samples representing 2 different batches must be employed in the test. Performance standard for this test: killing of the test microorganism on all carriers is required. These agency standards can be found in DIS/TSS-6.

Note: As an interim policy, the Agency is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes* and *Aspergillus niger*. The Agency recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until the Agency determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Hard Surface Mildew Fungistatic Test

This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 days of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth.

Supplemental Recommendations

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5×10^6 /ml) of conidia. These agency standards can be found in DIS/TSS-2.

IV. SUMMARY OF SUBMITTED STUDY

MRID 473202-05 "A Study of the Fungicidal Activity of Detox Versus T. mentagrophytes by the Methods of the AOAC Fungicidal Test 955.17" by Michelle Blankenship. Study conducted by MicroChem Laboratory, Inc., project ID numbers 07024-2, 071210-1. Study completed January 2, 2008.

This test was conducted according to the Fungicidal Activity Test, Official Methods of the AOAC (1995) against *Trichophyton mentagrophytes* (ATCC 9533). Two lots of the product, DETOX, were tested (Lot Nos. 090707-1 and 090707-2). The test substance was received ready to use. A soil load of 5% heat-inactivated calf serum was added. *T. mentagrophytes* cultures were prepared from fungal stocks on SAB agar slants by adding swabs to centers of SAB plates which were incubated for 15 days at 27±2ºC. Mycelial mats were scraped from the surface with 5 mL of saline solution and a sterile rubber policeman. Suspensions were homogenized with 5-10 strokes in a tissue homogenizer. The suspension was filtered through cotton into a glass funnel to separate mycelia from conidia, which were collected in a French square bottle and stored for up to two weeks at 3±2ºC until used in the test. On the day of the test, fungal density was estimated by counting on a hemacytometer then diluted to approximately 5 x 10^6 CFU/mL using saline solution. A 5.0 mL aliquot of test agent was added to 25x150mm tests tubes and brought to room temperature (20±1 ºC). One half (0.5) mL of fungal culture was added to the tube. After exposure times of 1.0, 5.0, 10.0 minutes, a sterile loop was used to transfer one loopful from the reaction tub to tubes containing **20 mL** of neutralizing broth (SAB broth containing 0.14% Lecithin and 1.0% Tween 80). The primary transfer tube was mixed and a sub-transfer was created with one loopful of tube 1 into a second tube containing 20 mL of neutralizer. All tubes were incubated at 27±2ºC for 10 days and scored for the presence or absence of growth of the organism. Phenol resistance was tested in the same manner at concentrations of 1:60, 1:70, 1:90, and 1:100 at 20±1 ºC with contact times of 5, 10, and 15 minutes. Neutralization controls were conducted on each lot with one loopful of test agent into **20 ml** neutralizing recovery medium. Approximately 100 CFU of the organism were added to each tube and incubated for 10 days at 27±2ºC. Growth in the test tubes validated that the neutralizer was effective. The same procedure was done with diluted phenol (1:60). For the numbers control, serial dilutions were made in neutralizing recovery medium and colonies enumerated from culture plates. Sterility and viability controls were also conducted.

Note: Phenol resistance test results were not included in the data report but were provided electronically at the Agency's request on 4/21/08.

**Update: The applicant provided rationale for the increased amount of neutralizer medium following receipt of the 4/23 review. They indicated that 20 mL of neutralizer media is needed to effectively neutralize their product. Furthermore, testing was done to demonstrate the growth of low numbers of organism. The applicant felt result this proved that the increased amount of neutralizer had no effect on growth.

V. RESULTS

Test Results

MRID Number	Organism	Lot Number	Start Spore Count (CFU/mL)	Results (CFU/10mL) Growth (+) No Growth (-)		
				1 min	5 min	10 min
473202-05	*Trichophyton mentagrophytes* (ATCC 9533)	090707-1	1.94×10^6	+	-	-
		090707-2		-	-	-

Phenol Resistance

Phenol Dilution	Results (CFU/10mL) Growth (+) No Growth (-)		
	1 min	5 min	10 min
1:60	-	-	-
1:70	-	-	-
1:80	+	+	+
1:90	+	+	+
1:100	+	+	+

VI. CONCLUSIONS

The submitted data (MRID473202-05) now support the use of the product, DETOX, as a fungicide against *Trichophyton mentagrophytes* at full strength at room temperature on with a contact time of 5 minutes. The test employed represents a deviation from AOAC method 955.17. In both test and neutralization tubes, loopfuls of test agent or test agent/ organism mixture were added to 20 mL of neutralization media, not 10 mL as specified in the AOAC Fungicidal Test Method. However, subsequent discussions with the testing laboratory and OPP microbiologists have determined that, although the testing laboratory should have explicitly stated the alteration to the AOAC method along with approved rationale, the alteration does not significantly affect the integrity of the results and is acceptable in this instance.

In addition, AOAC Method 955.17 states that Conidia of required resistance survive 10 min exposure at 20C to phenol dilution of 1:70 but not to 1:60. Subsequent phenol resistance

testing did not fit these parameters, however since ATCC stain 9533 was used (as specified in the method) and phenol resistance is no longer required, this is acceptable in this circumstance.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, DETOX, is an effective fungicide against *Trichophyton mentagrophytes* at full strength with a 5 minute contact time on non-porous surfaces. These claims are **now acceptable**.

   As discussed in the conclusions, the test method the applicant used deviated from the AOAC method by using double the volume of neutralizing solution and the same amount of test substance / inoculum, resulting in a greater neutralizer to test solution / fungi ratio. However, this alteration was determined to have not significantly impacted the integrity of the results and will be considered acceptable in this instance. All future alterations to the accepted AOAC methods must be pre-approved by the Agency and plainly stated in the testing report.

   The applicant may now have claims as a fungicide against *Trichophyton mentagrophytes* on hard, non-porous surfaces. The applicant needs to state this organism on the product label and the ATCC number either on the data matrix or on the label as optional text.

2. The applicant has not submitted a protocol to obtain fungicidal claims on porous surfaces, such as carpets. The applicant must remove all claims from the product label for use as a fungicide on porous surfaces.

3. The proposed label claims that the product will control the growth of mold and fungi. This claim is **not acceptable** because it implies mold inhibition (i.e. residual activity after application). In order to attain mold inhibition claims, the applicant would need to perform the Hard Surface Mildew Fungistatic Test method (§ 93-30(I) Item 2).

   For this same reason, the claim "...eliminate the spread of fungal spores and other contaminates" on page 4 of the proposed label must also be removed.

4. The proposed label claims that the product may be used to "treat" mold on various surfaces. These claims are **not acceptable**. The applicant must be more specific on what this means (i.e. cleaning, disinfecting). Any cleaning directions must be separate and distinct from mold/mildewcidal or fungicidal directions/claims.

5. The proposed label claims that the product may be used for mold remediation. The applicant must include language which instructs the user to isolate and control the source of moisture before application. The label for 67212-1 (available to the public at http://oaspub.epa.gov/pestlabl/ppls.home) provides a good example of such language on page 17, treatment for floors and walls.

MATERIAL TO BE ADDED TO JACKET

REG # 84368-1

Description: New Registration

check all that apply		
☑	new stamped accepted label	Send to CSC
☐	new CSF	
☐	notification	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's Name: Lisa McKelvin Date: 6-9-08

Phone: 308-7496 Division: AD

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
84368-1	June 9, 2008

Term of Issuance:
Unconditional

Name of Pesticide Product:
Detox™

NOTICE OF PESTICIDE:
_X_ Registration
____ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (***OPP Decision No. 379192***) is unconditionally registered in accordance with FIFRA sec 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "84368-1.".

Signature of Approving Official:

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

Date:
June 9, 2008

EPA Form 8570-6

b). In the first aid section, revise the instructions title to read "IF ON SKIN OR CLOTHING"

c). All products, except for residential/household use products, must bear the following statement: "Do not contaminate water, food, or feed by storage and disposal."

The statement should appear immediately under the "Storage and Disposal" heading. however, the statement can be placed elsewhere within the Storage and Disposal instructions.

For larger or non-residential container sizes, refer to PR Notice 83-3 for the appropriate "Storage and Disposal" instructions.

Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

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

Enclosure: (Stamped Label)

DETOX™

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

- Contains no ammonia, bleach, or acid
- Eliminates musty odors
- Colorless
- Bacteriostat, fungistat (mold and mildew), mildewstat and deodorizer
- Mildew stains remover

ACTIVE INGREDIENT
Ethyl alcohol.....29.4%
OTHER INGREDIENTS.....70.6%
TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN
WARNING

See side/back panel for First Aid
Directions for Use must be read completely prior to using this product.
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted con detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Net Contents 24 oz.
1 quart
1 gallon
5 gallon
55 gallon

EPA Reg. No. 84368 – R

EPA Est. No. 84368 - R-XX

Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUN 9 2008
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 84368-1

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

- For use in homes, businesses or institutions.
- Contains no bleach, ammonia and acid
- Colorless
- No fumes
- For use on nonporous (glass, metal) and semi-porous surfaces (concrete, plaster and wallboard)
- Deodorizer
- DETOX is [specially formulated] [a unique technology] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold and mildew
- Controls mold [leaving a fresh clean scent] [leaving rooms clean and fresh smelling].
- Eliminates musty odors [caused by mold].

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear such as goggles or safety glasses. Wash thoroughly with water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If on Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes. Then continue rinsing eye. • Call a poison control center or doctor for treatment advice
Hot Line Number: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on DETOX, call the **National Pesticides Information Center** at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.	

Physical or Chemical Hazards

Combustible. Do not use or store near hear or open flame.

DETOX contains no bleach, ammonia, and is suitable for use on most surfaces to eliminate musty odor.

For use on hard and semi-porous surfaces such as wallboard, [plaster], wood, metal, masonry, concrete and tile.

DIRECTIONS FOR USE

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

The person applying this product is responsible for following these directions under both state and federal laws.

1.0 General

DETOX is used to retard (or inhibit) odor, stain causing or other damage causing organisms including mold and mildew on floors, walls, contents and other interior building surfaces until such time as the cause of such growth can be identified and corrected. It is also used as one component mold remediation or water damage restoration program. The purpose of such a program is to minimize damage from growth of mold and other odor, stain and damaging organisms, limit re-growth and help building interiors continue in that condition. This product should only be used in those cases where visible microbial growth has been detected (or conditions are likely to immediately result in such growth) and then only as part of a program that removes that growth and identifies and corrects the conditions that led to that growth. If you need help understanding these instructions or have additional questions after reading these instructions, DO NOT APPLY THIS PROUCT until you received answers for all of your questions.

2.0 Causes of Microbial Growth

Microbial (including bacteria, mold, mildew, and other fungi) growth is present at all times both outdoors and in building interiors. Normally the natural balance of the environment limits such growth to acceptable levels. Under certain conditions, growth can reach problem levels and if not controlled, will cause foul odors, stain and damage furnishings and valuables, and may even destroy structural components of the building. Normally fungal spores, live organisms and food sources are plentiful in building interiors without uncontrolled growth taking place. Elevated water from the following can lead to growth:

2.1 Floods

If water floods the interior of a building it brings a massive load of organic matter, bacteria and fungal spores. If the water and excessive organic load is not cleaned quickly, massive growth will result. Floods can result from rising water and massive plumbing failures.

2.2 Leaks

Leaks release lesser amounts of water and often over extended time periods. Thus, they can lead to high levels of growth in wall cavities and other spaces where they are not visible until considerable damage has been done. Leaks can be both from plumbing and roof, wall or other structural failures.

2.3 Humidity

Microorganisms grow in moisture that form on surfaces and within porous materials. This is known as water activity of the maternal or surface. High levels of humidity can lead to sufficient surface water activity to support accelerated growth if that elevated level is maintained for as little as 24 hours. Accelerated growth takes place with some fungi within 24 hours at humidity levels between 66% - 70%.

3.0 Indications for Use and Guidelines

Homeowners and building managers should survey their buildings at least monthly for any of the following conditions. When they are found, they should be corrected according to the guidelines.

3.1 Visible Growth

Areas of visible growth of less than 32 square feet (the area of a single wall panel) can normally be remediated without elaborate procedures. When these areas are identified, mist (see application instruction below) lightly with DETOX to retard growth and spread of fungal spores and other contaminates 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, clean with detergent and water then mist with DETOX to retard future growth. If growth reappears in the same location, determine the cause and correct prior to attempting additional treatment.

Aras larger than 32 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 Association (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 DETOX in mitigation of large projects, you should be knowledgeable of one or more of these guidelines and follow them when using DETOX.

3.2 Water Damage

Evidence of possible water damage includes water stains on ceilings of walls, persistent wet spots or actual flowing water whether from plumbing failure or outside sources. 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 on 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 are wet with DETOX 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 DETOX, provides for the user and occupant safety and documentation and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, IICRC S500 contains excellent guidance. In the context of such a plan, DETOX can be used on materials to be removed and disposed of and in other applications where an Antimicrobial use is indicated. The Standard must be followed exactly and all growth and contaminated organic materials removed prior to using DETOX.

4.0 General Directions for Using DETOX

DETOX effectively controls by inhibiting growth of odor causing bacteria, fungi, and other odor, stain, or damage causing organisms on floors, walls, and other surfaces in residential, commercial, institutional, and industrial buildings. DETOX 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 a comprehensive preventative maintenance approach.

DETOX is a bacteriostat, fungistat (mold and 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 most interior surfaces. Test on an inconspicuous area if you are unsure of the surface on which you are working.

DETOX is formulated for use on all kinds of surfaces including:

- Painted wallboard
- Structural members and supports
- Ceilings and above ceiling spaces
- Basements and crawl spaces
- Cabinets and countertops
- Case goods and other furnishings
- Floor surfaces

Follow the directions for the specific type of component being treated. The following directions must be carefully read and understood prior to using the product.

4.1 Mixing Instructions

DETOX is a ready to use product – DO NOT DILUTE. Read the label before suing. DETOX must come in direct contact with the mold or other micro-organisms to be effective.

4.2 Application Equipment and Devices

Refer to the precautionary statements and other special instructions that must be followed.

4.2.1 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. When using brush or mop application, tools and materials used should be reserved only for application of DETOX, kept clean and protected between sues and replaced when worn or visibly soiled. Natural fiber brushes are preferred although any quality brush is acceptable. Where other types of cloths are used, they must be soft enough that they absorb a sufficient quantity of liquid to provide uniform application.

During Brush, Mop or Wipe Application, the applicator must have access to the surfaces being treated. Apply to a limited area at a time. Overlap applications to assure complete coverage. Cover completely while avoiding runs or pooling.

4.2.2 Spray Applications

Spray application is preferred on large surfaces that are easily accessible and uniformly shaped. The spray equipment chosen should provide a consistent fine (1 – 300 micron) particle size and uniform spray pattern. Powered medium pressure sprayers are preferred. However, airless sprayers are suitable.

Pump-up garden type sprayers can be used with 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 applications achieve complete uniform coverage. Avoid excessive wetting and do not allow the spray to run or pool.

4.2.3 ULV (Ultra Low Volume) or Mist Generating Sprayers

ULV, mist or other small particle application is preferable where surfaces are irregular or less accessible. Equipment capable of generating particles in the 15 – 60 micron range is most satisfactory. Do not use thermal type fog generators.

Generally a fog will carry and provide adequate coverage up to 8 feet from the point of application so the fog must be directed in all directions to assure coverage without over wetting. Personal protective equipment including HEPA filtered mask, hooded coveralls and rubber gloves must be used when applying in open space with mist generating application equipment.

4.3 Application Techniques
DETOX must be applied evenly over 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 desired results.

4.4 Rate of Application
DETOX is a ready to use product – do not dilute. Users of this product must carefully follow the rate of application instructions provided below.

4.4.1 Hard, Smooth surface (Glass, Metal)
Apply until surface is evenly wet. Mist, wipe or spray coverage rate is 400 ft^2 per gallon. If this rate results in surface runoff or liquid pooling, lower the application rate until the surface is thoroughly and evenly wet without runoff or pooling.

4.4.2 Semi-Porous Surfaces such as Concrete or Plaster or Wallboard
Apply until surface is evenly wet. Mist coverage rate is 200 ft^2 per gallon. Wipe is not recommended. Spray coverage rate is 100 ft^2 per gallon. DETOX 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 make multiple applications at a lower application rate on some surfaces as the first application will wet the surface and facilitate penetration of following applications.

4.5 Frequency of Application
Normally, infrequent application (once a year or less) will provide effective control. Do not apply more often than monthly and then only if there is evidence of re-growth. Prior to re-application in such cases, investigate to determine the cause of re-growth and correct that problem prior to re-application. Also make sure the re-occurrence of microbial growth does not have another cause such as persistently high humidity, standing water or hidden leaks.

Removed components that are contaminated with mold and other microbial growth may spread contamination while being removed from the building. To prevent this, smaller items should be placed in plastic bags that should then be sealed before being removed. Larger items that cannot be safely packaged should be treated before being moved through occupied spaces. An appropriately labeled disinfectant can be used for treatment. Care must be used during treatment to assure that fumes from the agent being sued are not released into occupied spaces. Products should be used according to their label directions.

STORAGE and DISPOSAL

Storage: Store in a cool, dry place inaccessible to children and pets.
Pesticide Disposal: If empty: Do not reuse this container. Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.
Do not contaminate water, food or feed by storage and disposal.

NOTICE ON CONDITIONS OF SALE

The **Directions For Use** of this product reflects the opinion of experts based on experimental use and tests. The directions are believed to be reliable and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result, because of factors such as the presence of other materials, or use of the product in a manner inconsistent with its labeling, all of which are beyond the control of Mandala Technologies or the Seller. All such risks are assumed by the Buyer.

To the extent consistent with applicable law, Mandala Technologies warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions For Use**, subject to the inherent risks, referred to above. To the extent consistent with applicable law, Mandala Technologies makes no other express or implied warranty of fitness or merchantability or any other express or implied warranty. To the extent consistent with applicable law, in no case shall Mandala Technologies or the Seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. To the extent consistent with applicable law, Mandala Technologies and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing **Conditions of Sale and Warranty** which may be varied only be agreement in writing signed by a duly authorized representative of Mandala Technologies.

DETOX™ is a trademark of Mandala Technologies, LLC

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Mandala Technologies LLC, 30777 Northwestern Hwy, Suite 300, Farmington Hills, MI 48334	EPA Registration Number/File Symbol XXXXX - R
Active Ingredient(s) and/or representative test compound(s) Ethyl alcohol 29.4%	Date May 1, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) mold and fungal disinfectant	Product Name DETOX

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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.

Signature	Date	Typed or Printed Name and Title
Olav Messerschmidt	May 1, 2007	Olav Messerschmidt

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Marcie Tidd/DC/USEPA/US
05/21/2008 12:01 PM

To "Norman Miner" <nminer@microchemlab.net>
cc Adam Heyward/DC/USEPA/US@EPA, "Valerie Harris" <vharris@microchemlab.net>, Tajah Blackburn/DC/USEPA/US@EPA, Michele
bcc
Subject Re: Fw: DETOX/84368-R

Dr. Miner,

Adam had forwarded me your email earlier today. Thank you for providing your justifications for the deviations to the protocol. The Fungicidal Activity of Disinfectants, AOAC Test 955.17 (2005 edition) states that 10 mL is to be used for the test, and that subcultures should be taken from these tubes. In all cases, deviations to the protocol should be accompanied with justifications for these changes at the time of submission. I am currently in discussions with colleagues to determine if a revised review will be issued in light of the information you've provided, and will let Adam know.

Thank you,

Marcie Tidd
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Phone: 703-308-0173
Fax: 703-308-8481
Email: tidd.marcie@epa.gov
"Norman Miner" <nminer@microchemlab.net>

"Norman Miner" <nminer@microchemlab.net>

05/21/2008 11:47 AM

To Marcie Tidd/DC/USEPA/US@EPA
cc Adam Heyward/DC/USEPA/US@EPA, "Valerie Harris" <vharris@microchemlab.net>
Subject Fw: DETOX/84368-R

Ms. Tidd:

Forwarded to you is a response I sent to Adam Heyward. I have re-read the directions for Fungicidal Activity of Disinfectants, AOAC Test 955.17, 15th Edition, 1990, and the statement on neutralizers ("To eliminate risk of faulty results ....") does not specify to use any specific volume of neutralizer, or even a specific chemical type of neutralizer. The Pesticide Assessment Guidelines, Subdivision G, Product Performance, at page 50, Section 91-1 (a) (3) identifies that the "neutralizer employed inactivates the active ingredients and does not possess any antimicrobial activity itself...." We believe it is intuitively correct to realize that one neutralizer chemistry or volume, or process does not fit all candidate disinfectants, and the scientifically correct approach is to validate that whatever neutralizer is used does neutralize the test chemistry, and is able to support the growth of low numbers of the test microbe. That is what our study does show. As described in the forwarded e-mail to Mr. Heyward, we acknowledge that volume does effect the concentration of the active antimicrobial ingredient, which is the reason we used 20.0 ml after initial tests showed that 10.0 ml was insufficient to neutralize this DETOX test chemistry, however, the volume of nutralizing growth medium is essentially irrelevent to allow the growth of 5, 10, 50, or 100 colony forming units of the test microbe. The test microbe will grow in all aof these volumes. We therefore respectfully request that your science review regarding volume of neutralizer be carefully

reconsidered in light of the above additional information, and data as given in the Final Study Report. Thank you.

