

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

APR 1 7 2009

Ms. Kari Mavian Lonza inc. 90 Boroline Road Allendale, NJ 07401

Subject:

Bardac 205M-50

EPA Reg. No. 6836-193

Notification Date: March 18, 2009 EPA-Receipt Date: March 20, 2009

Dear Ms. Mavian,

The letter acknowledges receipt of the following notification submitted in connection with registration under the provisions of PR Notice 98-10 and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

Proposed Notification

Revising Label per PR-Notice 2007-4

General Comments

Based on a review of the material submitted, your notification to revise the label with the changes mentioned above is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

Please read instructions on reverse before completing form. Fo	orm Approved, OMB N	No. 2070-0060, Approval	expires 05-31-98	
United States		Registrat	ion	OPP Identifier Number
EPA Environmental Protection	on Agency	Amendm		
Washington, DC 204	• •		iont.	·
		◯ Other		
		esticide - Section 1		
1. Company/Product Number	 	roduct Manager		3. Proposed Classification
6836-193	Velma	Noble		
4. Company/Product (Name) Lonza Formulation RTU	PM# 31	•		None Restricted
5. Name and Address of Applicant (Include ZIP Code)		ited Review. In accordan	ce with FIFRA Section	on 3(c)(3)(b)(I), my product is similar
Lonza Inc.		ıl in composition and labe		
90 Boroline Road	l			
Allendale, NJ 07401	EPA R			
	Produc	t Name		. 1
Check if this is a new address				
	Section	on – II		
Amendment - Explain below.		Final printed labor	els in response to Age	ncy letter dated
Resubmission in response to Agency letter dated		."Me Too" Applic	ation	,
Notification - Explain below.		Other - Explain b	elow	
Explanation: Use additional page(s) if necessary	. (For Section I as	nd Section II.)		
Notification of label c	hange per PR N	Notice 2007-4 *No	ot Subject to Pl	RIA*
This notification is consistent with the provisions				
changes have been made to the labeling or the co				
18 U.S.C. Sec. 1001 to willfully make any false st				
terms of PR Notice 98-10 and 40 CFR 152.46, thi	is product may be	in violation of FIFR	4 and may be sub	ject to enforcement action
and penalties under Sections 12 and 14 of FIFMA			1	•
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Signature: AN M		Date:	2/10/01	
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Material This Product Will Be Packaged In: Child-Resistant Packaging Unit Packaging		Water Soluble Packa	oino	2. Type of Container
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\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \		No No		Plastic
*Certification must be If "Yes"	No. per	If "Yes"	No. per	\equiv
submitted Unit Packaging v	•	Package wgt.	container	Glass
Suprime				Paper
Location of Net Contents Information 4. Size	(s) Retail Container		5. Location of I	Other (Specify)
Label Container	(s) Retail Container		On Label	Label Directions
Container			1 =	g accompanying product
6. Manner in Which Label is Affixed to Product	Lithograph	Other	Oit labeling	g accompanying product
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	Section	on - IV)))))))))))))))))))
1. Contact Point (Complete items directly below for identification)	ation of individual to b	ne contacted, if necessary,	to process this of pli	action)
Name .	Title		0	Telephone No. (Include Area Code)
Kari Mavian	Associate 1	Director, Regulator	y Services	3 01-316-9438 - '
	tification		ر ارد ان د ر	6. Date Application Received
I certify that the statements I have made on this form and all a	tification	true accurate and comple		0. Date Approach Received
that any knowingly false or misleading statement may be pun				(Stamped)
2 Signature 3 Title				
Mul/Min	Associate	Director, Regulator	y Services	
4. Typed Name	5. Date			
Kari Mavian	March 18	2000		

Lonza

Via DHL

Ms. Velma Noble, PM-31
Document Processing Desk (NOTIFY)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Lonza Inc Allendale 90 Boroline Road Allendale, NJ 07401, USA

Kari Mavian Lonza Life Science Ingredients Commercial Regulatory Services

Tel 201-316-9438 Fax 201-696-3544 kari.mavian@lonza:com

March 18, 2009

SUBJECT: Lonza Formulation RTU, EPA Reg. No. 6836-193
Application for Notification per PR Notice 2007-4

Dear Ms. Noble:

Please find enclosed the following documents in support of this label notification to revise the storage and disposal language per PR Notice 2007-4. This is a Ready-To-Use product, thus some of the language on the previous approved label was not applicable.

