

675-1

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

MAR - 1 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mary C. Pisculli
Regulatory & Registration Compliance Specialist
Reckitt Benckiser LLC
Morris Corporate Center IV
399 Interspace Parkway
Parisippany, NJ 07054

Subject: **Vani-Sol Bowel Cleanse**
EPA Registration Number: 675-1
Application Date: December 02, 2011
Receipt Date: December 05, 2011

Dear Ms. Pisculli:

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

Proposed Amendments

Registrant is consolidating Agency notifications onto Master Label, adding marketing claims, revising section headers, and updating storage and disposal instructions and clarifying use directions.

General Comment

A stamped accepted label is enclosed for your records. Submit a final printed label before selling or distributing the product bearing the revised label.

If you have further questions concerning this letter, then please contact me by telephone (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Glen McLeod by telephone at (703) 347-0181 or by email at mcleod.glen@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,

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

<< FRONT PANEL >>

ACTIVE INGREDIENT:

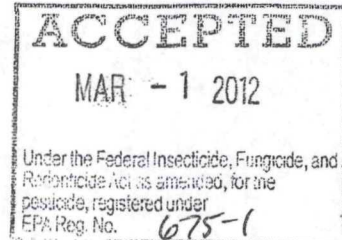
Hydrochloric Acid	23.0%
OTHER INGREDIENTS:	77.0%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER: CORROSIVE.

See (back) (side) panel for additional precautionary statements and first aid.
Use only in well ventilated areas.

NET CONTENTS:	24 FL. OZ.	(1 PT. 8 FL. OZ.)	709 mL
	32 FL. OZ.	(1 QT.)	946 mL



<< FRONT / BACK PANEL >>

EPA Reg. No.: 675-1
 EPA Est. No.: 777-NJ-2 55179-IN-1
 777-OH-1 075371-IN-002

(See bottom or side) (for Lot / Date code)

<< BACK PANEL >>

Questions? (Call): (1-800-228-4722) (1-800-677-9218)
For ingredient (and other) information, (www.rbnainfo.com) (website)

Made in U.S.A. © {year} RB

Distributed by: Reckitt Benckiser, Parsippany, NJ 07054 (-xxxx)

Contains no phosphates

This (bottle) (container) is made of 25% post-consumer recycled plastic.



Company graphic logo

<< BACK PANEL - Optional text >>

Monday – Friday, 8:45 a.m. – 4:30 p.m. (Eastern time)

Recycle Symbol

Important facts (about this product)

Encourage your local authorities to establish a program to recycle this (bottle) (container).



Limited Quantity Transportation Symbol

<< BACK PANEL – Optional text - PROFESSIONAL USE products only >>

An important part of a comprehensive infection control program

Part of an infection control program

NSF certification symbol:



Professional Vani-Sol® Bowl Cleanse is part of a system of infection control products provided by Reckitt Benckiser Inc. Now, more than ever, infection control is a major concern of yours, your staff and patients. We invite you to call us at (1-800-677-9218), Monday through Friday, 8:45 a.m. to 4:30 p.m. Eastern time if you have any questions or comments on our products.

Note: Bracketed information is denoted as: <<directive>>, {insert as noted}, (optional text), [required qualifier].
 The term "this product" used throughout this document may be replaced with the marketed product brand name.
 To use the term "germ*" the product must be efficacious against 2 of the 3 major classes of organisms.
 The product label must identify the specific bacteria*, virus*, fungus* & mold*.
 The term (x) is a placeholder that represents a number between 1 and 99.

<< NOTE: Any claim may appear on FRONT / BACK panel in bullet / paragraph format – Unless otherwise noted. >>

<< INTRODUCTORY 6-mos. CLAIMS – will only appear on graphic label for the first 6 months product is on shelf >>

(New) (Formula) (Scent) (Angel neck bottle) (Cap)

<< PACKAGING CLAIMS >>

Best value bottle
Better bottle
Better squirting than before
Buy me again
Click & Close (Indicator)
Click stop – audible close
Contains up to x uses
Convenient cap
Designed for (more) (better) dispensing
Easy grip bottle
Easy to close
Easy to reach under the rim
(Easy) (Easier) to squeeze cap
Easy to use (bottle)
Environmental friendly: Entire bottle can be recycled
Ergonomic bottle grip
Helps reach under the rim
Less time to open – more time to clean
Long (angle) neck bottle (reaches under the rim)
No slip grip
Non-drip (Less drip)
Non-removable cap
Open / Close indicator in contrasting colors – let's you know if the bottle is open / closed
Quicker to open
Removable cap
Repurchase time
Senior friendly cap
Senior tested cap
Shopping time
Specially designed angle neck – gets all the way up under the rim
Specially designed neck makes it easy to clean under the rim
Time to buy (a new Lysol® toilet bowl cleaner)
Time to replace
Twist and go cap
(Unique) Angle neck bottle (for hard to reach areas) (reaches under the rim)