Norman Miner, Ph.D.
President
MicroChem Laboratory

----- Original Message -----
From: Norman Miner
To: Heyward.Adam@epamail.epa.gov
Cc: Valerie Harris
Sent: Tuesday, May 20, 2008 3:50 PM
Subject: DETOX/84368-R

Mr. Heyward:

I have reviewed your letter of response to Mr. Messerschmidt regarding DETOX, EPA file symbol 84368 - R, in which you fault the use of 20.0 ml of neutralizing recovery medium rather than 10.0 ml. For any test material the first study we do at MicroChem Laboratory is determine an effective neutralizing medium or process. Different neutralizing media may be necessary from the standard published protocol due to different antimicrobial chemicals, and/or different concentrations. One neutralizing condition does not fit all. In the case of DETOX we initially found that 10.0 ml of neutralizing media would not neutralize the carried over test disinfectant, but 20.0 ml would so neutralize. The test for the effefctiveness of a neutralizer is that it will neutralize the carried over disinfectant, and will support the growth of low numbers of the test fungus. Our study determined that the 20.0 ml of neutralizing medium met both of those tests. Of course the numbers of fungi in the neutralizing growth medium will grow regardless of the concentration of the test fungus. One, five, ten, or one hundred fungal cells will grow in the recovery medium regardless of the volume of the medium. The concentration of the test disinfectant, however, is minimized with greater volume as was intended, and is the basis for the neutraization of the test disinfectant. We respectfully request your further consideration of this matter. I will be in the laboratory again tomorrow, Wednesday, May 21, at about 10:00 AM, if you wish to discuss this further. Thank you.

Norman Miner, Ph.D.
President
MicroChem Laboratory

Norman Miner, Ph.D.
Owner/President
MicroChem Laboratory, Inc.
www.microchemlab.net

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 20, 2008

OPP Decision Number: D-379192

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject:	Data Deficiency	
	Product Name:	DETOX
	EPA File Symbol:	84368-R
	Application Date:	10-May-2008
	EPA Receipt Date:	14-May-2007

Dear Mr. Messerschmidt:

The Agency has received and initially reviewed the subject application and has determined that the product referred to above may be acceptable for registration under section 3 (c) (5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), provided the following label revisions are made:

Unacceptable efficacy data:

1. The submitted data (MRID473202-05) do not support the use of the product, DETOX, as a fungicide against *Trichophyton mentagrophytes* at full strength at room temperature on with a contact time of 5 minutes. The test employed represents a deviation from AOAC method 955.17. In both test and neutralization tubes, loopfuls of test agent or test agent/ organism mixture were added to 20 mL of neutralization media, not 10 mL as specified in the AOAC Fungicidal Test Method. This compromises the test integrity in the following ways:

    - In the test tubes the ratio of the volume of neutralizer to test agent and organism is greater, resulting in a smaller amount of test agent to

neutralize and smaller numbers of organism that would be able to grow, effectively making efficacy easier to achieve.

- In neutralization confirmation tubes less test agent is added to the neutralizer, yet the number of organisms added to the tube (approximately 100 CFU) was independent of this. Therefore there is less test agent to neutralize as well as an increased amount of organisms, easing the ability to demonstrate growth.

In addition, AOAC Method 955.17 states that Conidia of required resistance survive 10 min exposure at 20C to phenol dilution of 1:70 but not to 1:60. Subsequent phenol resistance testing did not fit these parameters, however since ATCC stain 9533 was used (as specified in the method) and phenol resistance is no longer required, this is acceptable in this circumstance.

Labeling comments:

1. The proposed label claims that the product, DETOX, is an effective fungicide against *Trichophyton mentagrophytes* at full strength with a 5 minute contact time on porous and non-porous surfaces. These claims are **not acceptable**.

   The test method deviates from the AOAC method by using double the volume of neutralizing solution and the same amount of test substance / inoculum, resulting in a greater neutralizer to test solution / fungi ratio.

   Furthermore, no protocol was submitted to obtain fungicidal claims on porous surfaces, such as carpets. Therefore, the term "porous and all porous surface claims must be deleted form the label.

   You may have claims as a fungicide against *Trichophyton mentagrophytes* on hard, non-porous surfaces once acceptable efficacy data following AOAC 955.17 is submitted and found to be acceptable. Once the data is acceptable, the organism and ATCC number must be listed either on the data matrix or on the label as optional text.

2. The proposed label claims that the product will control the growth of mold and fungi. This claim is **not acceptable claim** because it implies mold inhibition (i.e. residual activity after application). In order to attain mold inhibition claims, you will need to perform the Hard Surface Mildew Fungistatic Test method (§ 93-30(I) Item 2).

   For this same reason, the claim "...eliminate the spread of fungal spores and other contaminates" on page 4 of the proposed label must also be removed.

3. The proposed label claims that the product may be used to "treat" mold on various surfaces. These claims are **not acceptable**. You must be more specific on what this means (i.e. cleaning, disinfecting). Any cleaning directions must be separate and distinct from mold/mildewcidal or fungicidal directions/claims.

4. The proposed label claims that the product may be used for mold remediation. You must include language which instructs the user to isolate and control the source of moisture before application. The label for 67212-1 (available to the public at http://oaspub.epa.gov/pestlabl/ppls.home) provides a good example of such language on page 17, treatment for floors and walls.

5. The proposed label (page 4) includes directions for application using a fogger. The label must be amended to specify that *"fogging is only to be used as an adjunct to surface disinfection"*, as efficacy has not been demonstrated for this application type (fogging is classified as a new use).

6. On page 5 of the proposed label, you must change the statement "The directions are believed to be reliable and should be followed carefully" to read "The directions *must* be followed carefully to be reliable." This change is necessary to conform to OPP's Guidance on Warranty Statements (October 17, 2006).

7. On the front panel of the draft master labeling, delete the following claims:

   - Suitable for use on most surfaces
   - 100% killing of household and residential mold and their spores (*where ever it appears on the label*).
   - 100% killing [elimination] of disease causing household and residential mold and their spores (*where ever it appears on the label*).
   - Kills [eliminates][destroy] tough mold
   - Attacks mold at its roots
   - Gets into and completely destroys [eliminates] common household molds.

8. On pages #2 *{Optional marketing claims, may be used on any panel}*, the following claims must be deleted from the master label.

   - [destroys] mold and fungal spores within 5 minutes (*where ever it appears on the label*).
   - Completely destroys [100% killing] of disease causing households and residential mold and their spores within 5 minutes (*where ever it appears on the label*).
   - penetrates to kill and completely destroy disease causing household and residential mold at its roots
   - penetrates to remove mildew stains at its source,
   - completely kills [destroy], spraying, etc….
   - most indoor and outdoor surfaces
   - a unique technology"

9. Add the following statement immediately following the storage and disposal heading, "Do not contaminate water, food, or feed by storage and disposal." Note that the appropriate storage and disposal instructions must be consistent with the container sizes. Refer to PR Notices 83-3 for detailed information.

10. The combustible statement and heading must read as follows:

    Physical or Chemical Hazards
    Combustible: Do not use or store near heat or open flame

11. On page #4, change "if is cosmetically necessary" to "cosmetically necessary."

12. For 1 gallon containers, add instructions to the "pesticide Storage" section that specify what to do if the product leaks or spills from it container. Refer to PR Notice 83-3 for detailed information.

13. Revise the first aid statement to read as follows:

FIRST AID

If On Skin Or Clothing:
•Take off contaminated clothing.
•Rinse skin immediately with plenty of water for 15-20 minutes.
•Call a poison control center or doctor for treatment advice.

If In Eyes:
•Hold eye open and rinse slowly and gently with water for 15-20 minutes.
•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
•Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information. [*may be different]*.

14. Since the First Aid section will not be placed on the front panel, the following: referral must appear on the front panel, in close proximity to the Signal Word:

    "See side/back panel for First Aid"

15. Remove the Spanish and English version of the statement *"If you do not understand the label, find some to explain it to you in detail"* from the first aid section and added the statement below the "Keep Out Of Reach of Children" statement.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on ***June 19, 2008.*** Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date**. Since this is the second extension for the subject application and the Agency generally limit negotiations to two per application, a new PRIA due date is not optional. Therefore, the above label revisions must be made and submitted to the Agency by June 2, 2008 for review and acceptance.

2. **Withdraw the application.** Alternatively, you may notify us not later than June 2, 2008 that you are withdrawing your application. Withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for responding to the application and a new registration service fee.

3. **Not respond.** If the Agency does not hear from you by June 2, 2008, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c) (6) of FIFRA or a withdrawal of the application.

Please respond to this letter by June 2, 2008 by contacting me by telephone at (703) 308-6422 or by e-mail at *heyward.adam@epamail.epa.gov* or Lisa Mckelvin by telephone at (703) 308-7496 or by email at *mckelvin.lisa@epa.gov* during the hours of 7:00 am to 4:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Efficacy review dated 4/23/08

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

May 16, 2008

DP BARCODE:		D350938
MRID:		47377701, 47377702
SUBJECT:		Detox
REG. NO. OR FILE SYMBOL:		84368-R
DOCUMENT TYPE:		Product Chemistry Review
Manufacturing-use [ ]	OR	End-use Product [X]
INGREDIENTS (PC Codes):		001501
CAS Number:		64-17-5
TEST LAB:		Product Development Services, LLC
SUBMITTER:		Mandala Technologies
GUIDELINE:		830 Guidelines
COMMODITIES:		Formulation
REVIEWER:		Chris Jiang CJ
ORGANIZATION:		AD
APPROVER:		Karen P. Hicks
APPROVED DATE:		5/16/08
COMMENT:		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

May 16. 2008

MEMORANDUM

Subject: Review for 84368-R

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang for KPH 5/16/08

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM 34\Lisa McKelvin
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies

Formulation from Label

Active Ingredient(s)	% by wt.
Ethyl alcohol	29.4 %
Other Ingredients	70.6 %
Total	100.0 %

BACKGROUND:

The registrant has submitted a label, a Confidential Statement of Formula (CSF) for the basic formulation, and MRIDs 47377701 and 47377702 in response to the review done under D248873. The contractor has done the primary review of this submission and Product Science Branch of Antimicrobials Division has done a secondary review which supersedes the primary review.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated 5/15/2008) is consistent with the label declaration. This CSF supersedes all previous CSFs for the respective formulation.

2. All ingredients are cleared for use in pesticidal formulations.

3. The product identity and composition is **acceptable**.

4. The descriptions of the starting materials and the manufacturing process are **acceptable**.

5. The discussion of the formation of impurities is **acceptable**.

6. All certified limits are **acceptable**.

7. The revised enforcement analytical method that was faxed on May 12, 2008 is **acceptable**.

8. The submittal of samples is **acceptable**.

9. The color, physical state, and odor are **acceptable** as the product is a clear colorless liquid with a mildly alcoholic odor.

10. The density is **acceptable** as the density was determined to be 7.94 lbs/gal (0.95 g/mL).

11. The pH is **acceptable** as the pH of a 1% solution was determined to be 7.4.

12. The oxidation/reduction potential is **acceptable** as the product does not contain oxidizing or reducing agents.

13. The flammability is **acceptable** as the flash point of the product was determined to be 85 ^{o}F.

14. The explodability is **acceptable** as the product is not potentially explosive.

15. A joint study for storage stability and corrosion characteristics is ongoing.

16. The viscosity is **acceptable** as the viscosity of the product was determined to be 6.0 cps.

17. The miscibility is **acceptable** as the product will only be diluted with water.

18. The dielectric breakdown voltage is **acceptable** as the product will not be used around electrical equipment.

19. The remainder of the data requirements were reviewed and accepted in the review done under D248873

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the submission for 84368-R to be acceptable.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 12, 2008

OPP Decision Number: D-379192

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject: Data Deficiency
Product Name: DETOX
EPA File Symbol: 84368-R
Application Date: 10-May-2008
EPA Receipt Date: 14-May-2007

Dear Mr. Messerschmidt:

The Agency has received and initially reviewed the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Act (PRIA). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter, ending June 30, 2008 to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet

that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for responding and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. The proposed label claims that the product, DETOX, is an effective fungicide against *Trichophyton mentagrophytes* at full strength with a 5 minute contact time on porous and non-porous surfaces. These claims are **not acceptable**.

   The test method deviates from the AOAC method by using double the volume of neutralizing solution and the same amount of test substance / inoculum, resulting in a greater neutralizer to test solution / fungi ratio.

   Furthermore, no protocol was submitted to obtain fungicidal claims on porous surfaces, such as carpets.

   You may have claims as a fungicide against *Trichophyton mentagrophytes* on hard, non-porous surfaces once acceptable efficacy data following AOAC 955.17 is submitted. At such time, you will need to state this organism on the product label and the ATCC number either on the data matrix or on the label as optional text.

2. The proposed label claims that the product will control the growth of mold and fungi. This claim is **not acceptable** because it implies mold inhibition (i.e. residual activity after application). In order to attain mold inhibition claims, you will need to perform the Hard Surface Mildew Fungistatic Test method (§ 93-30(I) Item 2).

   For this same reason, the claim "...eliminate the spread of fungal spores and other contaminates" on page 4 of the proposed label must also be removed.

3. The proposed label claims that the product may be used to "treat" mold on various surfaces. These claims are **not acceptable**. You must be more specific on what this means (i.e. cleaning, disinfecting). Any cleaning directions must be separate and distinct from mold/mildewcidal or fungicidal directions/claims.

4. The proposed label claims that the product may be used for mold remediation. You must include language which instructs the user to isolate and control the source of moisture before application. The label for 67212-1 (available to the public at http://oaspub.epa.gov/pestlabl/ppls.home) provides a good example of such language on page 17, treatment for floors and walls.

5. The proposed label (page 4) includes directions for application using a fogger. The label must be amended to specify that fogging is only to be used as an adjunct

to surface disinfection, as efficacy has not been demonstrated for this application type (fogging is classified as a new use).

6. On page 5 of the proposed label, you must change the statement "The directions are believed to be reliable and should be followed carefully" to read "The directions are believed to be reliable and *must* be followed carefully." This change is necessary to conform with OPP's Guidance on Warranty Statements (October 17, 2006).

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on ***June 19, 2008.*** Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date**. You may work with the Agency to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency no later than ***April 23, 2008*** to discuss a time frame that allows you to address the deficiencies listed above and the Agency time to make a regulatory decision. Due to the nature of your product chemistry data deficiency, an extension time of 90 days will be required to allow the Agency time to review your new data and make a regulatory decision. When requesting an extension, the 120-day review time starts after you have submitted your new data/fix. Therefore, you must state in your letter, the date you expect to submit your fix, and add an additional 120 days to the date you expect the Agency to receive your fix. You may request a shorter reasonable extension. Note that negotiations are generally limited to two per application.

2. **Withdraw the application.** Alternatively, you may notify us not later than April 23, 2008 that you are withdrawing your application. As noted above, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for responding to the application and a new registration service fee.

3. **Not respond.** If the Agency does not hear from you by April 23, 2008, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c) (6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such

application as long as EPA receives a response to the/a deficiency within the 75 days described above.

Please respond to this letter by April 23, 2008 by contacting me by telephone at (703) 308-6422 or by e-mail at *heyward.adam@epamail.epa.gov* or Lisa Mckelvin by telephone at (703) 308-7496 or by email at *mckelvin.lisa@epa.gov* during the hours of 7:00 am to 4:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Chemistry Memorandum dated 4/9/08

April 29, 2008

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF:** DETOX™

DP Barcode: [D350938] **Reg. No. or File Symbol:** [84368-R]
Manufacturing-Use Product [ ] **End-Use Product** [X]

TO: Karen Hicks, Team Leader
Product Science Branch
EPA Antimicrobials Division

FROM: CSC

THRU: Wallace Powell
Product Science Branch
EPA Antimicrobials Division

APPLICANT: Mandala Technologies LLC
Farmington Hills, MI

Product Formulation Active Ingredient(s):	**% by Wt.:**
Ethyl alcohol [as listed on the product label]	29.4%

BACKGROUND:

On behalf of Mandala Technologies LLC, OMC AG Consulting has submitted additional information in support of an application for registration of a new end-use product, DETOX™. This information was submitted in response to an EPA letter dated February 25, 2008 (copy provided). The product is a fungicide and deodorizer for use in household, commercial, and institutional environments. The product can be used to control mold. The applicant provided a Confidential Statement of Formula (CSF) for the basic formulation (dated March 13, 2008). The product is produced by an integrated formulation system (i.e., the product contains an active ingredient that is not an EPA-registered product).

FINDINGS:

Group A Requirements – Product Chemistry – Series A (MRID 473777-01)

- Group A product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.1600 (Description of Materials) and OPPTS

830.1620 (Production Process). See the "Recommendations" section of this report for deficiencies. See also Table A of this report.

Group B Requirements – DETOX™, Group B: Physical Properties Test Guidelines (MRID 473777-02)

- Group B product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics). See the "Recommendations" section of this report for deficiencies. See also Table B of this report.

- A Good Laboratory Practice (GLP) statement was provided stating that the study was conducted in compliance with GLP standards as published in 40 CFR 160, where applicable to physical-chemical characterization studies.

Confidential Statement of Formula

- Certain information on the CSF must be revised, as noted in the "Recommendations" section of this report.

Product Label

- Certain information on the product label must be revised, as noted in the "Recommendations" section of this report.

- Certain information on the product label could be improved, as noted in the "Recommendations" section of this report.

RECOMMENDATIONS:

- To satisfy OPPTS 830.1600 (Description of Materials) requirements, information regarding the starting materials used to produce ethyl alcohol, which is not derived from an EPA-registered product, must be provided, as requested under OPPTS 830.1600(b)(2)(ii).

- To satisfy OPPTS 830.1620 (Production Process) requirements, the following information must be provided, as requested under OPPTS 830.1620(b):

  - Information regarding the production (reaction) process used to produce ethyl alcohol, which is not derived from an EPA-registered product.

  - A flow chart of the chemical reactions at each step of the process used to product the product. At a minimum, it appears that [redacted]

Inert ingredient information may be entitled to confidential treatment

- The quantities of ingredients used to produce the product (per theoretical batch size).

- To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided. Storage and disposal information on the product label must be revised if product composition (or packaging) deteriorates over time.

- The following change to EPA Form 8570-1 (Application for Pesticide) is recommended:

  - Correct the applicant's city address to read "Farmington Hills."

- The following revision must be made to the CSF:

  - Identify the nominal concentration (i.e., 29.4), lower certified limits (i.e., 28.52), and upper certified limit (i.e., 30.28) of the active ingredient, ethyl alcohol. The information for the active ingredient must be placed in parentheses directly below the information for the active ingredient source.

- The following revision must be made to the product label:

  - Under the "Storage and Disposal" heading, add the following statement: "Do not contaminate water, food, or feed by storage and disposal."

- The following revisions to the product label are recommended:

  - In the "Combustible" statement on page 3 of the product label, change "Do not use or store near hear or open flame" to read "Do not use or store near heat or open flame."

  - On page 4 of the product label, change "if is cosmetically necessary" to read "if cosmetically necessary."

  - On page 4 of the product label, change "and other contaminates" to read "and other contaminants."

  - Add instructions to the "Pesticide Storage" section that specify what to do if the product leaks or spills from its container.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [ ]

Note: All inert ingredients are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," last updated on January 7, 2008 and available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

Note: The CSF identifies the nominal concentration and certified limits of the active ingredient source, Ethyl Alcohol USP 190 Proof. The CSF also needs to identify the nominal concentration, lower certified limit, and upper certified limit of the active ingredient, ethyl alcohol. The information for the active ingredient must be placed in parentheses directly below the information for the active ingredient source.

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Ethyl alcohol "source"	31.83	30.87	32.78
Ethyl alcohol	29.4	28.52*	30.28*

* Calculated by reviewer.

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [ ] No [X]

Note: The CSF identifies the nominal concentration and certified limits of the active ingredient source, Ethyl Alcohol USP 190 Proof. The CSF also needs to identify the nominal concentration, lower certified limit, and upper certified limit of the active ingredient, ethyl alcohol. The information for the active ingredient must be placed in parentheses directly below the information for the active ingredient source.

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [X] No [ ] Not applicable [ ]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [ ] No [X]

Note: The product label must be revised to include the following statement under the "Storage and Disposal" heading: "Do not contaminate water, food, or feed by storage and disposal."

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [ ]

Note: Storage stability studies were <u>not</u> provided in this data package.