- Application for Pesticide Notification
- One copy of the label with changes highlighted
- Two copies of the draft label

If you have any questions or need any additional information, please feel free to contact me at 201-316-9438.

Sincerely,

Lonza Inc. Jawan

Kari Mavian

Associate Director Commercial Regulatory Services

LONZA FORMULATION RTU

Disinfectant – Cleaner – Fungicide - Mildewstat- Virucide* - Deodorizer for Hospitals, Household, Institutional, Commercial and Industrial Use

Bactericidal against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis [in one minute]

> Virucidal against HIV-1 (the AIDS Virus), Influenza A / Hong Kong, and Herpes Simplex Type 2

[Citrus] [Floral] [Pine] [Fresh] [Mint] [Clean] [Lemon] [Scent] [Fragrance] [Odor]

KEEP OUT OF REACH OF CHILDREN CAUTION



See [back] [side] [right] [left] panel for Precautionary Statements and First Aid

EPA Reg. No. 6836-193
EPA Est. No. (<u>as indicated on container</u>.)
Net Contents (<u>as indicated on container</u>))

LONZA Inc. 90 Boroline Road Allendale, NJ 07401

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes eye and skin irritation. Do not get in eyes, on skin or clothing. Wash thoroughly with soap and water after handling.

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 eye. **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. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

(If container size is 5 gallons or larger, use the following Environmental Hazards statements:)

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

- Ready-to-Use
- Citrus Scent
- Fresh Mild Scent
- Cleaner
- Deodorizer
- Disinfectant.
- Cleans
- Disinfects
- Deodorizes
- Removes soap scum
- [Convenient] Ready To Use formula.
- [Economical] [Spray & Wipe] formula.
- Cuts [through] [tough] grease and grime.
- Kills [odor causing] Mold and Mildew
- Kills odor-causing bacteria.
- Inhibits [the growth of] [mold] [and] [mildew]
- Kitchen, Bathroom, Household Disinfectant Cleaner.
- For Kitchens Too!
- For Bathrooms Too!
- Leaves [your house with] a [clean] [fresh] scent.
- Trigger spray[er]
- Pump spray[er]
- Contains no phosphates.
- Cleans and deodorizes pet spills.
- Cleans rodent soiled areas.
- (for formulation without dye only): Dye Free
- (for sub-registrations that only sell to commercial establishments): For commercial use only
- Removes soap scum
- Scrub Free
- Bleach Free

Lonza Formulation RTU:

- delivers non-acid cleaning performance in an economical Ready-to-Use package.
- applies the proper strength for the job with no dilution required.
- [removes) [cleans) [ground-in) dirt, [tough) grease, grime, food stains, soap scum, fingerprints, [tough] soils, crayon / pencil marks and heel marks [in] (and around] [the house], [kitchen] [and bathroom].
- cuts [tough] grease and grime [without scrubbing].
- improves labor results by effectively controlling odors [for a long lasting clean].
- Leaves the [whole] house smelling [clean] [and] [fresh].
- leaves [kitchens], [bathrooms] and [households] clean [and smelling fresh].
- [cleans], [deodorizes] and [disinfects] most washable [household] surfaces.
- can be used on most washable surfaces. [Test a small area first.]
- cleans and deodorizes in one labor-saving step.
- cleans with a fresh scent.
- eliminates odors.
- will not leave grit or soap scum.
- is a versatile multi-purpose cleaner and broad spectrum disinfectant formulated for use in Ultrasonic Baths [Ultrasonic cleaning units].
- is a multi-purpose cleaner, disinfectant and deodorizer.
- is a hospital disinfectant offering broad spectrum disinfectant activity against a wide range of microorganisms.
- kills household germs.
- Is effective against Pseudomonas aeruginosa [Pseudomonas], Staphylococcus aureus [Staph] and *Influenza A/Hong Kong, while effectively controlling mildew.
- is a [Ready-to-Use] [Hospital] disinfectant cleaner
- is effective against a broad spectrum of bacteria, is virucidal* [including HIV-1, the AIDS Virus], fungicidal, and inhibits the growth of mildew and their odors when used as directed.
- kills germs
- helps prevent cross contamination on kitchen and household surfaces.
- helps prevent cross contamination on kitchen, bathroom, and other household surfaces.
- is formulated for use in daily maintenance programs with a balance of detergents, disinfectants, and malodor counteractants that deliver effective cleaning, disinfecting, and malodor control.