<< PERFORMANCE CLAIMS >>

For better results use at least (once) (twice) a week
Formulated especially for hard water mineral deposits, lime scale and rust
Helps maintain optimal water flow (through the S-bend)
Helps (to keep water flow optimal) (to optimize water flow)
Leaves (Restores) a sparkling shine
Leaves toilet sparkling clean and disinfected
No hard scrubbing
Prevents the build-up of {insert soils – See pg. 3} in the S-bend and pipes to help water flow optimally
Specially designed to (remove) (penetrate) (destroy) (dissolve) the toughest {insert soils – See pg. 3}
Works best in hard water areas
Works best on hard water stains

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<< USAGE CLAIMS >>

A great toilet bowl disinfectant and sanitizer for use in: {insert use site – See pg. 3}
An effective disinfectant (sanitizer) for use in the toilet
Frequent use (Regular use) helps prevent build-up of {insert soils – See pg. 3} (in the toilet bowl)
For use in {insert use site – See pg. 3}
Use in toilets (and urinals) located in: {insert use site – See pg. 3}
Used in {insert use site – See pg. 3}

<< MARKETING CLAIMS >>

(Antibacterial) (Antifungal) (Antimicrobial) (Antiviral) (Bactericidal*) (Deodorizes) (Disinfectant) (Disinfects) (Fungicidal) (Sanitizer) (Sanitizes) (Toilet Bowl Cleaner) (Virucidal†)

(Clean) (Fresh) (Minty) (Spearmint) (Wintergreen) Scent

(Complete) (Easily) (Effectively) (Quickly) (Thoroughly) (Cleans) (Shines) (Whitens) (toilet bowls) (and urinals)

(Maximum) (Power) (Protection) (Strength) (Cleaner) (Cleaning)

3-in-1 (Formula): (Cleans, Disinfects, Deodorizes) (Cleans, Disinfects, Refreshens) (Cleans, Disinfects, Removes Stains)
4-in-1: Cleans, Disinfects, Deodorizes, Sanitizes

Confidence of Lysol®
(Contains a) High level dissolving ingredient
Contains no phosphates and is germicidal when used as directed for disinfecting
Deep Down Clean!
Disinfectant Power of Lysol®
Great for everyday (cleaning), (deodorizing) (and) (disinfecting)
Great for heavy-duty cleaning
Keep your toilet looking new
Meets AOAC Use-Dilution efficacy test standards for hospital (disinfectants) (toilet bowl cleaners)
Used by professionals

<< USE SITE / SURFACES / SOILS >>			
<< May be listed on product label in the singular / plural form >>			
Use Sites:	Clinics Day Care Centers Dental Offices Doctor Offices Health Care Facilities Homes (Households)	Hospitals Hotels / Motels Infirmaries Institutions Laboratories	Nursing Homes Office Buildings Physician's Offices Restaurants Schools
Surfaces:	Bidets Toilets Urinals	<u>Porcelain</u> Vitreous china	
Soils:	Hard water <u>Lime</u> Lime scale Mineral	<u>Organic soil</u> Rust <u>Toilet rings</u>	Build-up Deposits Stains

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<< NOTE: ALL SUPPORTING CLAIM QUALIFIERS – must appear before 'Directions For Use' on Back Panel label >>