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A – The molecular formula, molecular structure, and molecular weight of the active ingredient, ethyl alcohol, were not provided; however, this information is readily available from the Internet.	473777-01 and CSF
830.1600 Description of Materials	G – Information regarding the starting materials used to produce ethyl alcohol, which is not derived from an EPA-registered product, was not provided, as requested under OPPTS 830.1600(b)(2)(ii).	473777-01
830.1620 Production Process[2]	G – Information regarding the production (reaction) process used to produce ethyl alcohol, which is not derived from an EPA-registered product, was not provided, as requested under OPPTS 830.1620(b). G – A flow chart of the chemical reactions at each step of the process used to produce the product was not provided, as requested under OPPTS 830.1620(b). At a minimum, it appears that [redacted] The quantities of ingredients used to produce the product (per theoretical batch size) also were not provided.	473777-01
830.1650 Formulation Process[3]	NA – It appears that the process used to produce the product is a production process, not a formulation process.	
830.1670 Formation of Impurities[4]	A	473777-01
830.1700 Preliminary Analysis[5]	A Note: This information was previously provided and acceptable to the Agency, as stated in the EPA/AD Product Science Branch chemistry memorandum, dated February 20, 2008.	
830.1750 Certified Limits[6]	A – Standard certified limits were proposed. A signed certification statement was provided. Note: This information was previously provided and acceptable to the Agency, as	473777-01

Inert ingredient information may be entitled to confidential treatment

Data Requirements	Acceptance of Information	MRID No.
	stated in the EPA/AD Product Science Branch chemistry memorandum, dated February 20, 2008.	
830.1800 Analytical Method[7]	A – A copy of a GC method was provided.	473777-01
830.1900 Submittal of Samples	[Samples are to be provided on a case-by-case basis for end-use products.]	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The color of the product is clear and colorless. Testing was conducted in compliance with GLP.	473777-02
830.6303 Physical State	A	The product is a liquid at 21°C (70°F). Testing was conducted in compliance with GLP.	473777-02
830.6304 Odor	A	The product has a mildly alcoholic odor at 21°C (70°F). Testing was conducted in compliance with GLP.	473777-02
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Based on known chemistry and prior practical experience, the product ingredients are not considered to be strong oxidizing or reducing agents.	473777-02
830.6315 Flammability/ Flame Extension	A	The flashpoint of the product was reported to be 85°F (29°C). Testing	473777-02

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		was conducted in compliance with GLP.	
830.6316 Explodability	A	The product ingredients are not high energy chemicals.	473777-02
830.6317 Storage Stability	G	Storage stability study results were not provided. It appears that such studies will be conducted as a condition of registration.	Letter to EPA (dated March 13, 2008)
830.6319 Miscibility[1]	A	The product is intended to be applied only as an aqueous dilution. The product label does not carry instructions for dilution with any organic liquid. Note: The product label states that the product is ready-to-use – do not dilute.	473777-02
830.6320 Corrosion Characteristics	G	Corrosion characteristic study results were not provided. The applicant requested that the Agency allow this study to be conducted as a condition of registration, in conjunction with the storage stability study.	Letter to EPA (dated March 13, 2008)
830.6321 Dielectric Breakdown Voltage	A	The product is not intended for use in or around electrical equipment.	473777-02
830.7000 pH[2]	A	The pH of a 1% (w/w) mixture of the product with water was reported to be 7.4 at 21°C (70°F). Testing was conducted in compliance with GLP. Note: The pH of the undiluted product is 10.	473777-02 and Letter to EPA (dated March 13, 2008)
830.7050 UV/Visible Absorption	NA	*[Not required for end-use products.]*	
830.7100 Viscosity	A	The viscosity of the product was reported to be 6.0 cps at 21°C (70°F) (as determined using a Brookfield viscometer). Testing was not conducted at another temperature (e.g., 20°C higher), although OPPTS 830.7100(d) notes that this is preferable. The report did not	473777-02

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		include individual values, as requested under OPPTS 830.7100(e). It is unknown whether two determinations were made at 21°C. Testing was conducted in compliance with GLP.	
830.7200 Melting Point/Melting Range	NA	*[Not required for end-use products.]* The product is a liquid.	
830.7220 Boiling Point/Boiling Range	NA	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	The density of the product was reported to be 0.951 g/mL (7.94 lb/gal) at 20°C (68°F). Testing was conducted in compliance with GLP.	473777-02
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 23, 2008

MEMORANDUM

Subject: Efficacy Review for Detox;
EPA Reg. No. 84368-R; DP Barcode: D348870

From: Marcie Tidd, Microbiologist Marcie Tidd 4/23/08
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Team Leader 4/30/08
Product Science Branch
Antimicrobials Division (7510P)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM 34 / Lisa McKelvin
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

Formulation from the Label:

Active Ingredient(s)	% by wt.
Ethyl alcohol	29.4%
Other Ingredients	70.6%
Total	100.0%

I. BACKGROUND

The product, Detox, is a new product which is intended for use as a fungicide and moldcide. Previously, the product was proposed as a fungicide solely against *Stachybotrys chartarum* (black mold) [see DP340591]. At that time, the applicant submitted data conducted under an experimental protocol that was not previously submitted to the Agency for review, and was determined to be unacceptable to satisfy Agency guidelines. The applicant is now data for *Trichophyton mentagrophytes*. The study was conducted by Microchem Laboratory located at 1107-C S. Airport Circle in Euless Texas.

The data package contained a letter from the applicant's representative to the Agency (dated January 8, "2007" which should read 2008), the Confidential Statement of Formula, the proposed label (dated January 2008), and one study (MRID 473202-05) with Statements of No Data Confidentiality and Good Laboratory Practice.

II. USE DIRECTIONS

The product is intended for use against "fungi, molds, and fungal spores" in residential / household, business, or institutional settings. The product claims that it will kill mold, fungi and their spores on "most indoor and outdoor surfaces" (specifying porous and nonporous surfaces) such as glazed ceramic tiles, grout, cements, shower doors, vinyl curtains, countertops, windowsills, refrigerator seals, wood, carpets, papers, wallboard, concrete, masonry block building materials, and under the sink. The proposed label also mentions that the product will control mold in basements, bathrooms, closets, and around windows on hard surfaces such as wallboard, plaster, wood, metal, masonry, concrete, and tile.

The proposed label lists the following use directions for killing household molds. Clean contaminated area to remove surface soil. 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. Apply Detox on cleaned area until evenly wet and let it stand for 5 minutes. Allow treated surfaces to dry completely. Wipe with wet sponge or cloth if cosmetically necessary.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Supplemental Efficacy- Disinfectant Use on Pathogenic Fungi

Effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 samples representing 2 different batches using the AOAC Fungicidal Test. Performance requirements for this test: the highest dilution that kills all fungal spores is the minimum effective concentration. Alternatively, the AOAC Use Dilution Method, modified to conform with appropriate elements in the AOAC Fungicidal Test, may be employed. If the product is intended for use as a spray, the AOAC Germicidal Spray Products Test must be employed. The inoculum in the above tests must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 samples representing 2 different batches must be employed in the

test. Performance standard for this test: killing of the test microorganism on all carriers is required. These agency standards can be found in DIS/TSS-6.

Note: As an interim policy, the Agency is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes* and *Aspergillus niger*. The Agency recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until the Agency determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Hard Surface Mildew Fungistatic Test

This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 days of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth.

Supplemental Recommendations

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5×10^6 /ml) of conidia. These agency standards can be found in DIS/TSS-2.

IV. SUMMARY OF SUBMITTED STUDY

MRID 473202-05 "A Study of the Fungicidal Activity of Detox Versus T. mentagrophytes by the Methods of the AOAC Fungicidal Test 955.17" by Michelle Blankenship. Study conducted by MicroChem Laboratory, Inc., project ID numbers 07024-2, 071210-1. Study completed January 2, 2008.

This test was conducted according to the Fungicidal Activity Test, Official Methods of the AOAC (1995) against *Trichophyton mentagrophytes* (ATCC 9533). Two lots of the

product, DETOX, were tested (Lot Nos. 090707-1 and 090707-2). The test substance was received ready to use. A soil load of 5% heat-inactivated calf serum was added. *T. mentagrophytes* cultures were prepared from fungal stocks on SAB agar slants by adding swabs to centers of SAB plates which were incubated for 15 days at 27±2ºC. Mycelial mats were scraped from the surface with 5 mL of saline solution and a sterile rubber policeman. Suspensions were homogenized with 5-10 strokes in a tissue homogenizer. The suspension was filtered through cotton into a glass funnel to separate mycelia from conidia, which were collected in a French square bottle and stored for up to two weeks at 3±2ºC until used in the test. On the day of the test, fungal density was estimated by counting on a hemacytometer then diluted to approximately 5 x 10^6 CFU/mL using saline solution. A 5.0 mL aliquot of test agent was added to 25x150mm tests tubes and brought to room temperature (20±1 ºC). One half (0.5) mL of fungal culture was added to the tube. After exposure times of 1.0, 5.0, 10.0 minutes, a sterile loop was used to transfer one loopful from the reaction tub to tubes containing **20 mL** of neutralizing broth (SAB broth containing 0.14% Lecithin and 1.0% Tween 80). The primary transfer tube was mixed and a sub-transfer was created with one loopful of tube 1 into a second tube containing 20 mL of neutralizer. All tubes were incubated at 27±2ºC for 10 days and scored for the presence or absence of growth of the organism. Phenol resistance was tested in the same manner at concentrations of 1:60, 1:70, 1:90, and 1:100 at 20±1 ºC with contact times of 5, 10, and 15 minutes. Neutralization controls were conducted on each lot with one loopful of test agent into **20 ml** neutralizing recovery medium. Approximately 100 CFU of the organism were added to each tube and incubated for 10 days at 27±2ºC. Growth in the test tubes validated that the neutralizer was effective. The same procedure was done with diluted phenol (1:60). For the numbers control, serial dilutions were made in neutralizing recovery medium and colonies enumerated from culture plates. Sterility and viability controls were also conducted.

Note: Phenol resistance test results were not included in the data report but were provided electronically at the Agency's request on 4/21/08.

V. RESULTS

Test Results

MRID Number	Organism	Lot Number	Start Spore Count (CFU/mL)	Results (CFU/10mL) Growth (+) No Growth (-)		
				1 min	5 min	10 min
473202-05	*Trichophyton mentagrophytes* (ATCC 9533)	090707-1	1.94 x 10^6	+	-	-
		090707-2		-	-	-

Phenol Resistance

Phenol Dilution	Results (CFU/10mL) Growth (+) No Growth (-)		
	1 min	5 min	10 min
1:60	-	-	-
1:70	-	-	-
1:80	+	+	+
1:90	+	+	+
1:100	+	+	+

VI. CONCLUSIONS

1. The submitted data (MRID473202-05) do not support the use of the product, DETOX, as a fungicide against *Trichophyton mentagrophytes* at full strength at room temperature on with a contact time of 5 minutes. The test employed represents a deviation from AOAC method 955.17. In both test and neutralization tubes, loopfuls of test agent or test agent/ organism mixture were added to 20 mL of neutralization media, not 10 mL as specified in the AOAC Fungicidal Test Method. This compromises the test integrity in the following ways:

   - In the test tubes the ratio of the volume of neutralizer to test agent and organism is greater, resulting in a smaller amount of test agent to neutralize and smaller numbers of organism that would be able to grow, effectively making efficacy easier to achieve.

   - In neutralization confirmation tubes less test agent is added to the neutralizer, yet the number of organisms added to the tube (approximately 100 CFU) was independent of this. Therefore there is less test agent to neutralize as well as an increased amount of organisms, easing the ability to demonstrate growth.

   In addition, AOAC Method 955.17 states that Conidia of required resistance survive 10 min exposure at 20C to phenol dilution of 1:70 but not to 1:60. Subsequent phenol resistance testing did not fit these parameters, however since ATCC stain 9533 was used (as specified in the method) and phenol resistance is no longer required, this is acceptable in this circumstance.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, DETOX, is an effective fungicide against *Trichophyton mentagrophytes* at full strength with a 5 minute contact time on porous and non-porous surfaces. These claims are **not acceptable**.

   As discussed in the conclusions, the test method the applicant used deviated from the AOAC method by using double the volume of neutralizing solution and the same amount of test substance / inoculum, resulting in a greater neutralizer to test solution / fungi ratio.

   Furthermore, the applicant has not submitted a protocol to obtain fungicidal claims on porous surfaces, such as carpets.

   The applicant may have claims as a fungicide against *Trichophyton mentagrophytes* on hard, non-porous surfaces once acceptable efficacy data following AOAC 955.17 is submitted. At such time, the applicant needs to state this organism on the product label and the ATCC number either on the data matrix or on the label as optional text.

2. The proposed label claims that the product will control the growth of mold and fungi. This claim is **not acceptable** because it implies mold inhibition (i.e. residual activity after application). In order to attain mold inhibition claims, the applicant would need to perform the Hard Surface Mildew Fungistatic Test method (§ 93-30(I) Item 2).

   For this same reason, the claim "...eliminate the spread of fungal spores and other contaminates" on page 4 of the proposed label must also be removed.

3. The proposed label claims that the product may be used to "treat" mold on various surfaces. These claims are **not acceptable**. The applicant must be more specific on what this means (i.e. cleaning, disinfecting). Any cleaning directions must be separate and distinct from mold/mildewcidal or fungicidal directions/claims.

4. The proposed label claims that the product may be used for mold remediation. The applicant must include language which instructs the user to isolate and control the source of moisture before application. The label for 67212-1 (available to the public at http://oaspub.epa.gov/pestlabl/ppls.home) provides a good example of such language on page 17, treatment for floors and walls.

5. The proposed label (page 4) includes directions for application using a fogger. The label must be amended to specify that fogging is only to be used as an adjunct to surface disinfection, as efficacy has not been demonstrated for this application type (fogging is classified as a new use).

6. On page 5 of the proposed label, the applicant must change the statement "The directions are believed to be reliable and should be followed carefully" to read "The directions are believed to be reliable and *must* be followed carefully." This change is necessary to conform with OPP's Guidance on Warranty Statements (October 17, 2006).

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 14, 2008

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 84368-R
DP Barcode 348872

From: Wallace Powell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward, PM 34/ Lisa McKelvin
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies LLC

ACTIVE INGREDIENT	% by wt.
Ethanol	29.4

BACKGROUND

The applicant has submitted an eye irritation study (MRID 473202-04) in order to complete the product-specific acute toxicity data support for registration of the subject product DETOX™, EPA File Symbol 84368-R. The other such support was reviewed in Product Science Branch memorandum of dated 9/11/2007, Data Package 340584.

RECOMMENDATION

The submitted eye irritation study is acceptable.

Recommended acute toxicity profile:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	Waiver request	IV	Waived
Acute Dermal Toxicity	Waiver request	IV	Waived
Acute Inhalation Toxicity	Waiver request	IV	Waived
Primary Eye Irritation	473202-04	II	Acceptable
Primary Skin Irritation	Waiver request	III	Waived
Dermal Sensitization	Waiver request	Non-sensitizer	Waived

Product labeling:

The proposed human-hazard precautionary labeling in the label draft (dated January 2008) is acceptable except that it omits the instruction to "avoid contact with skin" as indicated in the Agency's Label Review Manual (August 2007, Chapter 7, available at *www.epa.gov/oppfead1/labeling/lrm*).

The proposed First Aid statements are acceptable. However, if the First Aid section is not going to be placed on the front panel, a referral should be placed on the front panel. As stated in the Label Review Manual:

> *First Aid statements for toxicity categories II and III classification may appear on any panel of the label. However, any time First Aid statements appear other than on the front panel, a referral statement such as, "See side/back panel for First Aid" should appear on the front panel in close proximity to the Signal Word.*

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

Product Manager: 34
MRID No.: 473202-04

Reviewer: W. Powell
Study Completion Date: 10/22/2007
Report No.: 23035

Testing Laboratory: Eurofins | Product Safety Laboratories – Dayton, New Jersey
Author: Carolyn Lowe

Quality Assurance (40 CFR §160): Quality Assurance statement and Good Laboratory Practice statement were included.

Test Material: DETOX, Lot #090707-1, a clear liquid

Dosage: 0.1 mL

Species: Rabbit, New Zealand albino
Sex: 3 Females
Age: Young adult
Weight: Not indicated
Source: Robinson Services, Inc. – Clemmons, NC
Housing: Temperature Range: 19-22°C
Relative Humidity: 60-82% (The study report states that the "humidity reading of 82% was due to a temporary malfunction of the environmental control system.")
Photoperiod: 12-hour light/dark cycle
Acclimation: 19 days

Summary:

1. **Toxicity Category**: II
2. **Classification**: Acceptable

Procedure/Reporting Deviations from Guideline 870.2400: None noted

Results:

The test substance caused corneal opacity in all 3 animals, persisting to Day 7 in 2 of 3 animals; and iridal involvement in all 3 animals, persisting to Day 7 in 1 of 3 animals. "Positive" degree of conjunctival redness persisted to Day 4 in 2 of 3 animals. "Positive" degree of conjunctival swelling persisted to 72 Hours in 3 of 3 animals. Conjunctival redness and swelling reached no higher than grade 2 on the Draize scale Conjunctival discharge was advanced (grade 3 on the Draize scale) in 3 of 3 animals at 48 hours. No other adverse ocular effects were observed. All notable effects cleared by Day 10.

Based on these results, DETOX appears moderately irritating and is placed in eye irritation Toxicity Category II.

Incidence of Irritation

Time Post-Instillation	No. of Animals Testing "Positive" / No. of Animals Tested			
	Corneal Opacity	Iritis	Conjunctival Redness	Conjunctival Chemosis
1 hour	3 / 3	3 / 3	3 / 3	3 / 3
24 hours	3 / 3	3 / 3	3 / 3	3 / 3
48 hours	3 / 3	3 / 3	3 / 3	3 / 3
72 hours	3 / 3	3 / 3	3 / 3	3 / 3
Day 4	2 / 3	2 / 3	2 / 3	0 / 3
Day 7	2 / 3	1 / 3	0 / 3	0 / 3
Day 10	0 / 3	0 / 3	0 / 3	0 / 3

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

March 19, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MANDALA TECHNOLOGIES
30777 NORTHWESTERN HWY, SUITE 330
FARMINGTON HILLS, MI 48334-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 19-MAR-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

OMC Ag Consulting

473777-00

March 13, 2008

Mr. Adam Heyward
~~Herbicide~~ Product Manager (PM-~~34~~ 32)
Regulatory Branch II
Document Processing Desk (REGFEE)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: **Additional Information for New Pesticide Registration**
DETOX™ (Active Ingredient: Ethyl Alcohol 29.4%)
EPA File Symbol: 84368 – R
OPP Decision Number: D-379192

Dear Mr. Heyward:

On February 28, 2008, you sent Mandala Technologies the results of the EPA Prodcut Chemistry review regarding our application to register the end use product (EP), DETOX. This letter and occupying data are in response to the several deficiencies cited in your letter.

In response to your letter, enclosed are one copy of Volume 1 and three copies of the others:

1. **Volume 1 of 3** – Administrative:
   - A copy of this cover letter
   - Application for Pesticide Registration (EPA Form 8570-1)
   - Your letter dated February 28, 2008 on OPP Decision Number D-379192 and the February 20, 2008 Product Chemistry Review by Chris Jiang
   - EPA agreement to renegotiated the PRIA date
   - Five (5) copies of revised proposed labeling
47377701 2. **Volume 2 of 3**: Product Chemistry – Series A plus MSDS's
47377702 3. **Volume 3 of 3:** Physical and Chemical Properties Tests – Series B

In our response of January 8, 2008, we included only those data or studies that were requested in your letter of September 6, 2007. In other words, data that had been reviewed and accepted earlier were not resubmitted. It appears that Mr. Jiang may not have had access to those earlier Series A Product Chemistry data. Thus, several studies are being resubmitted. Specifically, the following Series A studies are resubmitted (*Note: MRID numbers are not known*):

- Product identity and composition
- Discussion of formation of impurities
- Description of the formulation process
- Enforcement analytical method

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

The product Physical and Chemical Properties studies have been redone under GLP and are included under Volume 3 of 3. Some specific points addressed in the Product Chemistry review are addressed as follows:

- The pH cited in the CSF remains at 10; this is different than the pH reported in the Product Development Services (PDS) Report (also occurred with the earlier submitted non-GLP studies). OPPTS 830.7000 requires a 1% dilution of the pH. When DETOX is diluted 100-fold, its pH drops to 7.4. When tested undiluted, its pH is 10. A note that the pH on the CSF reflects undiluted product has been added to the CSF.

- All other physical and chemical characteristics are addressed in the PDS with the exception of corrosion characteristics. We formally request that this study be conducted as a condition of registration in conjunction with the storage stability study. Based on prior art and known experiences, ethanol in solution will remain stable for long periods and it is well know which containers are stable in the presence of the various DETOX components.

Lastly, the label has been revised to add the statement,

"**Combustible.** Do not use or store near hear or open flame."

A separate letter requesting an extension of the PRIA to June 19, 2008, was sent to you on February 6, 2008. A copy of EPA's acceptance is included in Volume 1 of 3.

If you have any questions, please don't hesitate to contact me directly at 517-881-0106.

Sincerely,

Olav Messerschmidt

Olav Messerschmidt
OMC Ag Consulting

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[XX] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Mandala Technologies LLC/ 84368-R	2. EPA Product Manager Adam Heyward	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) Mandala Technologies LLC/ DETOX	PM# 32	
5. Name and Address of Applicant *(Include ZIP Code)* Mandala Technologies LLC 30777 Northwestern Hwy, Suite 300 Famington Hills, MI 48334 [ ] *Check if this is a new address*	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.
[X] Resubmission in response to Agency letter dated Febuary 28, 2008
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

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

Submitting cited Product Chemisty deficiencies: revised label, CSF, product chemistry data
OPP Decision No. D-379192

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Metal [XXX] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	24 oz, 1 Qt, 1, 5 and 55 Gallons	[ ]

6. Manner in Which Label is Affixed to Product [XXX] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olav Messerschmidt	Registration Agent	517-881-0106

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature Olav Messerschmidt	3. Title Registration Agent
4. Typed Name Olav Messerschmidt	5. Date March 13, 2008

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 28, 2008

OPP Decision Number: D-379192

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject: Incomplete Application for Registration
Product Name: DETOX
EPA File Symbol: 84368-R
Application Date: 10-May-2007
EPA Receipt Date: 14-May-2007

Dear Ms. Messerschmidt:

Our records indicate that the decision review period for the Agency to make a determination regarding the above referenced application ends on March 19, 2008 as pursuant to the Pesticide Registration Improvement Act (PRIA). The Agency has reviewed your application and determined, pursuant to 40 CFR 152.105, it not to be sufficient to complete the registration process; therefore, the application is considered incomplete. As such, you have 75 days from the date of this letter to make the required corrections to the application or the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. Any subsequent submission relating to the application must be submitted as a new PRIA application.

The Agency has accepted your request, dated February 6, 2008, for a negotiated PRIA due date of June 19, 2008. This revised due date is based upon your time needed to submit the "fix" and the Agency time needed to in-process and review the correction. It is our understanding that the "fix" will be submitted on or before March 19, 2008. If your "fix" is reviewed and found to be deficient, and the application remains incomplete, after 75 days the Agency will terminate any action on the application pursuant to 40 CFR 152.105 and will treat the application as if it has been withdrawn by the applicant.

If the "fix" is not received on or before March 19, 2008, then the Agency may issue a not grant determination prior to 75 days from the date of this letter. Because this determination is not a denial under section 3(c)(6) of FIFRA, you may request that EPA issue a formal denial under procedures outlined in section 3(c)(6) of FIFRA and 40 CFR § 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing.