Use Lonza Formulation RTU:

- to clean and disinfect kitchen surfaces.
- to clean and disinfect bathroom surfaces.
- to clean and disinfect household surfaces.
- for non-scratch cleaning of showers and tubs, shower doors and vinyl shower curtains, fixtures, and toilet bowls.
- to clean and disinfect nonporous salon [barber] tools and instruments: combs, brushes, scissors, blades, and manicure instruments.
- Use in the kitchen, bathroom and nursery for a deep down clean.

Use Lonza Formulation RTU on diaper pails, plastic laundry hampers [baskets] and baby furniture [cribs, changing tables].

This odor destroyer is effective at neutralizing odors caused by mildew, pets, smoke, urine, cooking, vomit, garbage, restrooms, etc. This is not a masking agent

When used as directed, **Lonza Formulation RTU** will clean and deodorize surfaces in rest room and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.

Cross-contamination is of major housekeeping concern. **Lonza Formulation RTU** has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions, and industry.

(Note to reviewer. The following may be used only if the supplemental registrant has obtained a Kosher Certification.)



(Any Kosher Symbol such as:)

(Kosher)

Lonza Formulation RTU is a Hospital Disinfectant, Bactericidal according to the current AOAC Use-Dilution Test method and Virucidal* according to the virucidal qualification on inanimate surfaces.

Lonza Formulation RTU is effective as a disinfectant against:

(Bacteria):

Pseudomonas aeruginosa [Pseudomonas] (in one minute)

Staphylococcus aureus [Staph] (in one minute)

Salmonella choleraesuis [Salmonella] (in one minute)

(Viruses:)

*Herpes Simplex Type 2 [Herpes] (in 10 minutes)

*HIV-1 (AIDS Virus) (in 30 seconds)

*Influenza A/Hong Kong [Influenza] (in 60 seconds)

(Fungi:)

Trichophyton mentagrophytes [The Athlete's Foot Fungus] [A Cause of Ringworm] [in 10 minutes)

Lonza Formulation RTU is a sanitizer for hard, nonporous (kitchen, bathroom and household) non-food contact surfaces according to the method for Sanitizers - Non Food Contact Surfaces, modified in the presence of 5% organic serum, in 30 seconds by killing 99.9% of:

Enterobacter aerogenes

Enterococcus (Streptococcus) faecalis [Vancomycin-resistant] [VREF]

Escherichia coli [E. coli]

Escherichia coli 0157:H7 [pathogenic E. coli

Salmonella choleraesuis [Salmonella]

Staphylococcus aureus [Staph]

Streptococcus pyogenes [Strep]

(AREAS OF USE:)				
Use Lonza Formulation RTU in:				
Bathrooms	Athletic facilities			
Homes (households)	Barber shops			
Kitchens	Business and office buildings			
	Camp grounds			
Clinics	Colleges			
Dental offices	Correctional facilities			
Health Care Facilities	Dressing rooms			
Hospitals	Exercise facilities			
Medical Offices	Factories			
Medical Related Facilities	Hotels			
Nursing homes	Institutional facilities			
Sick Rooms	Institutions			
	Locker rooms			
Day care centers	Motels			
Nurseries	Playground Equipment			
	Prisons			
Bars	Public facilities			
Cafeterias	Public rest rooms			
Convenience stores	Schools			
Institutional kitchens	Shower and bath areas			
Restaurants	Salons (Beauty)			

(AREAS OF USE:) Use Formulation HWS-256 in:				
Airplanes	Mobile homes			
Airports	Railcars			
Ambulances	Taxis			
Boats	Trailers			
Buses	Trains			
Campers	Transportation terminals			
Cars	Trucks (Box Trucks)			
Emergency (Police) (EMS) (Fire) (Rescue) vehicles	Ships			