<< CLEANING / DEODORIZING CLAIMS >>

(A) professional strength toilet bowl cleaner
All the power you need to clean your toilet bowl
Brightens as it cleans
Cleaning strength used in (places like) hospitals
Cleans and (disinfects) (deodorizes)
Cleans and disinfects (toilet bowls) (and urinals)
Cleans everyday dirt and grime (in toilet bowls)
Contains Hydrochloric Acid to remove rust and lime scale
Destroys (dissolves) toilet bowl rings
Destroys tough stains
Dissolves the toughest hard water deposits
(Easily) Breaks down stains without heavy (hard) brushing or scrubbing
Easy under-the-rim cleaning
Extra strength (Powerful) cleaner
Fast-Acting Cleaning Formula
Hard water (cleaner) formulation
Heavy-duty Cleaner
High strength cleaning for your toilet bowl and trap
Hospital strength cleaning
Hospital strength toilet bowl cleaning
Leaves (your) toilet bowl sanitary
Mineral dissolving action
Penetrates (dissolves) even the toughest stains
Powerful cleaner (for the toilet bowl)
Powerful cleaning (formula)
Powerful stain fighting
Powers out rust stains
Removes {insert soils – See pg. 3} through the 'S' bend (and pipes)
Removes (tough) rust (stains)
Starts to (lift) (dissolve) (remove) stains on contact
Strong enough for the dirtiest toilet bowl
Strong enough to clean the dirtiest toilet bowl
The professional strength cleaning power leaves the bowl sanitary
Tough cleaning power
Use regularly to maintain a clean, fresh & shiny toilet bowl (even under the rim)

(This product) quickly dissolves porous lime deposits, hard water, mineral and rust stains. Offensive odors are eliminated by removing the source. (This product) contains no phosphates or phosphorus and is harmless to plumbing and septic tanks.

<< SANITIZING CLAIMS – Hard, non-porous, non-food contact surface >>

Fast acting (sanitizer)
Kills 99.9% of (household) bacteria***
Kills bacteria on hard, non-porous surfaces in seconds***
Kills 99.9% of bacteria in 30 seconds***
Kills 99.9% of bacteria on hard, non-porous surfaces in 30 seconds***
Leaves (your) toilet bowl(s) sanitized
Sanitizes after 30 seconds***

<< SUPPORTING SANITIZING CLAIM QUALIFIER >>

*** Kills 99.9% of (Enterobacter aerogenes) (Escherichia coli O157:H7) (Staphylococcus aureus) inside the toilet above the waterline in 30 seconds.

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<< **DISINFECTING CLAIMS – Hard, non-porous surface** >>

Cleans and disinfects the bowl and beyond
Disinfects above and below the waterline
Disinfects beyond the bowl (and) (in the mouth trap)
Disinfects, (sanitizes) (deodorizes) and (kills) (eliminates) odor-causing bacteria
Disinfects the bowl and beyond (in the mouth trap) (where you can't see)
Disinfects the bowl (and in the mouth trap)
Disinfects where you can't see (under the rim)
Easily (and) (Effectively) disinfects toilet bowls (and urinals)
Gives you (full) (complete) (total) disinfection inside the toilet
Kills (99.9% of) germs**
Kills (99.9% of) germs beyond the bowl in the mouth trap**
Kills (99.9% of) germs in the bowl and beyond (in the mouth trap)**
Kills (99.9% of) germs in the bowl and in the mouth trap where you can't see**
Kills (99.9% of) germs in the bowl and the mouth trap**
Kills (99.9% of) germs where you can't see**
Kills 99.9% of Bacteria & Viruses**
Kills 99.9% of Viruses & Bacteria**
Kills germs in hard to reach places**
Kills germs in hidden places (under the rim)**
Kills (household) germs above and below the waterline**
Kills (household) (bathroom) (bacteria*) (fungi) (mold) (viruses†) (germs**) in the toilet
Kills odor-causing bacteria
Kills Rotavirus WA (a leading cause of children's diarrhea) in 30 seconds.
Kills the bacteria that cause (bad) odors
Kills viruses and bacteria**
Penetrates to (kill) (eliminate) and destroy tough (stains) (mold & mildew) and bacteria
Proven to kill: {insert micro-organisms – See pg. 6 }
Reduces odor-causing bacteria in toilets
Starts killing 99.9% of germs on contact**
Starts to kill 99.9% of germs on contact**
This product is (Bactericidal) (Fungicidal) (Virucidal) in killing: {insert micro-organisms – See pg. 6 }
Total disinfection for inside your toilet (above and below the waterline)