If you have further questions concerning this letter, please contact me by telephone at (703) 308-6422 or by e-mail at *heyward.adam@epamail.epa.gov* or Lisa McKelvin at (703) 308-7496 or by email at *mckelvin.lisa@epa.gov* during the hours of 8:00 am to 4:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch I
Antimicrobials Division (7510P)

Recommendation of Division Directors
Negotiated Due Dates

Decision#: 379192	**Registration#: 84368-R**	**Petition #:**
Fee Category: A54	**PRIA Decision Time Frame:** 90 Days	
Submitted by: Lisa McKelvin/Adam Heyward PM 34	**Branch:** RMBII	**Date:** February 26, 2008
Company: OMC Ag Consulting for MANDALA Technologies.		
Original Due Date: October 4, 2007	**Proposed New Due Date:** June 19, 2008	
Previous Negotiated Due Dates: March 19, 2008		
Is the "Fix" in-house? Yes	**If not, date "Fix" expected:**	

Issue (describe in detail):

The product chemistry data contains several deficiencies that must be corrected.

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

The company submitted fix two months after agreed upon date. Due to the late submission, the company requested a 90-day extension on February 6, 2008 via email.

Rationale for Proposed Due Date:

To allow the Agency sufficient time to review the new information/data and make a regulatory decision.

Other Comments/Deficiency Type:

Product Chemistry: X **Acute Tox:** __ **Efficacy:** ____ **Labeling:** ____ **Other:** ____

"75 Day" Letter appropriate? X **Yes** _____ **No Why Not**

Registrant notified that this is the last negotiation? X **Yes** ___ **No Why Not?**

Approve: ✓	**Disapprove:**

If disapproved, action to be taken:

OD or DOD Signature: Matt Manell	**Date:** 2-28-08

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 25, 2008

OPP Decision Number: D-379192

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject: Product Chemistry Data Deficiencies
Product Name: DETOX
EPA File Symbol: 84368-R
Application Date: 10-May-2007
EPA Receipt Date: 14-May-2007

Dear Mr. Messerschmidt:

The Agency has received and initially reviewed the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Act (PRIA). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending *May 1, 2008* to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the

same application must then be submitted as a new application with a new deadline for responding and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are listed in the enclosed EPA/AD Product Science Branch chemistry memorandum dated February 20, 2008. Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on **June 19, 2008.** You have the following two options:

1. **Withdraw the application:** Alternatively, you may notify us not later than March 7, 2008 that you are withdrawing your application. As noted above, **w**ithdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for responding to the application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.

2. **Not respond:** If the Agency does not hear from you by March 7, 2008, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to the/a deficiency within the 75 days described above.

Note that this is the second negotiations for the subject decision number. It is the Agency's policy to limit negotiations to two per application. Therefore, the required fix identified in the attached review must be resolved in a time frame that will allow the Agency to make a regulatory decision before or by June 19, 2008. It will take the Agency approximately 60 days to review your resubmitted information/data. Failure to submit the fix within a certain time frame may result in a determination to not grant your application.

Please respond to this letter by March 7, 2008 by contacting me by telephone at (703) 308-6422 or by e-mail at *heyward.adam@epamail.epa.gov* or Lisa McKelvin by telephone at (703) 308-7496 during the hours of 8:00 am to 4:00 pm EST with a response and for

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

Sincerely,

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

Enclosure: [Product Chemistry Memorandum]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

February 20, 2008

DP BARCODE:		D348873
MRID:		47320201, 47320202, 47320203
SUBJECT:		Detox
REG. NO. OR FILE SYMBOL:		84368-R
DOCUMENT TYPE:		Product Chemistry Review
Manufacturing-use [ ]	OR	End-use Product [X]
INGREDIENTS (PC Codes):		001501
CAS Number:		64-17-5
TEST LAB:		OMC Ag Consulting, Mandala Technologies LLC, Product Development Services, LLC
SUBMITTER:		Mandala Technologies
GUIDELINE:		830 Guidelines
COMMODITIES:		Formulation
REVIEWER:		Chris Jiang
ORGANIZATION:		AD
APPROVER:		Karen P. Hicks
APPROVED DATE:		2/20/08
COMMENT:		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

February 20, 2008

MEMORANDUM

Subject: Review for 84368-R

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM 34\Lisa McKelvin
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies

Formulation from Label

Active Ingredient(s)	% by wt.
Ethyl alcohol	29.4 %
Other Ingredients	70.6 %
Total	100.0 %

BACKGROUND:

The registrant has submitted a label, a Confidential Statement of Formula (CSF) for the basic formulation, and MRIDs 47320201, 47320202, and 47320203 to fulfill the product chemistry guidelines for this integrated end-use product.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated 13/02/2008) is consistent with the label declaration.

2. All ingredients are cleared for use in pesticidal formulations.

3. The product identity and composition is **unacceptable** because this guideline was not addressed.

4. The description of the starting materials is **unacceptable** because the CSF states that supplier of the pH adjuster is one company; however, the MSDS states that the supplier is another company. In addition, The CSF states that the purity of the pH adjuster is 45%; but the MSDS states that the purity of the pH adjuster is 100%.

5. The description of the manufacturing\production\formulation process is **unacceptable** because this guideline was not addressed.

6. The discussion of the formation of impurities is **unacceptable** because this guideline was not addressed.

7. The preliminary analysis is **acceptable**.

8. All certified limits are **acceptable**.

9. The enforcement analytical method is **unacceptable** because this guideline was not addressed.

10. MRID 47320201 states that the study contains Part A of the product chemistry requirements; however, this study only contains MSDS's and the Confidential Statement of Formula for the test substance.

11. The color, physical state, and odor are **unacceptable** because the test was not conducted under GLP compliance. The product is a clear colorless liquid with a mildly alcoholic odor.

12. The density is **unacceptable** as the test was not conducted under GLP compliance. The density was found to be 7.93 lbs/gal (0.95 g/mL).

13. The pH is **unacceptable** as the CSF states that the pH is 10; however, the study

states that the pH is 8.0. The study for pH was also not conducted under GLP compliance.

14. The oxidation/reduction potential is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

15. The flammability is **unacceptable** as this study was not conducted under GLP compliance. The flash point of the test substance was determined to be 84 °F.

16. The explodability is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

17. The storage stability is **unacceptable** because this guideline was not addressed. This study must be submitted under GLP compliance as confirmatory efficacy data was submitted with the application. The storage stability study is often conducted in conjunction with the study for corrosion charactereristics.

18. The viscosity is **unacceptable** as the study was not done under GLP compliance. The viscosity was determined to be 6.0 cps.

19. The miscibility is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

20. The corrosion characteristics are **unacceptable**. This guideline was not addressed. This study must be submitted under GLP compliance. The study for corrosion characteristics is often conducted in conjunction with the study for storage stability.

21. The dielectric breakdown voltage is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

22. The stability (guideline 830.6313), melting point (guideline 830.7200), and boiling point (guideline 830.7220) are not required for this product.

23. The label must read, "*Combustible.* Do not use or store near heat or open flame" if the flash point of the test substance was determined to be 84 °F.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the submission for 84368-R to be unacceptable for the reasons indicated in the findings. The registrant must remedy the issues discussed in the findings for registration to proceed.

OMC Ag Consulting

February 6, 2008

Mr. Adam Heyward
Herbicide Product Manager (PM-34)
Regulatory Branch II
Document Processing Desk (REGFEE)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: **Renegotiated PRIA Date**
DETOX™ (Active Ingredient: Ethyl Alcohol 29.4%)
EPA File Symbol: 84368 – R
OPP Decision Number: D-379192

Dear Mr. Heyward:

In response to your letter dated February 5, 2008, and to confirm our phone conversation earlier today, we request that an additional 3 months (90-days) be added to our present PRIA date of March 19, 2008, specifically **June 19, 2008**. This agreed upon date gives the Agency 6 months to compete its review of the relatively limited dataset consisting of a few product chemistry studies, an eye irritation study and an efficacy study which you received on January 14, 2008.

If you have any questions, please don't hesitate to contact me directly at 517-881-0106.

Sincerely,

Olav Messerschmidt
OMC Ag Consulting

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

Adam Heyward/DC/USEPA/US
02/27/2008 08:23 AM

To "Olav" <omesserschmidt@comcast.net>
cc Lisa Mckelvin/DC/USEPA/US,
bcc
Subject RE: OPP Decision Number: D-379192/EPA File Symbol: 84368-R

Dear Mr.Messerschmidt:

It was brought to my attention that the PRIA due date for OPP Decision Number: D-379192/EPA File Symbol: 84368-R is March 19, 2008, not June 19, 2008 as stated in my letter of 2/25/08, page #2, first and last paragraph under the heading "FIFRA Section 33/PRIA. Therefore, you must request a 60-days extension from the projected date in March, 2008 that you expect to submit the fix. Your extension request should be submit by 2/29/08.

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

"Olav" <omesserschmidt@comcast.net>

"Olav" <omesserschmidt@comcast.net>
02/26/2008 02:23 PM

To Adam Heyward/DC/USEPA/US@EPA
cc Lisa Mckelvin/DC/USEPA/US@EPA, Mark Hartman/DC/USEPA/US@EPA
Subject RE: OPP Decision Number: D-379192/EPA File Symbol: 84368-R

Dear Mr. Heyward,

We received your letter and Product Chemistry review. The studies are being re-done under GLP and the report and other deficiencies will be sent to you by late-march.

Olav Messerschmidt
****

Olav Messerschmidt
OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823
Tel: 1-517-881-0106
Fax: 1-517-336-9843
Email: omesserschmidt@comcast.net

```
-----Original Message-----
From: Heyward.Adam@epamail.epa.gov [mailto:Heyward.Adam@epamail.epa.gov]
Sent: Monday, February 25, 2008 10:35 AM
To: omesserschmidt@comcast.net
Cc: Mckelvin.Lisa@epamail.epa.gov; Hartman.Mark@epamail.epa.gov
```

Subject: OPP Decision Number: D-379192/EPA File Symbol: 84368-R

Dear Mr. Messerschmidt:

The Agency has completed it received of your resubmission for the subject application and has determined that further information is needed. Please attachments for detailed information. Note that this is the second negotiations for the subject decision number. It is the Agency's policy to limit negotiations to two per application. Therefore, the required fix identified in the attached review must be resolved in a time frame that will allow the Agency to make a regulatory decision before or by June 19, 2008. It will take the Agency approximately 60 days to review your resubmitted information/data. Failure to submit the fix within a certain time frame may result in a determination to not grant your application.

(See attached file: 84368-R 75 day Data Deficiency letter 25-Feb-2008.doc)

(See attached file: scan.pdf)
(Embedded image moved to file: pic06193.jpg)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 25, 2008

OPP Decision Number: D-379192

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject: Product Chemistry Data Deficiencies
Product Name: DETOX
EPA File Symbol: 84368-R
Application Date: 10-May-2007
EPA Receipt Date: 14-May-2007

Dear Mr. Messerschmidt:

The Agency has received and initially reviewed the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Act (PRIA). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending *May 1, 2008* to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that

scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for responding and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are listed in the enclosed EPA/AD Product Science Branch chemistry memorandum dated February 20, 2008. Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on **June 19, 2008.** You have the following two options:

1. **Withdraw the application:** Alternatively, you may notify us not later than March 7, 2008 that you are withdrawing your application. As noted above, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for responding to the application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.

2. **Not respond:** If the Agency does not hear from you by March 7, 2008, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to the/a deficiency within the 75 days described above.

Note that this is the second negotiations for the subject decision number. It is the Agency's policy to limit negotiations to two per application. Therefore, the required fix identified in the attached review must be resolved in a time frame that will allow the Agency to make a regulatory decision before or by June 19, 2008. It will take the Agency approximately 60 days to review your resubmitted information/data. Failure to submit the fix within a certain time frame may result in a determination to not grant your application.

Please respond to this letter by March 7, 2008 by contacting me by telephone at (703) 308-6422 or by e-mail at *heyward.adam@epamail.epa.gov* or Lisa McKelvin by telephone at (703) 308-7496 during the hours of 8:00 am to 4:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

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

Enclosure: [Product Chemistry Memorandum]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

February 20, 2008

DP BARCODE:		D348873
MRID:		47320201, 47320202, 47320203
SUBJECT:		Detox
REG. NO. OR FILE SYMBOL:		84368-R
DOCUMENT TYPE:		Product Chemistry Review
Manufacturing-use [ ]	OR	End-use Product [X]
INGREDIENTS (PC Codes):		001501
CAS Number:		64-17-5
TEST LAB:		OMC Ag Consulting, Mandala Technologies LLC, Product Development Services, LLC
SUBMITTER:		Mandala Technologies
GUIDELINE:		830 Guidelines
COMMODITIES:		Formulation
REVIEWER:		Chris Jiang
ORGANIZATION:		AD
APPROVER:		Karen P. Hicks
APPROVED DATE:		2/20/08
COMMENT:		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

February 20, 2008

MEMORANDUM

Subject: Review for 84368-R

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM 34\Lisa McKelvin
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies

Formulation from Label

Active Ingredient(s)	% by wt.
Ethyl alcohol	29.4 %
Other Ingredients	70.6 %
Total	100.0 %

BACKGROUND:

The registrant has submitted a label, a Confidential Statement of Formula (CSF) for the basic formulation, and MRIDs 47320201, 47320202, and 47320203 to fulfill the product chemistry guidelines for this integrated end-use product.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated 13/02/2008) is consistent with the label declaration.

2. All ingredients are cleared for use in pesticidal formulations.

3. The product identity and composition is **unacceptable** because this guideline was not addressed.

4. The description of the starting materials is **unacceptable** because the CSF states that supplier of the pH adjuster is one company; however, the MSDS states that the supplier is another company. In addition, The CSF states that the purity of the pH adjuster is 45%; but the MSDS states that the purity of the pH adjuster is 100%.

5. The description of the manufacturing\production\formulation process is **unacceptable** because this guideline was not addressed.

6. The discussion of the formation of impurities is **unacceptable** because this guideline was not addressed.

7. The preliminary analysis is **acceptable**.

8. All certified limits are **acceptable**.

9. The enforcement analytical method is **unacceptable** because this guideline was not addressed.

10. MRID 47320201 states that the study contains Part A of the product chemistry requirements; however, this study only contains MSDS's and the Confidential Statement of Formula for the test substance.

11. The color, physical state, and odor are **unacceptable** because the test was not conducted under GLP compliance. The product is a clear colorless liquid with a mildly alcoholic odor.

12. The density is **unacceptable** as the test was not conducted under GLP compliance. The density was found to be 7.93 lbs/gal (0.95 g/mL).

13. The pH is **unacceptable** as the CSF states that the pH is 10; however, the study

states that the pH is 8.0. The study for pH was also not conducted under GLP compliance.

14. The oxidation/reduction potential is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

15. The flammability is **unacceptable** as this study was not conducted under GLP compliance. The flash point of the test substance was determined to be 84 ^{o}F.

16. The explodability is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

17. The storage stability is **unacceptable** because this guideline was not addressed. This study must be submitted under GLP compliance as confirmatory efficacy data was submitted with the application. The storage stability study is often conducted in conjunction with the study for corrosion charactereristics.

18. The viscosity is **unacceptable** as the study was not done under GLP compliance. The viscosity was determined to be 6.0 cps.

19. The miscibility is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

20. The corrosion characteristics are **unacceptable**. This guideline was not addressed. This study must be submitted under GLP compliance. The study for corrosion characteristics is often conducted in conjunction with the study for storage stability.

21. The dielectric breakdown voltage is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

22. The stability (guideline 830.6313), melting point (guideline 830.7200), and boiling point (guideline 830.7220) are not required for this product.

23. The label must read, "*Combustible.* Do not use or store near heat or open flame" if the flash point of the test substance was determined to be 84 ^{o}F.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the submission for 84368-R to be unacceptable for the reasons indicated in the findings. The registrant must remedy the issues discussed in the findings for registration to proceed.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 5, 2008

OPP Decision Number: D-379192

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject: Late Fix/Data Submission
Product Name: DETOX
EPA File Symbol: 84368-R
Application Date: 10-May-2007
EPA Receipt Date: 14-May-2007

Dear Ms. Messerschmidt:

Our records indicate that the new decision review period for the Agency to make a determination regarding the above referenced application ends on March 19, 2008 as pursuant to the Pesticide Registration Improvement Act (PRIA). The Agency accepted your request dated September 17, 2007 for a negotiated PRIA due date of ***March 19, 2008.*** This revised due date was based upon your time needed to submit the "fix" and the Agency time needed to in-process and review the correction. It was our understanding that the "fix" would be submitted on or before ***November 10, 2007.*** However, the Agency did not receive your "fix/data" until ***January 14, 2008*** which is two months after the agreed upon date. Therefore, to meet the deadline for making a determination on the application under FIFRA Section 33, an additional two months (60-days) will be required for the Agency to make a determination on this application. Because the deadline for the agency to make a determination on this application expires on March 19, 2008, you have the following option:

You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the new data that was received on January 14, 2008. If you choose this option, you need to contact the Agency not later than ***February 14, 2008*** to discuss a time frame that allows the Agency to review the new data to make a regulatory decision or request an additional two months (60-days) from the date of the expiration of your negotiated PRIA due date of March 19, 2008.

Note that this is your second extension. The Agency normally ask registrants to include the worst-case scenario in their negotiated time frames in the event that the arguments do not change the outcome of the original reviews or additional information is needed so as to allow time to do whatever data/information might be needed. Please consider this as well since negotiations are generally limited to two per application.

Please respond to this letter by February 14, 2008 by contacting me by telephone at (703) 308-6422 or by e-mail at *heyward.adam@epamail.epa.gov* during the hours of 8:00 am to 4:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch I
Antimicrobials Division (7510P)

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

January 24, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MANDALA TECHNOLOGIES
30777 NORTHWESTERN HWY, SUITE 330
FARMINGTON HILLS, MI 48334-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 14-JAN-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

OMC Ag Consulting

473202-00

January 8, 2008

Mr. Adam Heyward
Herbicide Product Manager (PM-34)
Regulatory Branch II
Document Processing Desk (REGFEE)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: **Additional Information for New Pesticide Registration**
DETOX™ (Active Ingredient: Ethyl Alcohol 29.4%)
EPA File Symbol: 84368 – R
OPP Decision Number: D-379192

Dear Mr. Heyward:

On September 6, 2007, you sent Mandala Technologies the results of the EPA reviewers regarding our application to register the end use product (EP), DETOX. This letter and occupying data are in response to the several deficiencies cited in your letter.

In response to your letter, enclosed are one copy of Volume 1 and three copies of the others:

1. **Volume 1 of 6** – Administrative:
   - A copy of this cover letter
   - Application for Pesticide Registration (EPA Form 8570-1)
   - Corrected Page 5 of 9 under OPPTS 830.1550 of Volume 2 of 4 submitted May 1, 2007
   - Your letter dated September 6, 2007 on OPP Decision Number D-379192
   - Five (5) copies of revised proposed labeling

47320201 2. **Volume 2 of 6**: Product Chemistry – CSF and MSDS sheets
47320202 3. **Volume 3 of 6:** Product Chemistry – 5 batch analysis
47320203 4. **Volume 4 of 6:** Physical and Chemical Properties Tests – Series B
47320204 5. **Volume 5 of 6:** Eye irritation potential study
47320205 6. **Volume 6 of 6:** Efficacy study Detox on *T. mentagrophytes* (AOAC Test 955.17)

The revised DETOX label ahs been revised towards the consumer. The appropriate precautionary statements for a Toxicity Category II eye irritation potential have been added. If you have any questions, please don't hesitate to contact me directly at 517-881-0106.

Sincerely,

Olav Messerschmidt

Olav Messerschmidt
OMC Ag Consulting

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[XX] **Registration**
[ ] **Amendment**
[ ] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
Mandala Technologies LLC/ 84368-R

2. EPA Product Manager
Adam Heyward

3. Proposed Classification
[X] None [ ] Restricted

4. Company/Product (Name)
Mandala Technologies LLC/ DETOX

PM#
32

5. Name and Address of Applicant *(Include ZIP Code)*
Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

[ ] *Check if this is a new address*

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.
[X] Resubmission in response to Agency letter dated September 6, 2007
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

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

Submitting cited deficiencies: revised label, CSF, product chemistry, eye irritation study, efficacy data

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes	[ ] Yes	[ ] Yes	[ ] Metal
[XX] No	[XX] No	[XX] No	[XXX] Plastic
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____

3. Location of Net Contents Information
[X] Label [ ] Container

4. Size(s) Retail Container
24 oz, 1 Qt, 1, 5 and 55 Gallons

5. Location of Label Directions
[ ]

6. Manner in Which Label is Affixed to Product
[XXX] Lithograph
[ ] Paper glued
[ ] Stenciled
[ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olav Messerschmidt	Registration Agent	

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature: Olav Messerschmidt
3. Title: Registration Agent
4. Typed Name: Olav Messerschmidt
5. Date: January 8, 2008

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

White - EPA File Copy (original) Yellow - Applicant Copy

DETOX™

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

Controls fungi, molds and fungal spores on most surfaces (icon)
For Mold Remediation (in box)

- Contains no ammonia, bleach, or acid
- Suitable for use on most surfaces
- kills mold and fungi
- Eliminates musty odors
- Colorless
- Mold Control
- Mildew stains remover
- 100% killing of household and residential mold and their spores
- 100% killing [elimination] of disease causing household and residential mold and their spores.
- Kills [eliminates] [destroys] tough mold
- Attacks mold at its roots
- Gets into and completely destroys [eliminates] common household molds

ACTIVE INGREDIENT
Ethyl alcohol.....29.4%
OTHER INGREDIENTS.....70.6%
TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN
WARNING

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

Net Contents 24 oz.
1 quart
1 gallon
5 gallon
55 gallon

EPA Reg. No. 84368 – R

EPA Est. No. 84368 - R-XX

Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

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

- DETOX 's patented technology kills [destroys] mold and fungal spores within 5 minutes.
- DETOX's patented technology completely destroys [100% killing] of disease causing household and residential mold and their spores within 5 minutes.
- Detox penetrates to kill and completely destroy disease causing household and residential mold at its roots.
- Detox penetrates to remove mildew stains at its source
- Detox completely kills [destroys] mold in hard to clean places (tile grout, caulking and corners) without scrubbing.
- Detox completely destroys [100% killing] of disease causing household and residential mold by just spraying; no scrubbing is required.
- For use on most indoor and outdoor surfaces.

