

062296-00001-050699

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Systems Integration Group, Inc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 5-6-99 62296-1

PM 34

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MAY - 6 1999

Cristina Griffin RBR Productions, Inc. c/o Delta Analytical Corp. 7910 Woodmont Ave. Suite 1000 Bethesda, MD 20814

Dear Ms. Griffin:

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Subject: Notification of PR Notice 95-1 Minor Label Revision Let's Touch EPA Registration No. 62296-1 Amendment application of April 12, 1999

This will acknowledge receipt of your notification, minor labeling changes, submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the material, the following comment apply.

This application is acceptable and has been made a part of the records for this file.

If you have any question concerning this letter, please contact Portia Jenkins at (703) 308-6230.

Sincerely yours,

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

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DATE								
EPA Form 13	20-1A (1/90)	· · · · · · · · · · · · · · · · · · ·	.	• • • • • • • • • • • • • • • • • • •		•	OFFICI	AL FILE COPY

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SEPA	ore completing	United Environmental P	States rotection Agency n, DC 20460	☐ Regis ☐ Amen X Other	tration	OMB No. 2070-0060. OPP Identifier Number 245192
		Application for Pe	esticide - Section I	_		
Company/Product Number 6229	2. EPA Product Manager 3. Proposed		3. Proposed	d Classification		
4. Company/Product (Name) RBR P	Adam Heyward PM# 32		D None D Restricted			
5. Name and Address of Applicant (<i>Inclu</i> 3BR Productions, Inc. 20 Delta Analytical Corp. 7910 Woodmont Ave. Suite 1000 3ethesde MD 20814 Check if this is a new addre	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No					
		Secti	Product Name			
Amendment - Explain below Resubmission in response to Agency I K Notification - Explain below.	etter dated	<u> </u>	 Final printed labels in res "Me Too" Application. Other - explain below. 	ponse to Ageno	cy letter dated	
or the confidential statement of formu further understand that if this notifica may be subject to enforcement action	tion is not consi	stent with the terms of PR nder sections 12 and 14 of	Notice 98-10 and 40 CFR 15 FIFRA.	-	•	
·		Secti	on - III			
1. Material this Product will be Packaged in: Child-Resistant Packaging C Yes* No If "Yes,"			Water Soluble Packaging	□ Yes □ Metal □ No □ Plastic □ Glass		al tic Is
* Certification must be submitted.	Unit Package	e wgt. No. per container		per container	D Othe	ar (Specify)
Location of Net Contents Information 4. Size(s) of Retail Container Label Container			ner 5. Location of Label Direction □ On Label □ On Labeling accompanying product			
6. Manner In Which Label Is Affixed to P	roduct	□ Lithograph □ Paper glued □ Stenciled	[] Other			-
		Secti	on - IV	····		
1. Contact Point (Complete items direct)	y below for identi	lication of individual to be con	tacted, if necessary, to proces	s this applicatio	<u>n.)</u>	
Name			Title .		Telephone	No. (Include Area Code)
Cristina Griffin	<u> </u>		Agent for RBR Proc	ductions,	301-652	a e e g
I certify that the statements I have made of knowingly false or misleading stateme			ue, accurate and complete. I	acknowledge th	at any kind	େ ପରte Application Received
2. Signature			3. Title Agent for RBR Productions, Inc.			(Stamped)
Norman	_]]]			JUGUUUUS, IN		
4. Typed Name			5. Date			
Cristina Griffin			4/12/99			

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LOOSEN CAP TO FILL RESERVOIR DO NOT SQUEEZE BOTTLE WHILE POURING

ISABEL CRISTINA

LET'S TOUCH

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	<u>)3.76%</u>
TOTAL)0.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID

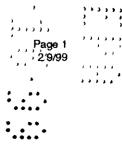
In case of eye contact, hold eyelids open and flush with a gentle stream of water for 15 minutes. Get prompt medical attention. For skin contact, flush with water. If swallowed drink large quantities of water. Do not induce vomiting. See back panel for additional precautionary statements and directions for use.

ISABEL CRISTINA THE PERFECT BLEND OF BEAUTY AND SCIENCE Manutactured by: RBR Productions, Inc. P.O. Box 3599, Teaneck, NJ 07666 800-247-4130 (outside NJ) 201-313-5700 (in NJ)

Net Contents:

EPA Reg. No. 62296-1

EPA Est. No. 8284-PA-1



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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.

Water	1 Pint (16 oz.)	1 Quart (32 oz.)	1/2 Gallon (64 oz.)	1 Gailon (128 oz.)
Let's Touch	1/2 fl. oz.	1 fl. oz. or	2 fl. oz. or	4 fl. oz. or
		1 packet	2 packets	4 packets

DIRECTIONS FOR MIXING WITH PACKETS AND TWIN-NECK CONTAINER

Always add 1 packet 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 HAIRSTYLIST 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). 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). Mix solution by replacing plunger and moving it up and down.

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

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FOR INSTRUMENT DISINFECTION - After cleaning instruments, place articles in Let's Touch solution for ten 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 of 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.

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 preciean 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.

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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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