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oves (Stovetops)	Valkers Angel (1987)		
ables (picnic tables)	Vheel chairs		

(TYPES OF SURFACES:)	
Use Lonza Formulation RTU on washable hard, nonporous surfaces of:	-
Other hard nonporous surfaces made of:	-
Glazed ceramic	
Glazed enameled surfaces	
Glazed porcelain	
aminated Surfaces	
Metal	
Plastic (such as polystyrene or polypropylene)	
Sealed granite	
Sealed limestone	
Sealed marble	
Sealed slate	
Sealed stone	
Sealed terra cotta	
Sealed terrazzo	
Stainless steel	
Jpholstery, vinyl and plastic	

Woodwork, finished

PELIGRO:

Si no sable el inglés, solicite instrucciones a su supervisor antes de esto producto.

DIRECTIONS FOR USE

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

GENERAL CLEANING / DEODORIZING DIRECTIONS:

(Spray) (Apply to) soiled area then wipe clean. Repeat for heavily soiled areas.

DISINFECTION DIRECTIONS:

Preclean prior to disinfection. Apply **Lonza Formulation RTU** until surfaces are thoroughly wet. Treated surfaces must remain wet for 1 minute for disinfection against bacteria. Follow virucidal or Fungicidal directions when using as a virucidal or fungicidal agent. Wipe dry with a clean cloth, sponge, mop or [tissue] [wiper] or allow to air dry.

Food contact surfaces must be rinsed with potable water after disinfection. Do not use to disinfect utensils, glassware and dishes.

Change this product at least daily or when solution becomes visibly dirty.

(Note to reviewer: Alternate directions for products sold in spray bottles:)

DISINFECTION DIRECTIONS:

Preclean prior to disinfection. Spray 6 - 8 inches from surface, until surfaces are thoroughly wet. Do not breathe spray. Treated surfaces must remain wet for 1 minute for disinfection against bacteria. Follow virucidal or Fungicidal directions when using as a virucidal or fungicidal agent. Wipe dry with a clean cloth, sponge, mop or [tissue] [wiper] or allow to air dry.

Food contact surfaces must be rinsed with potable water after disinfection. Do not use on utensils, glassware and dishes.

VIRUCIDAL DIRECTIONS:

Follow disinfection directions for application instructions. Treated surfaces must remain wet for 10 minutes for Herpes Simplex Type 2 and 60 seconds [1 minute] for Influenza A / Hong Kong.

MOLD AND MILDEW CONTROL DIRECTIONS:

LONZA FORMULATION RTU effectively inhibits the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow disinfection instructions. Allow to air dry on surface. Repeat when mildew growth returns,

FUNGICIDAL DIRECTIONS:

LONZA FORMULATION RTU is an effective fungicide against Trichophyton mentagrophytes [the Athlete's Foot Fungus] [A Cause of Ringworm] in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, health clubs and spas. Follow disinfection directions for application instructions. Treated surfaces must remain wet for 10 minutes.

(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:)

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally 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.) or

This product is not for use on medical device surfaces.

NON-ACID TOILET BOWL AND URINAL DISINFECTANT / CLEANER DIRECTIONS:

Empty toilet bowl or urinal and apply Lonza Formulation RTU to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer. Repeat and allow to stand for 1 minute, then flush.

ULTRASONIC BATH DISINFECTANT / CLEANER DIRECTIONS:

Use Lonza Formulation RTU to clean and disinfect hard nonporous noncritical objects compatible with Ultrasonic cleaning units.

Pour Lonza Formulation RTU directly into bath chamber. Preclean soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to manufacturers use directions.

Remove objects and rinse with sterile water (sterile water for injection), or allow to air dry. Replace product daily or when liquid becomes visibly dirty or discolored.

SALON / BARBER INSTRUMENTS AND TOOLS DISINFECTION [/ VIRUCIDAL / FUNGICIDAL / BACTERICIDAL] DIRECTIONS:

Preclean soiled instruments and tools. Completely immerse water safe nonporous salon instruments and tools in Lonza Formulation RTU for 10 minutes. Rinse thoroughly and dry before use. Use fresh product daily or more often if product becomes cloudy or soiled.