- Kills mold in places vulnerable to mold and hard to clean places including:
    - Basements
    - Bathrooms
    - Vacation homes
    - Boat interiors
    - Areas under construction

- For use in homes, businesses or institutions.

- Contains no bleach, ammonia and acid

- Colorless

- No fumes

- Fungicide

- [Porous and Nonporous Surfaces] Fungicide

- Effective against [fungi][mold]

[Controls] [Eliminates] [kills] [fungi][mold]

- Deodorizer

- DETOX is [specially formulated] [a unique technology] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold and mildew
- Controls mold [leaving a fresh clean scent] [leaving rooms clean and fresh smelling].

- Eliminates musty odors [caused by mold].

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear such as goggles or safety glasses. Wash thoroughly with water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted con detalle. (If you do not understand the label, find someone to explain it to you in detail.)	
If on Clothing:	• Take off and wash contaminated clothing.
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes. Then continue rinsing eye. • Call a poison control center or doctor for treatment advice
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	

Combustible. Do not use or store near hear or open flame.

DETOX liquid formula kills and eliminates mold and fungal spores within 5 minutes. When it dries on surfaces, it leaves a thin shield that eliminates the spread of mold and fungal spores by encapsulating them. DETOX contains no bleach, ammonia, and is suitable for use on most surfaces to eliminate musty odor.

Use DETOX 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
- Pre-treatment of building materials for killing any potential mold spores.

DIRECTIONS FOR USE

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

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

DETOX is used to treat wood, carpets, papers, wallboard, concrete and masonry (cinder) block building materials to kill or prevent the growth of mold organisms when the

materials are subjected to moist or wet environments. Before applying this product, conditions favorable to mold growth must be identified and corrected.

MILDEW STAINS REMOVAL

To remove mildew stains: apply Detox to the problem areas, wipe with a wet sponge or cloth, and rinse. Heavy mildew buildup may require two cleanings.

REMEDIAL TREATMENT

TO COMPLETELY DESTROY AND ELIMINATE (100% KILLLING) OF COMMON HOUSEHOLD MOLDS on glazed ceramic tiles, grout, cements, shower doors, vinyl curtains, countertops, windowsills, refrigerator seals and under the sink: apply Detox on the surface until thoroughly wet, let it stand for 5 minutes and wipe with wet sponge or cloth if is cosmetically necessary .

Areas of visible growth can normally be remediated without elaborate procedures. When these areas are identified, apply DETOX onto the surface and allow to penetrate to completely kill and eliminate the spread of fungal spores and other contaminates 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 DETOX 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 DETOX on cleaned area until evenly wet and let it stand for 5 minutes.
3. Allow treated surfaces to dry completely.
4. Wipe with wet sponge or cloth if cosmetically necessary.

DETOX 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 DETOX. Over-application may in some cases result in residue formation, which can easily be wiped away with a water-dampened cloth.

DETOX 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]. Reapplication of DETOX may be required if surfaces are washed or painted or are otherwise directly exposed to water.

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

REAPPLICATION

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

STORAGE and DISPOSAL

Storage: Store in a cool, dry place inaccessible to children and pets.
Pesticide Disposal: If empty: Do not reuse this container. Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

NOTICE ON CONDITIONS OF SALE

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DETOX™ is a trademark of Mandala Technologies, LLC

DETOX™

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

Controls fungi, molds and fungal spores on most surfaces (icon)
For Mold Remediation (in box)

- Contains no ammonia, bleach, or acid
- Suitable for use on most surfaces
- kills mold and fungi
- Eliminates musty odors
- Colorless
- Mold Control
- Mildew stains remover
- 100% killing of household and residential mold and their spores
- 100% killing [elimination] of disease causing household and residential mold and their spores.
- Kills [eliminates] [destroys] tough mold
- Attacks mold at its roots
- Gets into and completely destroys [eliminates] common household molds

ACTIVE INGREDIENT
Ethyl alcohol.....29.4%
OTHER INGREDIENTS.....70.6%
TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN
WARNING

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

Net Contents 24 oz.
1 quart
1 gallon
5 gallon
55 gallon

EPA Reg. No. 84368 – R

EPA Est. No. 84368 - R-XX

Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

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

- DETOX 's patented technology kills [destroys] mold and fungal spores within 5 minutes.
- DETOX's patented technology completely destroys [100% killing] of disease causing household and residential mold and their spores within 5 minutes.
- Detox penetrates to kill and completely destroy disease causing household and residential mold at its roots.
- Detox penetrates to remove mildew stains at its source
- Detox completely kills [destroys] mold in hard to clean places (tile grout, caulking and corners) without scrubbing.
- Detox completely destroys [100% killing] of disease causing household and residential mold by just spraying; no scrubbing is required.
- For use on most indoor and outdoor surfaces.

- Kills mold in places vulnerable to mold and hard to clean places including:
  - Basements
  - Bathrooms
  - Vacation homes
  - Boat interiors
  - Areas under construction

- For use in homes, businesses or institutions.

- Contains no bleach, ammonia and acid

- Colorless

- No fumes

- Fungicide

- [Porous and Nonporous Surfaces] Fungicide

- Effective against [fungi][mold]

[Controls] [Eliminates] [kills] [fungi][mold]

- Deodorizer

- DETOX is [specially formulated] [a unique technology] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold and mildew
- Controls mold [leaving a fresh clean scent] [leaving rooms clean and fresh smelling].

- Eliminates musty odors [caused by mold].

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear such as goggles or safety glasses. Wash thoroughly with water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

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If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes. Then continue rinsing eye. • Call a poison control center or doctor for treatment advice
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	

Combustible. Do not use or store near hear or open flame.

DETOX liquid formula kills and eliminates mold and fungal spores within 5 minutes. When it dries on surfaces, it leaves a thin shield that eliminates the spread of mold and fungal spores by encapsulating them. DETOX contains no bleach, ammonia, and is suitable for use on most surfaces to eliminate musty odor.

Use DETOX 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
- Pre-treatment of building materials for killing any potential mold spores.

DIRECTIONS FOR USE

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

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REMEDIAL TREATMENT

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

REAPPLICATION

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STORAGE and DISPOSAL

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DETOX™

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

Controls fungi, molds and fungal spores on most surfaces (icon)
For Mold Remediation (in box)

- Contains no ammonia, bleach, or acid
- Suitable for use on most surfaces
- kills mold and fungi
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- Colorless
- Mold Control
- Mildew stains remover
- 100% killing of household and residential mold and their spores
- 100% killing [elimination] of disease causing household and residential mold and their spores.
- Kills [eliminates] [destroys] tough mold
- Attacks mold at its roots
- Gets into and completely destroys [eliminates] common household molds

ACTIVE INGREDIENT
Ethyl alcohol.....29.4%
OTHER INGREDIENTS.....70.6%
TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN
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Directions for Use must be read completely prior to using this product.

Net Contents 24 oz.
1 quart
1 gallon
5 gallon
55 gallon

EPA Reg. No. 84368 – R

EPA Est. No. 84368 - R-XX

Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

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

- DETOX 's patented technology kills [destroys] mold and fungal spores within 5 minutes.
- DETOX's patented technology completely destroys [100% killing] of disease causing household and residential mold and their spores within 5 minutes.
- Detox penetrates to kill and completely destroy disease causing household and residential mold at its roots.
- Detox penetrates to remove mildew stains at its source
- Detox completely kills [destroys] mold in hard to clean places (tile grout, caulking and corners) without scrubbing.
- Detox completely destroys [100% killing] of disease causing household and residential mold by just spraying; no scrubbing is required.
- For use on most indoor and outdoor surfaces.

- Kills mold in places vulnerable to mold and hard to clean places including:
  - Basements
  - Bathrooms
  - Vacation homes
  - Boat interiors
  - Areas under construction

- For use in homes, businesses or institutions.

- Contains no bleach, ammonia and acid

- Colorless

- No fumes

- Fungicide

- [Porous and Nonporous Surfaces] Fungicide

- Effective against [fungi][mold]

[Controls] [Eliminates] [kills] [fungi][mold]

- Deodorizer

- DETOX is [specially formulated] [a unique technology] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold and mildew
- Controls mold [leaving a fresh clean scent] [leaving rooms clean and fresh smelling].

- Eliminates musty odors [caused by mold].

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

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Have the product container or label with you when calling a poison control center or doctor or going for treatment.	

Flammable. Keep away from heat and open flame.

DETOX liquid formula kills and eliminates mold and fungal spores within 5 minutes. When it dries on surfaces, it leaves a thin shield that eliminates the spread of mold and fungal spores by encapsulating them. DETOX contains no bleach, ammonia, and is suitable for use on most surfaces to eliminate musty odor.

Use DETOX 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
- Pre-treatment of building materials for killing any potential mold spores.

DIRECTIONS FOR USE

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

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materials are subjected to moist or wet environments. Before applying this product, conditions favorable to mold growth must be identified and corrected.

MILDEW STAINS REMOVAL

To remove mildew stains: apply Detox to the problem areas, wipe with a wet sponge or cloth, and rinse. Heavy mildew buildup may require two cleanings.

REMEDIAL TREATMENT

TO COMPLETELY DESTROY AND ELIMINATE (100% KILLLING) OF COMMON HOUSEHOLD MOLDS on glazed ceramic tiles, grout, cements, shower doors, vinyl curtains, countertops, windowsills, refrigerator seals and under the sink: apply Detox on the surface until thoroughly wet, let it stand for 5 minutes and wipe with wet sponge or cloth if is cosmetically necessary .

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

REAPPLICATION

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

STORAGE and DISPOSAL

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DETOX™

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

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EPA Reg. No. 84368 – R

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Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
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- For use in homes, businesses or institutions.

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- Colorless

- No fumes

- Fungicide

- [Porous and Nonporous Surfaces] Fungicide

- Effective against [fungi][mold]

[Controls] [Eliminates] [kills] [fungi][mold]

- Deodorizer

- DETOX is [specially formulated] [a unique technology] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold and mildew
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IDEAL for:

- Mold remediation in homes, businesses and institutions
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Product Identity and Composition
Guideline Number 830.1550

Product Name:	DETOX™
Active Ingredient:	Ethyl alcohol
A.I. Label Claim:	29.4%
CAS No.:	64-17-5
OPP Chemical Code:	1501

Also refer to the Confidential Statement of Formula (CSF)
Page 2CA in Confidential Attachment

Description of Materials to Produce Product
Guideline Number 880.1600
Refer to the Confidential Statement of Formula (CSF) on Page 2CA
and also Page 3CA in Confidential Attachment

Description of the Formulation Process
Guideline Number 880.1650
Refer to Page 3CA in Confidential Attachment

Discussion of Formation of Impurities
Guideline Number 880.1670
Page 4CA in Confidential Attachment

Statement of Confidentiality Claims

No information claimed contained in this volume is claimed as confidential on the basis of its falling within the scope of FIFRA Section 10(d)(1)(A), (B) or (C).

Company: OMC Ag Consulting for Mandala Technologies LLC

Signature: Olav Messerschmidt

Company Agent: M. Olav Messerschmidt

Title: Registration Agent

Date: 1/8/08

Study Title
Administrative Volume

Company Name
Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

Product Identification
DETOX™
EPA File Symbol 84368 – R
[Ethyl Alcohol: 29.4%]

Data Requirement
Administrative Documents

Author
Olav Messerschmidt

Volume Number
1 of 6

Study Completion Date
January 8, 2008

Performing laboratory
OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823

Good Laboratory Practices Statement

This study was not conducted according to 40 CFR Part 160.

Submitter: OMC Ag Consulting for Mandala Technologies LLC

Signature: Olav Messerschmidt

Company Agent: M. Olav Messerschmidt

Title: Registration Agent

Date: 1/8/08

Sponsor: OMC Ag Consulting for Mandala Technologies LLC

Study Sponsor: M. Olav Messerschmidt

Signature: Olav Messerschmidt

Title: Registration Agent

Date: 1/8/08

Study Director: OMC Ag Consulting for Mandala Technologies LLC

Signature: Olav Messerschmidt

Company: Registration Agent

Date: 1/8/08

Table of Contents

Administrative Documents (Volume 1 of 6)

DETOX

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Application for Pesticide EPA Form 8570-1	7	1
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EPA Letter dated September 6, 2007 on OPP Decision Number D-379192	9	3
Revised Proposed Detox™ Label – 5 copies	25	4

"Olav" <omesserschmidt@comcast.net>
01/11/2008 09:16 AM

To Adam Heyward/DC/USEPA/US@EPA
cc Lisa Mckelvin/DC/USEPA/US@EPA
bcc
Subject EPA File no. 84368-R (DETOX)

Dear Mr. Heyward and Ms. McKelvin,

This email is to inform you that Mandala's response to your letter of September 6, 2007 was sent to you yesterday by courier. Included were revised labeling and CSF. Also included were product chemistry data report, MSDS on all ingredients, 5-batch analysis, an eye irritation study and efficacy data on *T. mentagrophytes*.

Olav Messerschmidt
****

Olav Messerschmidt
OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823
Tel: 1-517-881-0106
Fax: 1-517-336-9843
Email: omesserschmidt@comcast.net

"Olav"
<omesserschmidt@comcast.net>
12/06/2007 01:54 PM

To Adam Heyward/DC/USEPA/US@EPA
cc Lisa Mckelvin/DC/USEPA/US@EPA, Mark Hartman/DC/USEPA/US@EPA, <azizcawad@aol.com>
bcc
Subject RE: EPA File no. 84368-R (DETOX)

Dear Mr. Heyward,

Thank you for your note. I spoke with Mandala and we request an extension until the end of January 31, 2008. There were some problems with the efficacy tests and those studies are in the process being repeated. We understand that this extension is our second and last request.

Thank you for your patience and consideration of our request.

Olav Messerschmidt
****

Olav Messerschmidt
OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823
Tel: 1-517-881-0106
Fax: 1-517-336-9843
Email: omesserschmidt@comcast.net

-----Original Message-----
From: Heyward.Adam@epamail.epa.gov [mailto:Heyward.Adam@epamail.epa.gov]
Sent: Tuesday, December 04, 2007 6:59 AM
To: Olav
Cc: Mckelvin.Lisa@epamail.epa.gov; Hartman.Mark@epamail.epa.gov
Subject: RE: EPA File no. 84368-R (DETOX)

Dear Mr. Messerschmidt:

The Agency expected to receive the fix for the proposed PRIA application on or before November 10, 2007. Your email below indicated that because the lab conducting the efficacy studies have had some unexpected difficulties, you were not able to meet the November 10 deadline. The Agency will accept your email notification that you expect to submit the data at a later date. Since your submission has not been received by EPA on November 10, 2007, it is agreed that the Agency may add additional days to the negotiated date for each day the submission has not been received. Therefore, when submitting your fix, you must request an extension for each day that the fix/data have not been received by the Agency.

Please note that negotiations are generally limited to two per application. This would be considered your second negotiation. I normally ask registrants to include the worst-case scenario in their negotiated time frames in the event that the fix do not change the outcome of the original reviews so as to allow time to do whatever fix of the application might be needed. If you have any questions please let me know.

(Embedded image moved to file: pic01876.jpg)

"Olav"
<omesserschmidt@
comcast.net>

11/30/2007 04:24
PM

To
Lisa Mckelvin/DC/USEPA/US@EPA

cc
Adam Heyward/DC/USEPA/US@EPA,
Mark Hartman/DC/USEPA/US@EPA

Subject
RE: EPA File no. 84368-R (DETOX)

Dear Ms. McKelvin,

We certainly understand the Agency's position and in light of PRIA and Congressional oversight, it does not give you much flexibility. Nonetheless, we ask you to reconsider. The lab conducting the efficacy studies have had some unexpected difficulties but those have been resolved. The fungicidal efficacy studies are complete and the report will be available next week. As was explained in my November 15, 2007 email to you, all of the other gaps or studies are finished and ready for submission.

If the Do Not Grant letter is issued, within two weeks Mandala would be submitting another application. In order to save resources both at the Agency and Mandala, we respectfully ask for another extension through next week.

Thank you for your reconsideration. Please contact me if you have any questions.

Olav Messerschmidt
****
Olav Messerschmidt
OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823
Tel: 1-517-881-0106
Fax: 1-517-336-9843
Email: omesserschmidt@comcast.net

-----Original Message-----
From: Mckelvin.Lisa@epamail.epa.gov
[mailto:Mckelvin.Lisa@epamail.epa.gov]
Sent: Thursday, November 29, 2007 2:30 PM
To: omesserschmidt@comcast.net
Cc: heyward.adam@epa.gov; Hartman.Mark@epamail.epa.gov
Subject: EPA File no. 84368-R (DETOX)

Mr. Messerschmidt:

On November 15, 2007, we communicated via voicemail and email regarding the status of when you were going to submit your fix for the referenced product in this email. I recall you stating that your efficacy data was being worked on and that completion would take place soon. I have not heard back from you since then. Therefore, the Agency is in the process of issuing a Do Not Grant letter for your product Detox (84368-R). A letter dated September 24, 2007 was sent to you accepting your request for an extension to March 19, 2008. It was the Agency's understanding that your fix was going to be submitted on or before November 10, 2007.

See attached Agency letter dated September 6, 2007 regarding your options. Please refer to comment no. 2

(See attached file: 84368-R 75-Day letter for incomplete application.pdf)

(Embedded image moved to file: pic18074.jpg)

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A

PRODUCT REVIEWER: Lisa Mckelvin	RMB II TEAM 34
Description of Action:	EPA File Symbol/Reg No. 84368-R

Decision No. 379192	Submission No. 810284	Fee for Service Action Code: A54
FQPA Action Code:	Non-FQPA Action Code:	PRIA FEE AMOUNT:

	DAY	MONTH	YEAR
APPLICATION DATE	04	June	2007
EPA PIN DATE	04	June	2007
DATE PM RECEIVED FROM FRONT END	12	June	2007
DATE SENT TO SCIENCE [VIVIAN COMPLETES]			
DATE DUE FROM SCIENCE			2007
FQPA DUE DATE			

Type of Data:	✓ PSB Product Chemistry XXXX	PSB Acute Toxicology XXXX	PSB Efficacy XXXXX	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

Comments:

ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS

B	For Arctic Slope Contract Only	
	Contract No.: 0052	*ARCTIC SLOPE/MANAGER*
	Final Task: Signature _____	_____ (Total hrs)
C	Reviewer Comments:	

DATE FEE PAID:	RESPONSE CODE:	RESPONSE DATE:

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 24, 2007

OPP Decision Number: D-379192

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject: Incomplete Application for Registration
Product Name: DETOX
EPA File Symbol: 84368-R
Application Date: 10-May-2007
EPA Receipt Date: 14-May-2007

Dear Ms. Messerschmidt:

Our records indicate that the decision review period for the Agency to make a determination regarding the above referenced application ends on October 2, 2007 as pursuant to the Pesticide Registration Improvement Act (PRIA). The Agency has reviewed your application and determined, pursuant to 40 CFR 152.105, it not to be sufficient to complete the registration process; therefore, the application is considered incomplete. As such, you have 75 days from the date of this letter to make the required corrections to the application or the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. Any subsequent submission relating to the application must be submitted as a new PRIA application.

The Agency has accepted your request, dated September 17, 2007, for a negotiated PRIA due date of ***March 19, 2008.*** This revised due date is based upon your time needed to submit the "fix" and the Agency time needed to in-process and review the correction. It is our understanding that the "fix" will be submitted on or before ***November 10, 2007.*** If your "fix" is reviewed and found to be deficient, and the application remains incomplete, after 75 days the Agency will terminate any action on the application pursuant to 40 CFR 152.105 and will treat the application as if it has been withdrawn by the applicant.

If the "fix" is not received on or before November 10, 2007, then the Agency may issue a not grant determination prior to 75 days from the date of this letter. Because this determination is not a denial under section 3(c)(6) of FIFRA, you may request that EPA issue a formal denial under procedures outlined in section 3(c)(6) of FIFRA and 40 CFR § 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing.

If you have questions concerning this letter, please contact me by telephone 703-308-6422 or by e-mail at heyward.adam@epa.gov.

Sincerely,

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

Recommendation of Division Directors
Negotiated Due Dates

Decision#: D-379192	**Registration#: 84368-R**	**Petition #: N/A**
Fee Category: A54	**PRIA Decision Time Frame: 4 Months**	
Submitted by: Adam Heyward	**Branch: RMBII**	**Date: 18-Sep-2007**
Company: OMC Ag Consulting for MANDALA Technologies		
Original Due Date: 04-Oct-2007	**Proposed New Due Date: 19-Mar-2008**	
Previous Negotiated Due Dates: None		
Is the "Fix" in-house? No	**If not, date "Fix" expected: 10-Nov-2007**	

Issue (describe in detail):

Product Chemistry, efficacy and Acute Toxicity data deficiencies.

Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D)
Product Chemistry: X Acute Tox: X Efficacy: X Labeling: ____ Other (describe): ____

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

OMC Ag Consulting, the Agent for MANDALA Technologies was contacted, via 75-days deficiency letter on September 6, and again by email on September 12, and 17, 2007. Company responded by requesting a 130 days time extension and agreed to submit the fix by November 20, 2007.

"75 Day" Letter sent? YES (Date sent): 09/06/07: ____No and reason for none?