<< **SUPPORTING DISINFECTING CLAIM QUALIFIERS** >>

- * Kills (Enterococcus faecalis) (Escherichia coli) (Escherichia coli O157:H7) (Klebsiella pneumoniae) (Mycobacterium bovis BCG) (Pseudomonas aeruginosa) (Salmonella enterica) (Shigella dysenteriae) (and) (Staphylococcus aureus) (on hard, non-porous surfaces) (in 10 minutes)
- ** Kills (Enterococcus faecalis) (Escherichia coli) (Escherichia coli O157:H7) (Klebsiella pneumoniae) (Mycobacterium bovis BCG) (Pseudomonas aeruginosa) (Salmonella enterica) (Shigella dysenteriae) (Staphylococcus aureus) (Hepatitis A Virus) (Human Immunodeficiency Virus Type 1) (Poliovirus Type 1) (Rotavirus WA) (Aspergillus niger) (Trichophyton mentagrophytes) (on hard, non-porous surfaces) (in 10 minutes).
- † Kills (Hepatitis A Virus) (Human Immunodeficiency Virus Type 1) (Poliovirus Type 1) (and) (Rotavirus WA) (on hard, non-porous surfaces) (in 10 minutes)

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This product has been test and found effective against the following micro-organisms:

Bacteria, Viruses & Fungi		
<< Disinfection – Hard, non-porous surfaces >>		
Bacteria (10 minutes)	<u>(ATCC No.)</u>	
Enterococcus faecalis	(828)	(leads to blood infections)
Escherichia coli	(11229)	(leading cause of diarrhea, vomiting, food poisoning and bloody diarrhea)
Escherichia coli O157:H7	(43888)	(leading cause of diarrhea, vomiting, food poisoning and bloody diarrhea)
Klebsiella pneumoniae	(4532)	(a leading cause of pneumonia & lung illnesses)
Mycobacterium bovis BCG	(35743)	
Pseudomonas aeruginosa	(15442)	(cause of skin ulcers, blood infections, hospital grade pneumonia)
Salmonella enterica	(10708)	(a fecal / orally transmitted bacteria which may lead to food borne disease, food poisoning, diarrhea, dehydration, stomach cramps, fever & vomiting)
Shigella dysenteriae	(11835)	(a leading cause of bloody diarrhea, breaks-down intestinal lining)
Staphylococcus aureus	(6538)	(a leading cause of skin infections, boils, food poisoning, blood infections)
Viruses (10 minutes)	<u>(ATCC No.)</u>	
Hepatitis A Virus	<u>n/a</u>	
Human Immunodeficiency Virus Type 1	<u>n/a</u>	(cause of AIDS Virus)
Poliovirus Type 1	<u>n/a</u>	
Rotavirus WA	(VR-2018)	(the leading cause of infectious diarrhea in children)
Viruses (30 seconds)	<u>(ATCC No.)</u>	
Rotavirus WA	(VR-2018)	(the leading cause of infectious diarrhea in children)
Fungi (10 minutes)	<u>(ATCC No.)</u>	
Aspergillus niger	(6275)	(mold & mildew)
Trichophyton mentagrophtes	(9533)	(athlete's foot fungus)
<< Sanitization – Hard, non-porous, non-food contact surfaces >>		
Bacteria (30-seconds)	<u>(ATCC No.)</u>	
Enterobacter aerogenes	(13048)	
Escherichia coli O157:H7	(43888)	
Staphylococcus aureus	(6538)	

<u>Symbol Designation – used on product labels</u>		
Single asterisk (*)	Bacteria *	Used for identifying disinfection against specific bacteria
Dagger (†)	Viruses †	Used for identifying disinfection against specific viruses
Double asterisk (**)	Germs **	Used for identifying disinfection against specific bacteria & viruses / fungi
Triple asterisk (***)	Sanitizes ***	Used for identifying sanitization against specific bacteria

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<< USE DIRECTIONS >>

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label before using product.

Apply Carefully – Use extreme caution when applying this product – Contains 23% Hydrochloric Acid

To Open Child Resistant Cap: Hold bottle firmly with one hand on a flat surface. With other hand, squeeze sides of cap where indicated while turning counterclockwise. Do not remove cap. **Avoid squeezing bottle when opening.** To reseal, twist cap clockwise until tightly closed.

<< Optional Side panel pictogram – can only be used in conjunction with required back panel instructions >>

<< Non-removable Pictogram text >>

To Open Child Resistant Cap:

1. Place fingers on marked cap ridges.
2. Squeeze cap firmly and turn counterclockwise until it stops. **Do not remove cap.**
3. To reseal, squeeze cap again and turn clockwise.
DO NOT squeeze bottle when opening.



1. Place fingers on marked cap ridges.
 2. Squeeze cap firmly and turn counterclockwise until it stops. Do not remove cap.
 3. To reseal, squeeze cap again and turn clockwise.
- DO NOT squeeze bottle when opening.

