

62296-1

8-5-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 5, 2003

Christina Griffin
Agent for RBR Productions, IND.
C/o Delta Analytical Corp
7910 Woodmont Avenue, Suite 1000
Bethesda, MD 20814

Subject: **Let's Touch®**
EPA Registration No. 62296-1
Your Application Dated June 23, 2003

Dear Ms. Griffin:

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments.

Proposed Amendment:

- Response to PR Notice 2001-1

Label Comments:

1. The EPA establishment number must be listed on the label.
2. Revise the Storage and Disposal Statement to read as follows:

STORAGE AND DISPOSAL

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

Pesticide Storage: (Add storage text)

Pesticide Disposal: This germicide...pesticides.


Container Disposal: Triple rinse...for pesticide containers.

General Comment:

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

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

Sincerely,


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

Enclosure

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[Optional language] [LOOSEN CAP TO FILL RESERVOIR
DO NOT SQUEEZE BOTTLE WHILE POURING]

NO RUST !!!

ISABEL CRISTINA

LET'S TOUCH®

DOES NOT RUST
DOES NOT DULL

HOSPITAL AND TUBERCULOCIDAL METAL SALON DISINFECTANT

For Disinfection and Storage
of All Quality Metal
Instruments Used In Salons

Bactericidal Fungicidal Tuberculocidal
Virucidal Staphylocidal Pseudomonacidal

Active Ingredients:

o-Benzyl-p-chlorophenol 5.25%
o-Phenylphenol 0.99%

Other Ingredients 93.76%

Total 100.00%

ACCEPTED
with COMMENTS
EPA Letter Dated:

AUG - 5 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 62296-1

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID

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.

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 swallowed: Call a poison control center immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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 the Poison Center 1-800-222-1222 for emergency medical treatment information.

See side panel additional precautionary statements.

Net Contents: _____

ISABEL CRISTINA
THE PERFECT BLEND OF BEAUTY AND SCIENCE
Manufactured by: RBR Productions, Inc.
P.O. Box 3599, Teaneck, NJ 07666
800-247-4130 (outside NJ) 201-498-1044 (in NJ)

EPA Reg. No. 62296-1

EPA Est. No. _____

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LET'S TOUCH®

Let's Touch® is a hospital and tuberculocidal disinfectant concentrate especially formulated for the beauty care profession. It provides broad spectrum protection: bactericidal, fungicidal, virucidal, staphylocidal, pseudomonacidal, tuberculocidal, and prevents cross contamination from all metal salon instruments when used as directed. Use it to disinfect all precleaned metal salon instruments including manicurist nippers and cuticle pushers, shears, and metal skin care instruments. Let's Touch® does not rust or dull quality metal instruments, is pH buffered, and is biodegradable.

DIRECTIONS FOR USE

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

Before immersion in Let's Touch®, all instruments and devices must be thoroughly cleaned to remove excess dirt, rinsed and then rough dried. The removal of heavy soils and the cleaning of all surfaces prior to application of this product is required.

When using Let's Touch® for the first time, thoroughly clean and rinse trays and containers in order to remove any residues. Mixing Let's Touch® in a container which had another disinfectant in it can cause a brown gel like substance to form. If this happens, thoroughly clean and rinse all contaminated instruments, trays or containers and remix Let's Touch®.

Use one part Let's Touch® to 32 parts water for disinfection of precleaned metal instruments and equipment. Let's Touch® is distributed in concentrated form in Twin-Neck containers and in 1 oz. [packets] [bottles].

DIRECTIONS FOR MIXING WITH [PACKETS] [BOTTLES] AND TWIN-NECK CONTAINER

Water	1 Pint (16 oz.)	1 Quart (32 oz.)	½ Gallon (64 oz.)	1 Gallon (128 oz.)
Let's Touch®	½ fl. oz.	1 fl. oz. or 1 [packet] [bottle]	2 fl. oz. or 2 [packets] [bottles]	4 fl. oz. or 4 [packets] [bottles]

Always add 1 [packet] [bottle] or 1 oz. of Let's Touch® to every 32 fl. oz. of water. When using the Twin-Neck Container, squeeze the bottle until the easy-measure reservoir is filled to the desired amount.

DIRECTIONS FOR MIXING WITH THE MANICURIST AND HAIRSTLIST SYSTEMS

Manicurist System

1. Fill the tall plastic mixing jar to the 32 oz. fill line with water.
2. Add 1 oz. of Let's Touch® [1 packet][bottle]. Cap and mix by turning upside down a few times.
3. Pour the mixed solution into the glass manicurist jar to the suggested use level line.
4. Store the remaining solution until needed.

Hairstylist System

1. Remove the plunger mechanism.
2. Fill the glass jar to the 32 oz. fill line with water.
3. Add 1 oz. Let's Touch® [1 packet][bottle]. Mix solution by replacing plunger and moving it up and down.

Always leave instruments in Let's Touch® solution at all times and overnight for storage. Replace solution daily or earlier if cloudy or dirty.

FOR INSTRUMENT DISINFECTION - After cleaning instruments, place articles in Let's Touch® solution for 10 minutes. NOTE: Articles must be fully submerged in solution at all times.

FOR METAL INSTRUMENT STORAGE - A solution of one part Let's Touch® to 32 parts of water (see table above) does not rust or dull, and does not stain or otherwise attack metal instruments such as quality salon shears, manicurist and skin care implements. The solution may be used for prolonged (overnight) storage of all but non metal instruments, plastic or rubber items.

LET'S TOUCH® IS A COMPLETE PRODUCT. DO NOT MIX WITH OTHER CHEMICALS. Use only as directed. If frozen, thaw and remix before use.