Rationale for Proposed Due Date:

To allow the company time to submit the fix and the Agency sufficient time to review the new data and provide a regulatory decision.

Registrant notified that this is the last negotiation? _Yes: Not Applicable, first extension request.

Approve: ✓	**Disapprove:**

If disapproved, action to be taken:

OD or DOD Signature: Matt Manull	**Date:** 9-19-07

OMC Ag Consulting

September 17, 2007

Mr. Adam Heyward (PM-34)
Regulatory Branch II
Document Processing Desk (REGFEE)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: **Deficiency Response**
DETOX™ (Active Ingredient: Ethyl Alcohol 29.4%)
EPA File Symbol: 84368 – R
OPP Decision Number: D-379192

This letter is in response to your letter dated September 6, 2007 (received September 10 via your email), regarding deficiencies in the subject application. All requested data will be submitted to the Agency within 75 days of that September 6 letter. We expect to submitted all requested data on or before November 10, 2007; all studies are either completed or in progress.

Since the Agency did not accept the *S. charterum* data that were included with the initial application because the Agency does not have an acceptable protocol for *S. charterum,* we will in a separate letter request a formal protocol review. In this regard, the proposed use of *S. charterum* will be removed from the proposed label upon submission of the additional data.

Regarding the new PRIA due date, 130 days from November 10 is March 19, 2008. We suggest that March 19, 2008 is the new PRIA due date.

If you have any questions, please don't hesitate to contact me directly at 517-881-0106 (email: omesserschmidt@comcast.net).

Sincerely,

Olav Messerschmidt

M. Olav Messerschmidt
Registration Agent
OMC Ag Consulting

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

Recommendation of Division Directors
Negotiated Due Dates

Decision#: D-379192	**Registration#: 84368-R**	**Petition #: N/A**
Fee Category: A54	**PRIA Decision Time Frame: 4 Months**	
Submitted by: Adam Heyward	**Branch: RMBII**	**Date: 18-Sep-2007**
Company: OMC Ag Consulting for MANDALA Technologies		
Original Due Date: 04-Oct-2007	**Proposed New Due Date: 19-Mar-2008**	
Previous Negotiated Due Dates: None		
Is the "Fix" in-house? No	**If not, date "Fix" expected: 10-Nov-2007**	

Issue (describe in detail):

Product Chemistry, efficacy and Acute Toxicity data deficiencies.

Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D)
Product Chemistry: X Acute Tox: X Efficacy: X Labeling: ____ Other (describe): ____

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

OMC Ag Consulting, the Agent for MANDALA Technologies was contacted, via 75-days deficiency letter on September 6, and again by email on September 12, and 17, 2007. Company responded by requesting a 130 days time extension and agreed to submit the fix by November 20, 2007.

"75 Day" Letter sent? YES (Date sent): 09/06/07: ____No and reason for none?

Rationale for Proposed Due Date:

To allow the company time to submit the fix and the Agency sufficient time to review the new data and provide a regulatory decision.

Registrant notified that this is the last negotiation? _Yes: Not Applicable, first extension request.

Approve: ✓	**Disapprove:**

If disapproved, action to be taken:

OD or DOD Signature:	**Date:** 9-19-07

OMC Ag Consulting

September 17, 2007

Mr. Adam Heyward (PM-34)
Regulatory Branch II
Document Processing Desk (REGFEE)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: **Deficiency Response**
DETOX™ (Active Ingredient: Ethyl Alcohol 29.4%)
EPA File Symbol: 84368 – R
OPP Decision Number: D-379192

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Since the Agency did not accept the *S. charterum* data that were included with the initial application because the Agency does not have an acceptable protocol for *S. charterum,* we will in a separate letter request a formal protocol review. In this regard, the proposed use of *S. charterum* will be removed from the proposed label upon submission of the additional data.

Regarding the new PRIA due date, 130 days from November 10 is March 19, 2008. We suggest that March 19, 2008 is the new PRIA due date.

If you have any questions, please don't hesitate to contact me directly at 517-881-0106 (email: omesserschmidt@comcast.net).

Sincerely,

Olav Messerschmidt

M. Olav Messerschmidt
Registration Agent
OMC Ag Consulting

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

"Olav"
<omesserschmidt@comcast.net>
09/11/2007 10:20 AM

To Adam Heyward/DC/USEPA/US@EPA
cc <AzizCAwad@aol.com>, Lisa Mckelvin/DC/USEPA/US@EPA, Mark Hartman/DC/USEPA/US@EPA
bcc
Subject RE: Agency letter for incomplete application and science reviews: for product 84368-R DETOX

Dear Mr. Heyward,

This is in response to yesterday's email.

As you mentioned, "*at present, no method for assessing the product efficacy against S. chartarum (black mold) on porous surfaces has been accepted. The data submitted were created under a novel protocol, which has not been approved* ." In a separate letter, we will request a formal protocol review to evaluate DETOX on porous surfaces.

However, can we assume since this comment is directed towards porous surfaces, with the necessary efficacy data we could label *S. chartarum* on hard surfaces? In this regard, we have asked the contract lab (ATS Labs) to include *S. chartarum* in its AOAC Fungicidal test. Your earliest response to this proposal would be appreciated.

In response to your comments on the additional data needed for the registration of DETOX, all studies are either in progress or have already been completed. Specifically,

- **5 Batch Analysis:** the GLP report study for the 5-batch analysis has been completed. All other deficiencies in regards to product chemistry can also be addressed.
- **Eye Irritation Study:** this study will be initiated early next week and a report is expected by mid-October.
- **AOAC Fungicidal Test:** the preliminary tests on contact time have been completed and the actual studies will be initiated soon. A report is expected by late October or early November. This will be the limiting item. However, the report is expected close the 75 day limit.

If this is acceptable, could you give us some guidance on how we should proceed? Thank you in advance for your help.

Olav Messerschmidt

****

Olav Messerschmidt
OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823
Tel: 1-517-881-0106
Fax: 1-517-336-9843
Email: omesserschmidt@comcast.net

```
-----Original Message-----
From: Heyward.Adam@epamail.epa.gov [mailto:Heyward.Adam@epamail.epa.gov]
Sent: Monday, September 10, 2007 10:33 AM
To: Olav
Cc: AzizCAwad@aol.com; Mckelvin.Lisa@epamail.epa.gov;
Hartman.Mark@epamail.epa.gov
Subject: RE: Agency letter for incomplete application and science reviews: for
```

product 84368-R DETOX

Dear Mr. Messerschmidt:

As pointed out in the Agency's letter of 9/6/09 {efficacy memo dated 8/23/07}, comment # 4, "at present, no method for assessing the product efficacy against S. chartarum (black mold) on porous surfaces has been accepted. The data submitted were created under a novel protocol, which has not been approved."

It goes on to say that if you wishes to do a formal protocol review submission, you may do so, or you have the option of waiting until a protocol for S. chartarum has been approved and conduct data under the newly approved protocol. Until such time, you may revise your labeling to indicate that the proposed product can be used to clean surfaces with black mold, but you would need to make these cleaning directions separate and distinct from any mold/mildewcidal or fungicidal directions/claims.

Note that when submitting your schedule for responding to the deficiencies and request for a negotiated PRIA due date, you must include in your schedule, the time it will take you find labs, plus the time it will take the labs to conduct the studies (under GLP) and format the data in accordance with PR Notice 86-5, the time you expect to submit the data/fix to the EPA, plus an additional 120-days for the EPA to review your new data/fix and render a regulatory decision.

(Embedded image moved to file: pic06617.jpg)

"Olav"
<omesserschmidt
@comcast.net>

09/06/2007
04:18 PM

To
Lisa Mckelvin/DC/USEPA/US@EPA

cc
Adam Heyward/DC/USEPA/US@EPA,
<AzizCAwad@aol.com>

Subject
RE: Agency letter for incomplete application and science reviews: for product 84368-R DETOX

Thank you for copies of all technical reviews. I have spoken with Mandala about the Product Chemistry and Efficacy data reviews. The 5-batch analyses have been completed and a draft report has been issued. The other points raised in the Chemistry review can be easily remedied.

The AOAC Fungicidal Test has been initiated and by tomorrow we expect to learn when the report will be available.

Regarding the Toxicology review, we will have to contact a lab to see how quickly an eye irritation study can be conducted; we should have an answer in a couple of days.

I expect to contact you by this coming Monday.

Olav
****
Olav Messerschmidt
OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823
Tel: 1-517-881-0106
Fax: 1-517-336-9843
Email: omesserschmidt@comcast.net

-----Original Message-----
From: Mckelvin.Lisa@epamail.epa.gov
[mailto:Mckelvin.Lisa@epamail.epa.gov]
Sent: Thursday, September 06, 2007 2:50 PM
To: omesserschmidt@comcast.net
Cc: heyward.adam@epa.gov
Subject: Agency letter for incomplete application and science reviews: for product 84368-R DETOX

Mr. Messerschmidt, see attachment regarding Agency letter and science reviews for product DETOX 84368-R. Adam Heyward will contact you within the next couple of days to discuss.

(See attached file: 84368-R letter and science reviews.pdf)

(Embedded image moved to file: pic27200.jpg)

Adam Heyward/DC/USEPA/US
09/10/2007 09:39 AM

To "Olav" <omesserschmidt@comcast.net>
cc AzizCAwad@aol.com, Lisa Mckelvin/DC/USEPA/US@EPA, Mark Hartman/DC/USEPA/US,
bcc
Subject RE: Agency letter for incomplete application and science reviews: for product 84368-R DETOX

Dear Mr. Messerschmidt:

As pointed out in the Agency's letter of 9/6/09 {efficacy memo dated 8/23/07}, comment # 4, *"at present, no method for assessing the product efficacy against S. chartarum (black mold) on porous surfaces has been accepted. The data submitted were created under a novel protocol, which has not been approved."*

It goes on to say that if you wishes to do a formal protocol review submission, you may do so, or you have the option of waiting until a protocol for *S. chartarum* has been approved and conduct data under the newly approved protocol. Until such time, you may revise your labeling to indicate that the proposed product can be used to clean surfaces with black mold, but you would need to make these cleaning directions separate and distinct from any mold/mildewcidal or fungicidal directions/claims.

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

"Olav" <omesserschmidt@comcast.net>

"Olav" <omesserschmidt@comcast.net>
09/06/2007 04:18 PM

To Lisa Mckelvin/DC/USEPA/US@EPA
cc Adam Heyward/DC/USEPA/US@EPA, <AzizCAwad@aol.com>
Subject RE: Agency letter for incomplete application and science reviews: for product 84368-R DETOX

Thank you for copies of all technical reviews. I have spoken with Mandala about the Product Chemistry

and Efficacy data reviews. The 5-batch analyses have been completed and a draft report has been issued. The other points raised in the Chemistry review can be easily remedied.

The AOAC Fungicidal Test has been initiated and by tomorrow we expect to learn when the report will be available.

Regarding the Toxicology review, we will have to contact a lab to see how quickly an eye irritation study can be conducted; we should have an answer in a couple of days.

I expect to contact you by this coming Monday.

Olav
****

Olav Messerschmidt
OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823
Tel: 1-517-881-0106
Fax: 1-517-336-9843
Email: omesserschmidt@comcast.net

-----Original Message-----
From: Mckelvin.Lisa@epamail.epa.gov [mailto:Mckelvin.Lisa@epamail.epa.gov]
Sent: Thursday, September 06, 2007 2:50 PM
To: omesserschmidt@comcast.net
Cc: heyward.adam@epa.gov
Subject: Agency letter for incomplete application and science reviews: for product 84368-R DETOX

Mr. Messerschmidt, see attachment regarding Agency letter and science reviews for product DETOX 84368-R. Adam Heyward will contact you within the next couple of days to discuss.

(See attached file: 84368-R letter and science reviews.pdf)

(Embedded image moved to file: pic27200.jpg)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 6, 2007

OPP Decision Number: D-379192

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject: Incomplete Application for Registration
Product Name: DETOX
EPA File Symbol: 84368-R
Application Date: 10-May-2007
EPA Receipt Date: 14-May-2007

Dear Mr. Messerschmidt:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on October 2, 2007 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. Information as specified below must be submitted before the processing of the application can be completed. If such deficiencies cannot be corrected within 75 days from the date of this letter, you must notify the Agency by September 12, 2007. Include an explanation of why it will take longer to submit the requested information, including your schedule to respond to the deficiencies and a request for a negotiated PRIA due date.

If, after 75 days from the date of this letter, you do not respond, or you subsequently fail to submit a completed application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. This action would result in your submission being removed from the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and PRIA. Any subsequent re-submission relating to the application must be submitted as a new PRIA application and subject to a fee.

The following data must be submitted:

Efficacy Data Review:

The submitted data (MRID 471297-03) do not support the use of the product, DETOX, as a fungicide against *Stachybotrys chartarum* spores at full strength at room temperature with an unspecified contact time.

1. The proposed label claims that the product, DETOX, is an effective mildewcide against *Stachybotrys chartarum* (black mold) at full strength with an unspecified contact time on hard, nonporous surfaces. These claims are **not acceptable**.

   The Agency does not allow claims for limited mold/mildewcides (against one organism other than *Aspergillus niger*). Furthermore, you must follow the Use-Dilution Mildew Fungicidal Test Method (§ 93-30(I) Item 6) in a GLP certified laboratory to attain claims as a mold/mildewcide as well as hard surface efficacy against *S. chartarum.*

   In addition, if the above mentioned efficacy testing is performed you will need to include a clear contact time on the product label.

2. The proposed label also claims that the product is fungicidal. This claim is **not acceptable** and would need to be supported by data against *Trichophyton mentagrophytes* to remain on the label.

3. The proposed label claims that the product will inhibit the growth of mold and fungi. This claim is **not acceptable**. In order to attain mold inhibition claims, you will need to perform the Hard Surface Mildew Fungistatic Test method (§ 93-30(I) Item 2).

4. The proposed label claims that the product may be used to "treat" mold (*S. chartarum*) on porous materials. These claims are **not acceptable**. At present, no method for assessing the product efficacy against black mold on porous surfaces has been accepted. The data submitted were created under a novel protocol, which has not been approved.

   If you wish to do a formal protocol review submission, you may do so. You also have the option of waiting until a protocol for *S. chartarum* has been approved and conducting data under the newly approved protocol.

   You may indicate that the product can be used to clean surfaces with black mold, but you would need to make these cleaning directions separate and distinct from any mold/mildewcidal or fungicidal directions/claims.

Product Chemistry Data Review:

1. See attached Confidential CBI Appendix.

2. See attached Confidential CBI Appendix.

3. The self-certification option utilized is not accepted. The Office of Pesticide Programs (OPP) of the US EPA made the "self-certification" program available for certain product chemistry data of manufacturing-use products (MP) and end-use products (EP) that are produced by a non-integrated formulation system. Since this formulation utilizes a non-registered active ingredient it therefore is considered an integrated formulation system and therefore does not qualify for the "self-certification" program.

4. You failed to provide a Good Laboratory Practices (GLP) compliant five (5) batch analysis for the active ingredient, ethanol. Again, the product is produced by an integrated system since it contains an active ingredient made from non-registered sources.

5. The product identity and composition under OPPTS 830.1550 (page 5 of 9) was incorrectly identified as the manufacturing-use product (MP) Plasma Neem Oil containing the active ingredient azadirachtin at a 0.3% level.

6. You did not provide specifications and/or MSDS for the active ingredient ethanol and the potassium hydroxide aqueous solution as is required, particularly in new registrations.

Acute Toxicity Data Review:

The eye irritation data waiver request is unacceptable. It is not known what effect the surfactant or the pH of the product will have on acute eye effects (though corrosiveness is not expected).

The other five acute toxicity data requirements can be waived. However, skin irritation may be modestly affected by the presence of the surfactant and the pH adjustor, so the product is placed in Toxicity Category III for skin irritation.

Recommended acute toxicity profile:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	Waiver	IV	Waived
Acute Dermal Toxicity	request	IV	Waived
Acute Inhalation		IV	Waived
Primary Eye Irritation		?	Required
Primary Skin Irritation		III	Waived

Dermal Sensitization		Non-sensitizer	Waived

These deficiencies must be corrected before the Agency can proceed further with this application. Please include your proposed re-negotiated due date for this PRIA action along with an explanation as to how you will resolve the deficiencies by September 12, 2007.

You have the following two options.

1. Resolve the issue(s). You may resolve the issue(s) identified in this letter by submitting the information/data by September 12, 2007 or an explanation of why it will take longer to correct the deficiencies. Please include your proposed re-negotiated PRIA due date and the date you expect to submit the fix (new data) at this time. Your re-negotiated PRIA due date must include the date that you expect to submit the fix plus an additional 10 days for in-processing of new data and 90-days for Agency review. If no other issues arise as a result of your response to this letter, and the data is found to be acceptable, it is the Agency's expectation that resolution of the deficiencies will result in the granting of your application.

2. Do nothing. If you do not respond to this letter by September 12, 2007, or if you do not wish to re-negotiate the PRIA deadline, the Agency will issue a determination not to grant your application. A determination not to grant your application would remove your application from the provisions of PRIA. Subsequent re-submissions after 75 days from the date of this letter would require a new PRIA application and fee. Because this determination is not a denial under section 3(c) (6) of FIFRA, you may request that EPA issue a formal denial under procedures outlined in section 3(c) (6) of FIFRA and 40 CFR § 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing. If the request for a formal denial is not received 75 days from the date of this letter, the Agency will administratively withdraw the submission pursuant to 40 CFR 152.105.

If you have questions concerning this letter, please contact me by telephone 703-308-6422 or by e-mail at heyward.adam@epa.gov.

Sincerely,

Adam Heyward
Product Manager
Regulatory Branch
Antimicrobials Division (7510P)

Enclosure (Science Reviews)

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 11, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 84368-R
DP Barcode: D340584

To: Adam Heyward, PM 34/ Lisa McKelvin
Regulatory Management Branch I
Antimicrobials Division (7510C)

From: Wallace Powell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Mandala Technologies, LLC

ACTIVE INGREDIENT:	% by wt.
Ethanol	29.4

BACKGROUND

In support of product registration for DETOX, EPA File Symbol 84368-R, the applicant has requested data waivers for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, eye irritation, skin irritation, and skin sensitization. In each waiver rationale, the applicant refers to the very low acute effects of ethanol (as indicated in the public literature and the Agency's

Aliphatic Alcohols Reregistration Eligibility Decision [RED] document) and of the other formulation components that are present at significant concentration.

RECOMMENDATION

The eye irritation data waiver request is unacceptable. It is not known what effect the surfactant or the pH of the product will have on acute eye effects (though corrosiveness is not expected).

The other five acute toxicity data requirements can be waived. However, skin irritation may be modestly affected by the presence of the surfactant and the pH adjustor, so the product is placed in Toxicity Category III for skin irritation.

Recommended acute toxicity profile:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	Waiver request	IV	Waived
Acute Dermal Toxicity		IV	Waived
Acute Inhalation Toxicity		IV	Waived
Primary Eye Irritation		?	Required
Primary Skin Irritation		III	Waived
Dermal Sensitization		Non-sensitizer	Waived

Product labeling:

Based on the above acute toxicity profile and the Agency's *Label Review Manual*, the signal word (*CAUTION* or other, depending on eye irritation) is required on the front/main panel. The *Precautionary Statements* heading and the *Hazard to Humans and Domestic Animals* subheading are also required, followed by the statement: *Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.*

A First Aid section is required. (If it is not placed on the front/main panel, a referral statement such as "see side/back panel for first aid" should appear on the front panel in close proximity to the Signal Word.) The section should include this statement:

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

General information to include near the first aid statement:

> *Have the product container or label with you when calling a poison control center or doctor or going for treatment.*

Any further labeling comments regarding the human-hazard precautionary and first aid statements will be completed after the eye irritation data requirement is met.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 23, 2007

MEMORANDUM

Subject: Efficacy Review for Detox;
EPA Reg. No. 84368-R; DP Barcode: D340591

From: Marcie Tidd, Microbiologist Marcie Tidd 8/23/07
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510P) 8/28/07

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM 34 / Lisa McKelvin
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

Formulation from the Label:

Active Ingredient(s)	% by wt.
Ethyl alcohol	29.4%
Other Ingredients	70.6%
Total	100.0%

I. BACKGROUND

The product, Detox, is a new product which is intended for use as a fungicide solely against *Stachybotrys chartarum* (black mold). The applicant is submitting data conducted under an experimental protocol that was not previously submitted to the Agency for review. Testing was conducted the Food Science and Human Nutrition Laboratory in the Department of Microbiology and Molecular Genetics at Michigan State University, located at 234 G. Malcom Trout Building in East Lansing, Michigan.

The data package contained two letters from the applicant's representative to the Agency (dated May 10 and May 31, 2007), the Confidential Statement of Formula, the proposed label (dated May 31, 2007), and one study (MRID 471297-03) with Statements of No Data Confidentiality and Good Laboratory Practice (indicating that the data was not conducted under GLP conditions).

A copy of the novel study protocol used was later acquired from the applicant's representative at the Agency's request.

II. USE DIRECTIONS

The product is intended for use against *Stachybotrys chartarum* only and carries claims for the prevention, inhibition, and killing of mold in commercial, residential, and industrial buildings and facilities. The product claims that it will kill *S. chartarum* on hard, non-porous surfaces such as floors, tabletops, benchtops, drains, troughs, drip pans, desks, locker room benches and bath mats. The proposed label also mentions that the product will "treat" porous surfaces such as wood, tile grout, drywall, ceiling tile, carpets, upholstery cubical walls, wallpaper, posting boards in buildings and offices.

The label indicates that use of the product must be performed in conjunction with water damage remediation, source containment, and cleaning of fungal material. Use directions are separated into sections for small, medium, and large areas and further categorized by surface material: hard non-porous surfaces, wallboard, wood surfaces, carpet and textiles, and painted or sealed concrete/masonry/cinder block.