NOTE: Plastics may remain immersed until ready to use. Stainless steel shears and metal instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

*KILLS HIV ON PRE-CLEANED 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-1 ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

PERSONAL PROTECTION: Clean-up must always be done wearing protective gloves, gowns, masks and eye protection.

CLEANING PROCEDURE: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of **Lonza Formulation RTU**.

CONTACT TIME: Leave surface wet for 30 seconds. Use a 1 minute contact time for disinfection against [Influenza A/Hong Kong [Influenza] and] bacteria and a 10 minute contact time against all other viruses and fungi claimed.

DISPOSAL OF INFECTIOUS MATERIALS: Blood, body fluids, cleaning materials and clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

TO SANITIZE AND DEODORIZE NON-FOOD CONTACT SURFACES: [Spray] [Apply] Lonza Formulation RTU until thoroughly wet. Treated surfaces must remain wet for 30 seconds. Then wipe. For heavily soiled areas, a precleaning is required.

(Note for reviewer: If product is <u>not</u> sold in a spray bottle:)

Change this product at least daily or when solution becomes visibly dirty.

DEODORIZER DIRECTIONS:

Air Freshener, porous surfaces: Apply a light spray onto surfaces such as upholstery, drapes, bedding, carpet, A/C filters, etc.

Pet Odors: Saturate precleaned area with enough **Lonza Formulation RTU** to remain damp for at least 8 minutes, then blot with clean cloth. Repeat if necessary. Effective on bedding and litter boxes. Allow to dry.

Laundry: 3 ounces during the final rinse will deodorize offensive odors.

Potpourri: Easy to use. Just pour into pot or small pan and simmer.

Automobile/RV: Spraying liberally onto seats, carpets, headliner and ashtray or into the trunk will eliminate odors from tobacco, beverage spills and musty carpet.

Hard Surfaces: Apply directly to odor source such as diaper or garbage pails, fishing gear, bed pans, hampers, toilets, shower curtains, fireplace, athletic or work shoes, etc. Use in sick rooms, closets, basements or anywhere there are odors.

Refill Directions:

Remove top from empty spray bottle.

Unscrew cap on refill and pour contents directly into empty bottle until full. Replace trigger sprayer. If liquid remains in refill bottle, replace cap. Store for future use. Use product according to label directions.

To operate: Turn nozzle to on position and spray.

REFILL

50% More Free! 33 oz. at 22 oz. Price

(Note to reviewer: If the container size is one gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Wrap [container] and put in trash or offer for recycling if available.

(Note to Reviewer: For Nonrefillable Containers.)
Nonrefillable container

(Note to reviewer. One of the following statements must be used for Nonrefillable Containers.)

Do not reuse or refill this container

-OR

(Only if the label does not include household/residential use)

Do not reuse this container to hold materials other than pesticides (this product) or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide related materials in the container. Contact your state regulatory agency to determine allowable practices in your state.

(Note to reviewer. One of the following statements must be used for Refillable Containers.) Refillable Container. Refill this container with pesticide (this product) only. Do not reuse this container for any other purpose.

_--OR

Refillable Container. Refill this container with [this product] only. Do not reuse this container for any other purpose."

(If container is greater than one gallon, use the following storage and disposal statements:)

STORAGE AND DISPOSAL

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

Pesticide Storage

Open dumping is prohibited. Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls.

Pesticide Disposal

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

Container Disposal

[Insert Statements from below]

(*Plastic containers*): Triple rinse (or equivalent). Then offer for recycling or reconditioning 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.

(Metal Containers): Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(Note to Reviewer: For Nonrefillable Containers.)
Nonrefillable container

(Note to reviewer. One of the following statements must be used for Nonrefillable Containers.)

Do not reuse or refill this container

—OR

(Only if the label does not include household/residential use)

Do not reuse this container to hold materials other than pesticides (this product) or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide related materials in the container. Contact your state regulatory agency to determine allowable practices in your state.

(Note to reviewer. One of the following statements must be used for <u>Refillable Containers</u>.) Refillable Container. Refill this container with pesticide (this product) only. Do not reuse, this container for any other purpose.

OR

Refillable Container. Refill this container with [this product] only. Do not reuse this container for any other purpose."