Let's Touch® is recommended for use in salons, hospitals, dental offices or other facilities requiring disinfection of metal instruments.

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FOR HOSPITAL AND DENTAL OFFICE USE - Let's Touch® is a concentrated disinfectant to be used at a 1:32 dilution with water for cold decontamination/disinfection of pre-cleaned equipment. For disinfection, immerse instruments for 10 minutes.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced with the bloodstream or normal sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

The 1:32 dilution kills pathogenic bacteria and fungi such as *S. aureus*, *S. cholersuis*, *Ps. aeruginosa*, *M. tuberculosis* (effective in 10 minutes at 20° C), and *C. albicans*. Let's Touch® is virucidal against Influenza A2 (Hong Kong), Herpes Simplex 1 and 2, Adenovirus Type 2 and Vaccina on hard, inanimate surfaces in 10 minutes at 20° C.

A 1:32 dilution is effective against *M. tuberculosis* on hard, inanimate surfaces in 10 minutes at 20° C. Remove heavy soil or gross filth and thoroughly clean surfaces.

When tested by the EPA-approved Dilution Method, the HIV-1 (AIDS) virus was completely inactivated by a 1:32 solution in 10 minutes at 25° C.

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). Harmful if swallowed. Avoid prolonged skin contact. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

STORAGE AND DISPOSAL

Prohibitions: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

Pesticide Disposal: This germicide, its solutions or rinsing from empty containers should be disposed of in a toilet or service sink served by a sanitary sewer or in a landfill approved for pesticides.

Container Disposal: Triple rinse and deposit in a waste container for incineration or burial in a landfill approved for pesticide containers.

General: Consult federal, state and local disposal authorities for approved alternative procedures such as limited open burning.

KILLS HIV (AIDS virus) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV (AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Disposable latex or vinyl gloves, gowns, masks, and/or eye coverings as appropriate must be worn during all cleaning and decontamination procedures of blood and other body fluids.

Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before applying disinfectant.

Disinfectant Use and Contact Time: Effective against HIV-1 (AIDS virus) on hard non-porous surfaces/objects in the presence of organic soil (5% blood serum). Prepare disinfectant by mixing one part Let's Touch® to 32 parts water. Leave surfaces wet for 10 minutes.

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

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MANICURIST SYSTEM BOX LABEL – (Optional box language)

METAL TOOL DISINFECTANT
MANICURIST KIT

NO RUST !!!

ISABEL CRISTINA

LET'S TOUCH®

HOSPITAL AND TUBERCULOCIDAL METAL SALON DISINFECTANT

DOES NOT RUST

DOES NOT DULL

STORES QUALITY METAL INSTRUMENTS OVERNIGHT

Bactericidal Fungicidal Tuberculocidal
Virucidal Staphylocidal Pseudomonacidal

EPA Reg. No. 62296-1

EPA Est. No. _____

CONTENTS:

- One Full Immersion Glass Instrument Jar with Stainless Steel Lid, Basket and Plunger for Easy Placement and Removal of Instruments
- One 32 oz. Solution Preparation and Storage Container with Leak Proof Cap
- Four 1 ounce Let's Touch® Disinfectant [Packets][Bottles] Makes 4 Quarts
- Client Awareness Card

KEEP OUT OF REACH OF CHILDREN

WARNING

See enclosed [packets] [bottles] for additional precautionary statements.

Active Ingredients:

o-Benzyl-p-chlorophenol	5.25%
o-Phenylphenol	0.99%
Other Ingredients	93.76%
Total	100.00%

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STYLIST SYSTEM BOX LABEL – (Optional box language)

METAL TOOL DISINFECTANT
STYLIST KIT

NO RUST !!!

ISABEL CRISTINA

LET'S TOUCH®

HOSPITAL AND TUBERCULOCIDAL METAL SALON DISINFECTANT

DOES NOT RUST

DOES NOT DULL

STORES QUALITY METAL INSTRUMENTS OVERNIGHT

Bactericidal Fungicidal Tuberculocidal
Virucidal Staphylocidal Pseudomonacidal

EPA Reg. No. 62296-1

EPA Est. No. _____

CONTENTS:

- One 32 oz. Full Immersion Glass Instrument Jar with Stainless Steel Lid, Basket and Plunger for Easy Placement and Removal of Instruments
- Ten 1 ounce Let's Touch® disinfectant [packets] [bottles] Makes 10 Quarts
- Client Awareness Card and Window Decal

KEEP OUT OF REACH OF CHILDREN

WARNING

See enclosed [packets] [bottles] for additional precautionary statements.

Active Ingredients:

o-Benzyl-p-chlorophenol	5.25%
o-Phenylphenol	0.99%
Other Ingredients	93.76%
Total	100.00%

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BOX LABEL – (Optional box language)

DISINFECTANT REFILL [PACKETS] [BOTTLES]

NO RUST !!!

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See enclosed [packets] [bottles] for additional precautionary statements.

Active Ingredients:

o-Benzyl-p-chlorophenol	5.25%
o-Phenylphenol	0.99%
Other Ingredients	<u>93.76%</u>
Total	100.00%

CONTENTS: 12 - 1 Ounce [Packets] [Bottles] (29.5 ml)

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(Included in kits) SALON WINDOW DECAL FOR LET'S TOUCH® DISINFECTANT – (Optional language)

**THIS SALON DISINFECTS
QUALITY METAL INSTRUMENTS WITH
LET'S TOUCH®
DISINFECTANT**

ISABEL CRISTINA

the perfect blend of beauty and science

Hospital & Tuberculocidal Disinfection

In 10 Minutes

EPA Reg. No. 62296-1 EPA Est. No. _____