For hard, non-porous surfaces the proposed label lists the following use directions. After surfaces are thoroughly cleaned, apply DETOX by wiping, brushing, or pouring or by spraying using smooth back and forth motions to cover the entire target area to ensure complete coverage, nominally apply 15-40 ml of DETOX per square meter (0.5-1.4 fl oz. per square yard) and allow treated surfaces to air dry completely. For large areas, use of PPE, containment of affected materials, and testing before and after remediation are also listed. (No contact time was mentioned).

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Supplemental Efficacy- Disinfectant Use on Pathogenic Fungi

Effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 samples representing 2 different batches using the AOAC Fungicidal Test. Performance requirements for this test: the highest dilution that kills all fungal spores is the minimum effective concentration. Alternatively, the AOAC Use Dilution Method, modified to conform with appropriate elements in the AOAC Fungicidal Test, may be employed. If the product is intended for use as a spray, the AOAC Germicidal Spray Products Test must be employed. The inoculum in the above tests must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 samples representing 2 different batches must be employed in the test. Performance standard for this test: killing of the test microorganism on all carriers is required. These agency standards can be found in DIS/TSS-6.

Note: As an interim policy, the Agency is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes* and *Aspergillus niger*. The Agency recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until the Agency determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Hard Surface Mildew Fungistatic Test

This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 days of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth.

Efficacy against *Stachybotrys chartarum* on porous surfaces

Currently there is no accepted protocol for *S. chartarum* (black mold) on porous surfaces, such as wallboard, carpets, and building materials. At present, Antimicrobials Division scientists are working toward an acceptable protocol.

Supplemental Recommendations

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is

appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5 X 10^6 /ml) of conidia. These agency standards can be found in DIS/TSS-2.

IV. SUMMARY OF SUBMITTED STUDY

MRID 471297-03 "Efficacy of DETOX in the Remediation of Black Mold Contaminated Buildings" by James J. Pestka and Dr. Aziz Awad. Study conducted by Food Science and Human Nutrition, Microbiology & Molecular Genetics, Michigan State University. Study completed September 16, 2004.
This study was conducted under non-GLP conditions with an experimental protocol that had not been previously approved by the Agency. *Stachybotrys chartarum* spores (obtained from Sorenson, W.G., NIOSH, Morgantown, West Virginia) were used in testing against varying concentrations of acid and basic formulations of the product. Spore counts following exposure to the test suspensions were taken after 1 and 5 minutes of exposure by plating aliquots of the dilutions on PDA agar and incubating for 7 days. A yeast toxicity assay was also performed, although the study report indicated that results were inconclusive. Tests were also conducted using formulation FB(50%) on the following building materials: carpet, white printer paper, and ceiling tile cut into 2 inch squares. Squares were treated with the test solution along with bleach and water as controls. Results were reported in the form of optical density and visuals of the materials post-treatment. Although reductions in OD were seen, these are non-quantifiable and were not related back to spore counts.

V. RESULTS

Results of 60% FB, identified as the identical formula to DETOX in suspension testing.

MRID Number	Organism	Start Spore Count (CFU/10mL)	Results (CFU/10mL)	
			1 min	5 min
471297-03	*Stachybotrys chartarum* spores	$10^{5.8}$	0	0

Results were also presented for formulation FB(50%) (not identical to the product, DETOX) against *S. chartarum* spores on carpet, paper, and ceiling tile squares. Results were formatted as photographs and optical density of extraction cultures.

VI. CONCLUSIONS

1. The submitted data (MRID 471297-03) do not support the use of the product, DETOX, as a fungicide against *Stachybotrys chartarum* spores at full strength at room temperature with an unspecified contact time.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, DETOX, is an effective mildewcide against *Stachybotrys chartarum* (black mold) at full strength with an unspecified contact time on hard, nonporous surfaces. These claims are **not acceptable**.

   The Agency does not allow claims for limited mold/mildewcides (against one organism other than *Aspergillus niger*). Furthermore, the applicant must follow the Use-Dilution Mildew Fungicidal Test Method (§ 93-30(I) Item 6) in a GLP certified laboratory to attain claims as a mold/mildewcide as well as hard surface efficacy against *S. chartarum.*

   In addition, if the above mentioned efficacy testing is performed the applicant will need to include a clear contact time on the product label.

2. The proposed label also claims that the product is fungicidal. This claim is **not acceptable** and would need to be supported by data against *Trichophyton mentagrophytes* to remain on the label.

3. The proposed label claims that the product will inhibit the growth of mold and fungi. This claim is **not acceptable**. In order to attain mold inhibition claims, the applicant would need to perform the Hard Surface Mildew Fungistatic Test method (§ 93-30(I) Item 2).

4. The proposed label claims that the product may be used to "treat" mold (*S. chartarum*) on porous materials. These claims are **not acceptable**. At present, no method for assessing the product efficacy against black mold on porous surfaces has been accepted. The data submitted by the applicant were created under a novel protocol, which has not been approved.

   If the applicant wishes to do a formal protocol review submission, they may do so. They also have the option of waiting until a protocol for *S. chartarum* has been approved and conducting data under the newly approved protocol.

   The applicant may indicate that the product can be used to clean surfaces with black mold, but they would need to make these cleaning directions separate and distinct from any mold/mildewcidal or fungicidal directions/claims.

VI. CONCLUSIONS

1. The submitted data (MRID 471297-03) do not support the use of the product, DETOX, as a fungicide against *Stachybotrys chartarum* spores at full strength at room temperature with an unspecified contact time.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, DETOX, is an effective mildewcide against *Stachybotrys chartarum* (black mold) at full strength with an unspecified contact time on hard, nonporous surfaces. These claims are **not acceptable**.

   The Agency does not allow claims for limited mold/mildewcides (against one organism other than *Aspergillus niger*). Furthermore, the applicant must follow the Use-Dilution Mildew Fungicidal Test Method (§ 93-30(I) Item 6) in a GLP certified laboratory to attain claims as a mold/mildewcide.

   In addition, if the above mentioned efficacy testing is performed the applicant will need to include a clear contact time on the product label.

2. The proposed label also claims that the product is fungicidal. This claim is **not acceptable** and would need to be supported by data against *Trichophyton mentagrophytes* to remain on the label.

3. The proposed label claims that the product will inhibit the growth of mold and fungi. This claim is **not acceptable**. In order to attain mold inhibition claims, the applicant would need to perform the Hard Surface Mildew Fungistatic Test method (§ 93-30(I) Item 2).

4. The proposed label claims that the product may be used to "treat" mold (*S. chartarum*) on porous materials. These claims are **not acceptable**. At present, no method for assessing the product efficacy against black mold on porous surfaces has been accepted. The data submitted by the applicant were created under a novel protocol, which has not been approved.

   If the applicant wishes to do a formal protocol review submission, they may do so. They also have the option of waiting until a protocol for *S. chartarum* has been approved and conducting data under the newly approved protocol.

   The applicant may indicate that the product can be used to clean surfaces with black mold, but they would need to make these cleaning directions separate and distinct from any mold/mildewcidal or fungicidal directions/claims.

Lisa Mckelvin/DC/USEPA/US
08/01/2007 09:55 AM

To omesserschmidt@comcast.net
cc Adam Heyward,
bcc
Subject Product Chemistry Review for DETOX 84368-R

Mr. Messerschmidt:

Please see attached Product Chemistry Review for your product DETOX. The review is not acceptable. The Acute Tox and Efficacy reviews are still being reviewed and have not been completed yet. Please keep in mind the PRIA due date for this product is October 4, 2007.

84368-R DETOX Product Chem Review.pdf

Lisa

Lisa R. McKelvin
mckelvin.lisa@epa.gov
Environmental Protection Specialist
Voice: (703) 308-7496
Fax: (703) 308-6467

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

July 27, 2007

DP BARCODE: # 340573

MRID : # 471463-01

SUBJECT: Detox
(Name of Product)

REG. NO. OR FILE SYMBOL: 84368-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR **End-use Product [X]**

INGREDIENTS (PC Codes): 001501

CAS Number: 64-17-5

TEST LAB: OMC Ag Consulting

SUBMITTER: Mandala Technologies LLC

GUIDELINE: OPPTS Test Guidelines 830 Group A

COMMODITIES: not applicable

REVIEWER: Alex Traska **ORGANIZATION: AD**

APPROVER: Karen P. Hicks **APPROVED DATE:**

COMMENT: [illegible] for Karen P. Hicks
July 30, 2007

TO: **Adam Heyward**
PM Team # 34

FROM: Alex Traska, Chemist 7/27/07
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

APPLICANT:
Action code : A54 New Product, non-fast track
Due out date: 04 Oct 2007

Product Formulation

Active Ingredient(s):	**% by wt.**
Ethyl alcohol.....	**29.4**

BACKGROUND:

This application for a new product registration, covering the subject industrial mold, mildew and fungal control product used for mold/mildew/fungal remediation and prevention was made by OMC Ag Consulting on behalf of the registrant, Mandala Technologies LLC.

The registrant, in this new product application, has requested approval to register the new end-use product, **Detox**. The proposed new product is based on the use of the active ingredient, ethanol at a 29.4% level. Although this alcohol level is below the Agency's recommended minimum level of 30% ethanol per EPA'S 1994 RED stipulation, the registrant has offered efficacy data to support the proposed 29.4% ethanol usage level.

The following documents were submitted and examined in the chemistry review of this submission: agent's cover letter dated May 10, 2007, letter of resubmission covering incomplete application dated May 31, 2007, new product pesticide application dated May 1, 2007, proposed

Basic CSF dated 5/1/2007, product label (version 2) dated 5/31/2007, Certification with Respect to Citation of Data dated May 1, 2007, Data Matrices (Agency Use and Public File copies) dated 5/01/2007, Self-Certification for the Physical/Chemical Properties (PR Notice 98-1) dated May 1, 2007 and Summary of Physical and Chemical Properties dated May 1, 2007.

Also reviewed were OPPTS Product Chemistry Data for Test Guidelines 830 Group A under MRID # 471463-01 dated May 1, 2007.

FINDINGS:

1. See attached Confidential CBI Appendix.

2. See attached Confidential CBI Appendix.

3. The self-certification option utilized is not accepted. The Office of Pesticide Programs (OPP) of the US EPA made the "self-certification" program available for certain product chemistry data of manufacturing-use products (MP) and end-use products (EP) that are produced by a non-integrated formulation system. Since this formulation utilizes a non-registered active ingredient it therefore is considered an integrated formulation system and therefore does not qualify for the "self-certification" program.

4. The registrant failed to provide a Good Laboratory Practices (GLP) compliant five (5) batch analysis for the active ingredient, ethanol. Again, the product is produced by an integrated system since it contains an active ingredient made from non-registered sources.

5. The product identity and composition under OPPTS 830.1550 (page 5 of 9) was incorrectly identified as the manufacturing-use product (MP) Plasma Neem Oil containing the active ingredient azadirachtin at a 0.3% level.

6. Registrant did not provide specifications and/or MSDS for the active ingredient ethanol and the potassium hydroxide aqueous solution as is required, particularly in new registrations.

CONCLUSIONS:

This resubmission, in support of the new product registration covering the new end-use product for use as an industrial mold/mildew and fungal control product under the **Detox** registration, is not accepted.

Registrant must address all deficiencies noted above in the Findings.

Inert ingredient information may be entitled to confidential treatment

[redacted]

Fax Cover Sheet

May 23, 2007

Name:	**M. Olav Messerschmidt**
Organization:	**OMC Ag Consulting**
Fax:	**517.336.9843**
Phone:	**517.881.0106**
From:	**Lisa McKelvin/Adam Heyward**
Date:	**May 23, 2005**
	Subject: 86-5 Rejection of study
Pages:	~~1~~ 3

Comments:

Your application for product DETOX has been rejected due to 86-5 deficiency. Please submit corrected deficiency to further process application. If you have any questions, please contact me at mckelvin.lisa@epa.gov or via phone at 703.308.7496 or Adam Heyward at heyward.adam@epa.gov or via phone at 703.308.6422.

Sincerely,

Lisa McKelvin

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

TED STATES ENVIRONMENTAL PR TION AGENCY
WASHINGTON, D.C. 20460

June 6, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MANDALA TECHNOLOGIES
30777 NORTHWESTERN HWY, SUITE 330
FARMINGTON HILLS, MI 48334-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 04-JUN-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

OMC Ag Consulting

May 31, 2007

Mr. Adam Heyward
Herbicide Product Manager (PM-34)
Regulatory Branch II
Document Processing Desk (REGFEE – WAIVER - NEWCO)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: **Resubmission of Incomplete Application for New Pesticide Registration**
DETOX™ (Active Ingredient: Ethyl Alcohol 29.4%)
EPA File Symbol: 84368 – R
OPP Decision Number: D-379192

On behalf of its client, Mandala Technologies LLC (Mandala), OMC Ag Consulting is re-submitting an application to register the end use product (EP), DETOX, an anti-mold and anti-fungal product per your emails and letters on May 22 and May 29, 2007.

Per your email of May 29, the Detox label has been revised to read similar to the Clean Earth Technologies LLC Peridox™ label dated May 15, 2007, with the following key differences:

- Detox should not be diluted. Detox is a ready to use formulation.
- Detox kills mold immediately (<30 seconds) and thus does not require a long exposure period.
- Sine Detox's active ingredient is ethyl alcohol, the Peridox limitations on "*not for use in areas where food/feed are present*" has been removed.
- Detox is for *Stachybotrys chartarum* and other molds, not *Aspergillus.*
- A front label, storage and disposal instructions and warranty statements have also been added.

In support of the application, enclosed are three (3) copies of the following:

- **Volume 1 of 4** – Administrative:
  1. A letter from Mandala authorizing OMC Ag Consulting to be its Registration Agent
  2. Applications for Pesticide Registration (EPA Form 8570-1)
  3. Application for Registration of Pesticide-Producing Establishments (EPA Form 3540-8). This application is both for the EPA company Number and to register Mandala's Pesticide Producing Establishment.

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

4. Confidential Statement of Formula (EPA Form 8570-4) – in CBI Section
5. Certification with Respect to Citations of Data (EPA Form 8570-34)
6. Data Matrix (EPA Form 8570-35) – Agency internal use copy
7. Data Matrix (EPA Form 8570-35) – Public file copy
8. Summary of Physical and Chemical Properties (EPA Form 8570-36)
9. Self Certification of Physical/Chemistry Data (EPA Form 8570-37)
10. Voluntary Small Business Certification Form for Pesticide Registration Fee Waiver and supporting Tax Documents.
11. Five (5) copies of proposed labeling

- **Volume 2 of 4**: Product Chemistry - Series A
- **Volume 3 of 4:** Acute Toxicity Data Waiver Requests
- **Volume 4 of 4:** Efficacy Data

Since the initial application was not in compliance with PR Notice 86-5, we propose a re-negotiated PRIA due date of October 15, 2007. However, since we have had several pre-registration meetings and conversations with you, and, more importantly, in light of the limited data set and very low toxicity of the active and inert components, we hope that can be completed before the PRIA date.

If you have any questions, please don't hesitate to contact me directly at 517-881-0106 (email: omesserschmidt@comcast.net).

Sincerely,

M. Olav Messerschmidt
Registration Agent
OMC Ag Consulting

OMC Ag Consulting

471463-00

May 10, 2007

Mr. Adam Heyward
Herbicide Product Manager (PM-34)
Regulatory Branch II
Document Processing Desk (REGFEE – WAIVER - NEWCO)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: **Application for New Pesticide Registration**
DETOX (Active Ingredient: Ethyl Alcohol 29.4%)
EPA Registration No. XXXXX - R

On behalf of its client, Mandala Technologies LLC (Mandala), OMC Ag Consulting is submitting an application to register the end use product (EP), DETOX, an anti-mold and anti-fungal product. OMC Ag Consulting will act as the company's sole agent in this endeavor.

This product is Mandala's first pesticide label application. Subsequently, Mandala does not have an EPA Company Number.

In support of the application, enclosed are the following:

- **Volume 1 of 4** – Administrative:
  1. A letter from Mandala authorizing OMC Ag Consulting to be its Registration Agent
  2. Applications for Pesticide Registration (EPA Form 8570-1)
  3. Application for Registration of Pesticide-Producing Establishments (EPA Form 3540-8). This application is both for the EPA company Number and to register Mandala's Pesticide Producing Establishment.
  4. Confidential Statement of Formula (EPA Form 8570-4) – in CBI Section
  5. Certification with Respect to Citations of Data (EPA Form 8570-34)
  6. Data Matrix (EPA Form 8570-35) – Agency internal use copy
  7. Data Matrix (EPA Form 8570-35) – Public file copy
  8. Summary of Physical and Chemical Properties (EPA Form 8570-36)
  9. Self Certification of Physical/Chemistry Data (EPA Form 8570-37)
  10. Voluntary Small Business Certification Form for Pesticide Registration Fee Waiver and supporting Tax Documents.
  11. Five (5) copies of proposed labeling

47146301 • **Volume 2 of 4**: Product Chemistry - Series A
47129702 • **Volume 3 of 4**: Acute Toxicity Data Waiver Requests
47129703 • **Volume 4 of 4**: Efficacy Data

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

OMC Ag Consulting

May 10, 2007

Mr. Adam Heyward
Herbicide Product Manager (PM-34)
Regulatory Branch II
Document Processing Desk (REGFEE – WAIVER - NEWCO)
Antimicrobial Division (AD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency (US EPA)
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- **Volume 3 of 4:** Acute Toxicity Data Waiver Requests
- **Volume 4 of 4:** Efficacy Data

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

DETOX's active ingredient is ethyl alcohol at 29.4%, which is slightly below the minimum limit in EPA's 1994 Registration Eligibility Document (RED) which stipulated that a product's antimicrobial use of ethanol must contain a minimum of 30% ethanol. In other correspondence with the Antimicrobial Division, an unofficial limit of 40 to 50% ethanol is required. However, the Other Ingredients are not active ingredients either. We agree with the Agency that when ethanol alone is used at this concentration, it is not an effective antimicrobial agent. However, when combined with the other ingredients a synergistic effect is obtained and the resulting product, DETOX, has demonstrated to be a very effective anti-mold and anti-fungal agent. To support our case, efficacy data are included in Volume 4 of 4.

A Voluntary Small Business Certification Form for Pesticide Registration Fee Waiver is requested for this application. Mandala's federal tax forms and documentation to demonstrate that its annual income meet the requirements of the PRIA waiver are enclosed.

Because DETOX's ethanol concentration is less than other ethyl alcohol disinfectants, due to its similarity in label claims, we respectfully request that the Agency consider reviewing this application per PRIA charts, A53, a "New Product, Me-Too Fast Track." If not, "New Product, Non-Fast Track" may be an alternate category for this application.

If you have any questions, please don't hesitate to contact me directly at 517-881-0106 (email: omesserschmidt@comcast.net).

Sincerely,

M. Olav Messerschmidt

M. Olav Messerschmidt
Registration Agent
OMC Ag Consulting

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 29, 2007

OPP Decision Number: D-379192

M. Olav Messerschmidt
OMC Ag Consulting
Registration Agent for
Mandala Technologies LLC
30777 Northwestern Hills
Farmington, MI 48334
Parsippany, NJ 07054-0225

Subject: Incomplete Application for Registration
Product Name: DETOX
EPA File Symbol: 84368-R
Application Date: 10-May-2007
EPA Receipt Date: 14-May-2007

Dear Ms. Messerschmidt:

The Agency has reviewed the subject product application and concluded that the application is not sufficient to be process. The proposed product is rejected under PR Notice 86-5 and must be corrected before the review process can be initiated. Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on ***October 2, 2007*** as pursuant to the Pesticide Registration Improvement Act (PRIA). The Agency has reviewed your application and determined the action to be deficient for the reasons stated in the attached "Report of Analysis for Compliance with PR Notice 86-5" dated May 22, 2007. A copy of this report was faxed to you. These deficiencies must be corrected before the Agency can proceed further with this application.

You may resolve the issue(s) identified in the attached Report by submitting the information to fix the studies within 10 business days or an explanation of why it will take longer to correct the deficiency or deficiencies. **Please include your proposed re-negotiated PRIA due date at this time.** If no other issues arise as a result of your response to this letter, it is the Agency's expectation that resolution of the deficiencies will result in the granting of your application.

Once the corrections have been made, and the subject data passes the 86-5 screen, the Agency will be able to process your action further. Pursuant to 40 CFR § 152.105, you are hereby given 75 days in which to respond to these deficiencies.

If you do not respond to this letter, the Agency will administratively withdraw your application on August 13, 2007. Once the application is administratively withdrawn, you will need to submit a new application to the Agency and will be subject to a new PRIA fee.

If you have questions concerning this letter, please contact me by telephone 703-308-6422 or by e-mail at heyward.adam@epa.gov.

Sincerely,

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

Attachment: Report of Analysis for Compliance with PR Notice 86-5

Adam Heyward/DC/USEPA/US
05/29/2007 09:56 AM

To "Olav" <omesserschmidt@comcast.net>
cc Lisa Mckelvin/DC/USEPA/US@EPA, Norman Spurling/DC/USEPA/US@EPA, Teresa Downs/DC/USEPA/US@EPA
bcc
Subject RE: EPA File Symbol #84368-R. 86-5 Rejection for product DETOX

Dear Olav Messerschmidt:

The best method to handle this issue is to re-submit three (3) copies of the product chemistry data - Series A, study [01] to the Agency's front-end processing center along with your cover letter that was faxed to you and the "Report of Analysis for Compliance with PR Notice 86-5 letter. With respect to point two, i.e. "Confidential Data was not provided in Volume 2", call Teresa Downs at (703) 305-5363 or Norman Spurling at (703) 305-5835 for further clarification.

In addition, for mold control, the labeling must be revised to read similar/identical to the attached labeling texts.

scan.pdf

86-5 Rejection for product DETOX.pdf

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

"Olav" <omesserschmidt@comcast.net>

"Olav" <omesserschmidt@comcast.net>
05/24/2007 04:36 PM

To Lisa Mckelvin/DC/USEPA/US@EPA
cc Adam Heyward/DC/USEPA/US@EPA
Subject RE: 86-5 Rejection for product DETOX

Hello Lisa,

I just received your email.

Sorry, I didn't realize 3 copies were required. What is the best way to forward you the other two copies?

In point two, you said that the Confidential Data was not provided in Volume 2. Was the whole volume missing or page 6 (mentioned in point 3)? I am certain the dossier container the CBI section of Volume 2, but I could certainly send another copy. If so, what is the best way to submit that information?

Olav Messerschmidt

****

Olav Messerschmidt
OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823
Tel: 1-517-881-0106
Fax: 1-517-336-9843
Email: omesserschmidt@comcast.net

-----Original Message-----
From: Mckelvin.Lisa@epamail.epa.gov [mailto:Mckelvin.Lisa@epamail.epa.gov]
Sent: Thursday, May 24, 2007 3:22 PM
To: omesserschmidt@comcast.net
Cc: heyward.adam@epa.gov
Subject: 86-5 Rejection for product DETOX

Ms. Messerschmidt:

Please see attached a copy of the 86-5 rejection notice applied to your application. I have also faxed you the same information. If you have any questions, please contact me at 703.308.7496 or Adam Heyward at 703.308.6422.

thank you

(See attached file: 86-5 Rejection for product DETOX.pdf)

(Embedded image moved to file: pic09091.jpg)

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

May 22, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MANDALA TECHNOLOGIES
30777 NORTHWESTERN HWY, SUITE 330
FARMINGTON HILLS, MI 48334-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 14-MAY-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [01]:

* You provided fewer than the required three complete copies of submitted data.
* You failed to provide the Confidential Data in the Confidential attachment.
* This study is incomplete; data is missing from thefollowing page(s):____6____.

Please read instructions on reverse before [illegible]ing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[XX] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

284

Application for Pesticide - Section I

1. Company/Product Number 84368 - R Mandala Technologies LLC/ ~~XXXXX~~-R	2. EPA Product Manager Adam Heyward	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) Mandala Technologies LLC/ DETOX	PM# 34	
5. Name and Address of Applicant *(Include ZIP Code)* Mandala Technologies LLC 30777 Northwestern Hwy, Suite 300 Famington Hills, MI 48334 [ ] *Check if this is a new address*	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.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

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

New registration. First product and registration action for this company (i.e. no EPA company number), Fee waiver request.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Metal [XXX] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	24 oz, 1 Qt, 1, 5 and 55 Gallons	[ ]

6. Manner in Which Label is Affixed to Product [XXX] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Olav Messerschmidt	Registration Agent	

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature Olav Messerschmidt	3. Title Registration Agent	6. Date Application Received (Stamped)
4. Typed Name Olav Messerschmidt	5. Date May 1, 2007	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 5/1/2007	EPA Reg No./File Symbol XXXXX - R	Page 1 of 11
Applicant's/Registrant's Name & Address Mandala Technologies, LLC, 30777 Northwestern Highway - Suite 300, Farmington Hills, Michigan 48334	Product DETOX	
Ingredient Ethyl Alcohol 29.4%		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Identity and Composition					
Group A - Product Identity, Comp.					
830.1550	Product Identity and Composition		Mandala Technologies	OWN	
830.1600	Description of materials to produce product		Mandala Technologies	OWN	
830.1620	Description of production process				2
830.1650	Description of formulation process		Mandala Technologies	OWN	
830.1670	Discussion of formation of impurities		Mandala Technologies	OWN	
830.1700	Preliminary analysis		Mandala Technologies	OWN	
830.1750	Certified Limits		Mandala Technologies	OWN	
830.1800	Enforcement analytical method		Mandala Technologies	OWN	
Group B - Phys/Chem Properties					
830.6302	Color		Mandala Technologies	OWN	
830.6303	Physical state		Mandala Technologies	OWN	
830.6304	Odor		Mandala Technologies	OWN	
830.6313	Stability (sunlight, temperatures, metals, and ions_				2

Signature M. Olav Messerschmidt	Name and Title Olav Messerschmidt, Registration Agent	Date 05/01/2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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DATA MATRIX

Date 5/1/2007	EPA Reg No./File Symbol XXXXX - R	Page 2 of 11
Applicant's/Registrant's Name & Address Mandala Technologies, LLC, 30777 Northwestern Highway - Suite 300, Farmington Hills, Michigan 48334	Product DETOX	

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/redcution; chemical stability		Mandala Technologies	OWN	
830.6315	Flammability		Mandala Technologies	OWN	
830.6316	Explodability				2
830.6317	Storage Stability				2
830.6319	Miscibility		Mandala Technologies	OWN	
830.6320	Corrosion characteristics		Mandala Technologies	OWN	
830.6321	Dielectric breakdown voltage				5
830.7000	pH		Mandala Technologies	OWN	
830.7050	UV.visible absorption		Mandala Technologies	OWN	
830.7100	Viscosity		Mandala Technologies	OWN	
830.7200	Melting point			PL	9
830.7220	Boiling point			PL	9
830.7300	Density, bulk density, or specific gravity		Mandala Technologies		
830.7370	Dissociation constant			PL	9
830.7520	Particle size, fiber strength, diameter distribution				2

Signature M. Olav Messerschmidt	Name and Title Olav Messerschmidt, Registration Agent	Date 05/01/2007

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DATA MATRIX

Date 5/1/2007	EPA Reg No./File Symbol XXXXX - R	Page 3 of 11
Applicant's/Registrant's Name & Address Mandala Technologies, LLC, 30777 Northwestern Highway - Suite 300, Farmington Hills, Michigan 48334	Product DETOX	

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7550	Partition coefficient (n-Octanol/water) shake flask method				9
830.7560	Partition coefficient (n-Octanol/water) generator column				9
830.7570	Partition coefficient (n-Octanol/water) est. by liquid chroma				9
830.7840	Water solubility: column elution/shake				9
830.7860	Water solubility: generator column method				9
830.7950	Vapor pressure				9

Signature	Name and Title	Date
M. Olav Messerschmidt	Olav Messerschmidt, Registration Agent	05/01/2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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Applicant's/Registrant's Name & Address Mandala Technologies, LLC, 30777 Northwestern Highway - Suite 300, Farmington Hills, Michigan 48334	Product DETOX	

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Residue Chemistry Data					
171-2	Chemical Identity		Mandala Technologies	OWN	
171-3	Directions For Use		Mandala Technologies	OWN	
171-4	Nature of Residues - plants/livestock				2
171-4	Residue analytical method				2
171-4	Magnitude of the Residues				2
171-5	Reduction of Residues				2
171-6	Proposed Tolerances				2
171-7	Reasonable Grounds in Support of Tolerance				2
171-13	Submittal of Reference standards				2
Environmental Fate Data					
161-1	Hydrolysis			PL	9
161-2	Photodegradation - water			PL	9
161-3	Photodegradation - soil			PL	9
161-4	Photodegradation - air				2

Signature	Name and Title	Date
Olav Messerschmidt	Olav Messerschmidt, Registration Agent	05/01/2007

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Date 5/1/2007	EPA Reg No./File Symbol XXXXX - R	Page 5 of 11
Applicant's/Registrant's Name & Address Mandala Technologies, LLC, 30777 Northwestern Highway - Suite 300, Farmington Hills, Michigan 48334	Product DETOX	

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
162-1	Aerobic soil metabolism				2
162-3	Anaerobic aquatic metabolsim				2
162-4	Aerobic aquatic metabolism				2
163-1	Leaching/Adsorption				2
163-2 & 3	Volatility				2
164-1	Soil Dissipation				2
164-2	Aquatic Dissipation				2
164-3	Forestry Dissipation				2
164-5	Combination Studies				2
164-5	Soil, long-term				2
165-1 & 2	Accumulation Study - Rotational Crops				2
165-3	Accumulation Study - Irrigated Crops				2
165-4	Accumulation Study - in Fish				2
165-5	Accumulation Study - Aquatic Non-Target Organisms				2

Signature Olav Messerschmidt	Name and Title Olav Messerschmidt, Registration Agent	Date 05/01/2007

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 5/1/2007	EPA Reg No./File Symbol XXXXX - R	Page 6 of 11
Applicant's/Registrant's Name & Address Mandala Technologies, LLC, 30777 Northwestern Highway - Suite 300, Farmington Hills, Michigan 48334	Product DETOX	

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Toxicology Data					
81-1	Acute oral toxicity		Mandala Technologies	OWN	10
81-2	Acute dermal toxicity		Mandala Technologies	OWN	10
81-3	Acute inhalation toxicity		Mandala Technologies	OWN	10
81-4	Primary eye irritation		Mandala Technologies	OWN	10
81-5	Primary dermal irritation		Mandala Technologies	OWN	10
81-6	Dermal sensitization		Mandala Technologies	OWN	10
81-7	Acute delayed neurotoxicity			PL	9
82-1	90-day feeding			PL	9
82-2	21-day dermal			PL	9
82-3	90-day dermal				2
82-4	90-day inhalation			PL	9
82-5	90-day neurotoxicity: hen & mammal			PL	9
83-1	Chronic feeding: rodent and non-rodent			PL	9
83-2	Oncogencity: rat and mouse			PL	9

Signature Olav Messerschmidt	Name and Title Olav Messerschmidt, Registration Agent	Date 05/01/2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 5/1/2007	EPA Reg No./File Symbol XXXXX - R	Page 7 of 11
Applicant's/Registrant's Name & Address Mandala Technologies, LLC, 30777 Northwestern Highway - Suite 300, Farmington Hills, Michigan 48334	Product DETOX	

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-3	Teratogenicity: 2 species			PL	9
83-4	Reproduction, 2 generation			PL	9
Other genotoxic effects					
84-2	Gene mutation			PL	9
84-2	Sturctural chromosome aberration			PL	9
84-4	Other genotoxic effects			PL	9
Special testing	Proposed Tolerances				
85-1	General metabolism			PL	9
85-2	Dermal penetration			PL	9
86-1	Domestic animal safety			PL	9
Re-entry Data					
132-1	Foliar Dissipation				2
132-1	Soil Dissipation				2
133-3	Dermal exposure			PL	

Signature	Name and Title Olav Messerschmidt, Registration Agent	Date 05/01/2007

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 5/1/2007	EPA Reg No./File Symbol XXXXX - R	Page 7 of 11
Applicant's/Registrant's Name & Address Mandala Technologies, LLC, 30777 Northwestern Highway - Suite 300, Farmington Hills, Michigan 48334	Product DETOX	

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-3	Teratogenicity: 2 species			PL	9
83-4	Reproduction, 2 generation			PL	9
Other genotoxic effects					
84-2	Gene mutation			PL	9
84-2	Sturctural chromosome aberration			PL	9
84-4	Other genotoxic effects			PL	9
Special testing	Proposed Tolerances				
85-1	General metabolism			PL	9
85-2	Dermal penetration			PL	9
86-1	Domestic animal safety			PL	9
Re-entry Data					
132-1	Foliar Dissipation				2
132-1	Soil Dissipation				2
133-3	Dermal exposure			PL	

Signature Olav Messerschmidt	Name and Title Olav Messerschmidt, Registration Agent	Date 05/01/2007

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
133-4	Inhalation exposure				9
Spray Drift Data					
201-1	Droplet size spectrum				2
202-1	Drift field evaluation				2
Wildlife & Aquatic Organisms Data					
71-1	Avian Oral LD50				2
71-2	Avian Dietary OC50				2
71-3	Wild Mammal Toxicity				2
71-4	Avian Reproduction				2
71-6	Simulated field testing				2
72-1	Freshwater fish LC50				2
72-2	Acute LC50 aquatic invertebrate				2
72-3	Acute LC50 estuarine and marine				2
72-4	Fish early life stage				2
72-5	Fish life cycle				2

Signature M. Olav Messerschmidt	Name and Title Olav Messerschmidt, Registration Agent	Date 05/01/2007

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Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
72-6	Aquatic organism accumulation				2
72-7	Simulated or actual field testing - aquatic organisms				2
Plant Protection Data					
121-1	Target area phytotoxicity				2
122-1	Tier 1: seed germination				2
122-1	Tier 1: vegetative vigor				2
122-2	Tier 1: aquatic plant growth				2
123-1	Tier 2: seed germination				2
123-1	Tier 2: vegetative vigor				2
123-2	Tier 2: aquatic plant growth				2
124-1	Tier 3: terestrial field				2
124-2	Tier 3: aquatic field				2
Non-target Insect Data					
141-1	Honey bee LD50				2
141-2	Honey bee - toxicity of residues				2

Signature Olav Messerschmidt	Name and Title Olav Messerschmidt, Registration Agent	Date 05/01/2007

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122-1	Tier 1: vegetative vigor				2
122-2	Tier 1: aquatic plant growth				2
123-1	Tier 2: seed germination				2
123-1	Tier 2: vegetative vigor				2
123-2	Tier 2: aquatic plant growth				2
124-1	Tier 3: terestrial field				2
124-2	Tier 3: aquatic field				2
Non-target Insect Data					
141-1	Honey bee LD50				2
141-2	Honey bee - toxicity of residues				2

Signature	Name and Title Olav Messerschmidt, Registration Agent	Date 05/01/2007

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Date 5/1/2007	EPA Reg No./File Symbol XXXXX - R	Page 1 of 11
Applicant's/Registrant's Name & Address Mandala Technologies, LLC, 30777 Northwestern Highway - Suite 300, Farmington Hills, Michigan 48334	Product DETOX	

Ingredient Ethyl Alcohol 29.4%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
141-4	Honey bee - subacute feeding study				2
141-6	Field testing for pollinators				2
Efficacy of Anti-Microbial Agents					
91-2	Products for use on hard surfaces				2
91-3	Products requiring confirmatory data		Mandala Technogies	OWN	
91-4	Products for use on fabrics and textiles				2
91-5	All sanitizers				2
91-7	Products for control of microbial pests assoc. w/ wastes				2
91-8	Products for treating water systems				2

Signature Olav Messerschmidt	Name and Title Olav Messerschmidt, Registration Agent	Date 05/01/2007

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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DATA MATRIX

Date: May 1, 2007	**EPA Reg. No./File Symbol:** XXXXX-R	**Page 11 of 11**
Apllicant's Name and Address: Mandala Technologies, LLC 30777 Northwestern Highway - Suite 300 Farmington Hills, Michigan 48334	**Product:** DETOX	
Ingredient: Ethyl Alcohol 29.4%		

NOTES

1	Submitted upon Agency request.
2	N/A: these data are not applicable to this product or not required for TGAI/MUP
3	N/A: Not expected to affect performance, thus not required per PR Notice 92.5
4	N/A
5	Will be tested at a later date.
6	N/A: product to be applied only as aqueous solutions
7	N/A: Not intended or labeled for use in or around electrical equipment
8	N/A: Product is a liquid
9	Not a data gap per EPA March, 1995 Registration Eligibility Document (RED) on aliphatic alcohols (C1 - C5)
10	Waiver request submitted

Signature: M. Olav Messerschmidt	**Name and Title:** Olav Messerschmidt Registration Agent	**Date:** May 1, 2007

DETOX's active ingredient is ethyl alcohol at 29.4%, which is slightly below the minimum limit in EPA's 1994 Registration Eligibility Document (RED) which stipulated that a product's antimicrobial use of ethanol must contain a minimum of 30% ethanol. In other correspondence with the Antimicrobial Division, an unofficial limit of 40 to 50% ethanol is required. However, the Other Ingredients are not active ingredients either. We agree with the Agency that when ethanol alone is used at this concentration, it is not an effective antimicrobial agent. However, when combined with the other ingredients a synergistic effect is obtained and the resulting product, DETOX, has demonstrated to be a very effective anti-mold and anti-fungal agent. To support our case, efficacy data are included in Volume 4 of 4.

A Voluntary Small Business Certification Form for Pesticide Registration Fee Waiver is requested for this application. Mandala's federal tax forms and documentation to demonstrate that its annual income meet the requirements of the PRIA waiver are enclosed.

Because DETOX's ethanol concentration is less than other ethyl alcohol disinfectants, due to its similarity in label claims, we respectfully request that the Agency consider reviewing this application per PRIA charts, A53, a "New Product, Me-Too Fast Track." If not, "New Product, Non-Fast Track" may be an alternate category for this application.

If you have any questions, please don't hesitate to contact me directly at 517-881-0106 (email: omesserschmidt@comcast.net).

Sincerely,

M. Olav Messerschmidt

M. Olav Messerschmidt
Registration Agent
OMC Ag Consulting

Ph: 517-881-0106 ** Fax: 517-336-9843 ** email: omesserschmidt@comcast.net

Form Approved. OMB Nos. 2070-0060; 2070-0057; 2070-0107

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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SELF-CERTIFICATION STATEMENT FOR THE PHYSICAL/CHEMICAL PROPERTIES (PR NOTICE 98-1)

Product Name: DETOX

Reg. No./File Symbol No.
(if known) or Company No. XXXXX - R

SELF-CERTIFICATION STATEMENT:

I certify that the reported information on the "Summary Form" represents a true and accurate record of the test results of studies generated or owned by (Company Name): Mandala Technologies LLC and that the values of the properties reported are reliable. I further certify that such data were generated in substantial conformity with OPPTS Test Guideline Series 830 Product Properties, applicable to my product, and in effect at the time of submission.

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of section 12(a)(2)(N) of FIFRA without opportunity for hearing, if I have not submitted to EPA within thirty (30) days of receipt of a request by the Agency, or within a specified time agreed to by the Agency, test results of studies summarized in the "Summary Form."

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of sections 12(a)(2)(N), 12(a)(2)(Q), or 12(a)(2)(R) of FIFRA without opportunity for hearing, if I fail to provide to EPA within thirty (30) days of receipt of a notification of error, or within a specified time agreed to by the Agency, information that EPA determines is required to correct the error.

Type Applicant's Name: Olav Messerschmidt for Mandala Technologies LLC

Title: Registration Agent	Telephone No. 517-881-0106
Applicant's Signature: Olav Messerschmidt	Date: May 1, 2007

EPA Form 8570-37 (12-2003)

Attach-2

Print Form

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)

1. PRODUCT NAME: DETOX		**2. Reg. No.** XXXXX - R
3. COMPANY NAME: Mandala Technologies, LLC		**4. SUBMISSION DATE:** May 1, 2007
5. FIRST SUBMISSION ☒ **6. RESUBMISSION** ☐	**7. PESTICIDE TYPE:** Disinfectant	**10. REGISTRATION** [☒
8. FORMULATED MANUFACTURING-USE PRODUCT [☐ **or 9. END-USE PRODUCT** [☒		**11. REREGISTRATION** [☐
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN): Adam Heyward		**12. REREG CASE #**

14. GUIDELINE REFERENCE NO.(GRN)/TITLE		15. VALUE or QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES	16. MRID or REPORT NO.
Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)			
-6302	Color	Clear, colorless at 17C	
-6303	Physical State	Liquid at 17C	
-6304	Odor	Mild alcoholic odor at 17C	
-6314	Oxidation/Reduction: Chemical Incompatibility	Alcohol reacts with oxidizing agents	
-6315	Flammability/Flame Extension	84F	
-6316	Explodability	N/A	
-6317	Storage Stability	N/A - Ethyl alcohol is stable in water	
-6319	Miscibility	Water and alcohol	
-6320	Corrosion Characteristics	To be submitted after registration	
-6321	Dielectric Breakdown Voltage	N/A	
-7000	pH	1% W/W aqueous is 8.0 at 20C; Neat (100%) 10.0 at 20C	
-7100	Viscosity	#2 spindle @3 RPM off scale (too low) at 19C; @30 RPM, 6 cps	
-7300	Density/Relative Density/ Bulk Density	0.950 g/ml (=7.93 lb/gal) at 20C	

EPA Form 8570-36 (07/JAN/1998)

Statement of Confidentiality Claims

Information claimed confidential on the basis of its falling within the scope of FIFRA Section 10(d)(1)(A), (B) or (C) has been removed and is cited by cross reference number in the body of this volume.

Company: OMC Ag Consulting for Mandala Technologies LLC

Signature: M. Olav Messerschmidt

Company Agent: M. Olav Messerschmidt

Title: Registration Agent

Date: 5/10/07

Good Laboratory Practices Statement

This study was not conducted according to 40 CFR Part 160.

Submitter: OMC Ag Consulting for Mandala Technologies LLC

Signature: M. Olav Messerschmidt

Company Agent: M. Olav Messerschmidt

Title: Registration Agent

Date: 5/10/07

Sponsor: OMC Ag Consulting for Mandala Technologies LLC

Study Sponsor: M. Olav Messerschmidt

Signature: M. Olav Messerschmidt

Title: Registration Agent

Date: 5/10/07

Study Director: OMC Ag Consulting for Mandala Technologies LLC

Signature: M. Olav Messerschmidt

Company: Registration Agent

Date: 5/10/07

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DETOX

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EPA Form 8570-4, Confidential Statement of Formula (CSF)
is located in
Volume 1 of 4 CBI Attachment (Page 2CA)

Study Title

Acute Toxicity Data Waiver Requests

Company Name

Mandala Technologies LLC
30777 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334

Product Identification

DETOX™
EPA File Symbol XXXX – R_
[Ethyl Alcohol: 29.4%]

Data Requirement

Toxicology Data
OPPTS 81-1, 81-2. 81-3, 81-4, 81-5, 81-6

Author

Olav Messerschmidt

Volume Number

3 of 4

Study Completion Date

May 1, 2007

Performing laboratory

OMC Ag Consulting
828 Tanglewood Ln.
East Lansing, MI 48823

276-284 *Access to FIFRA Registration Data is restricted under FIFRA section 10(g)*

285-294 - *Inert ingredient information may be entitled to confidential treatment*