To Clean / Disinfect (/ Sanitize):

1. Flush toilet before cleaning.
2. Apply 4 oz. to coat the bowl including under the rim. **Do not close lid.**
3. To Clean: Scrub entire bowl and under rim thoroughly.
Disinfect: Let sit for 10 minutes. (Sanitize: Let sit for 30 seconds.)
Then flush.
- (4. Rinse brush in fresh water after use.)
(Repeat if needed.)

To Remove Tough Stains: Apply a generous amount of liquid directly onto the tough stains. For severe rust stains, if possible, remove water from bowl first. Let soak for 15 minutes. **Do not close lid.** Follow cleaning directions above. Repeat if necessary.

This product has been specially formulated for use only in (vitreous china) (glazed porcelain) toilet bowls (bidets) (and urinals). It should not be used or placed on toilet bowl lids, vanities, sinks, bathtubs, cabinets, countertops, rugs, etc. Clean up spills and drips immediately. **Do not use with chlorine bleach or any other chemical products.** Will not harm plumbing or septic systems.

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1 AIDS Virus] 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 OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface / object to remain wet for 10 minutes.

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

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<< PRECAUTIONARY / FIRST AID / CHEMICAL HAZARD / STORAGE & DISPOSAL INSTRUCTIONS >>

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

DANGER: CORROSIVE. Contains Hydrochloric Acid. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing vapor or fumes. Wear goggles or face shield [safety glasses], protective clothing and chemical resistant rubber gloves. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID	
If in Eyes	<ul style="list-style-type: none">• 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.
If swallowed	<ul style="list-style-type: none">• Call a Poison Control Center or doctor 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 <u>the</u> Poison Control Center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• 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 Inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably <u>by</u> mouth-to-mouth if possible.• Call a Poison Control Center or doctor for further treatment advice.
CONTACT NUMBER	
Questions? Comments or In case of an emergency call toll free (1-800-228-4722) (1-800-677-9218). Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

PHYSICAL AND CHEMICAL HAZARDS: Do not use with chlorine bleach or any other chemical products.

<< STORAGE & DISPOSAL – Residential containers >>

STORAGE AND DISPOSAL:

STORAGE: Store in original container, in a cool, well-ventilated area, inaccessible to small children. Keep securely closed.

PESTICIDE DISPOSAL: To avoid waste, use all material in this container according to label directions.

CONTAINER DISPOSAL: Non-refillable 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.

<< STORAGE & DISPOSAL – Commercial / Institutional / Industrial containers >>

(NOTE: Residue removal statement is not applicable for this container because it has a CRC plug making it inherently non-refillable.)

STORAGE AND DISPOSAL:

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

STORAGE: Store in original container in a cool, well-ventilated area, inaccessible to children. Keep securely closed.

PESTICIDE DISPOSAL: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. (To avoid waste, use all material in this container according to label directions.) If empty: Place in trash or offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions.

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Enlarged View Graphic(s)

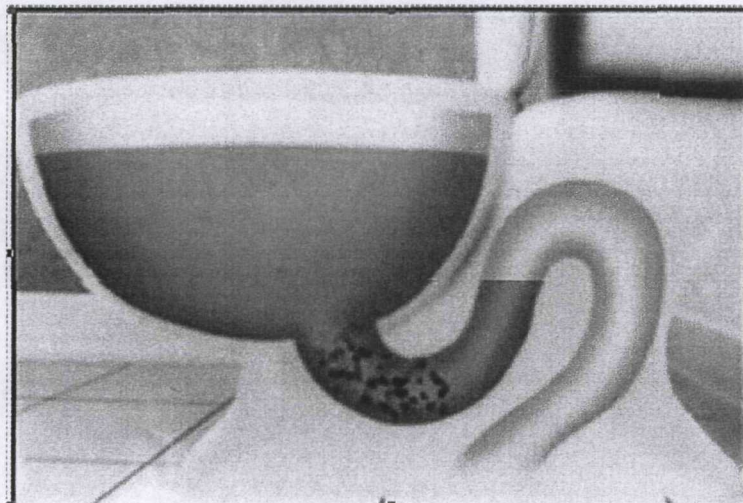
<< CRC graphic >>



1. Place fingers on marked cap ridges.
2. Squeeze cap firmly and turn counterclockwise until it stops. Do not remove cap.
3. To reseal, squeeze cap again and turn clockwise.

DO NOT squeeze bottle when opening.

<< 'S' bend graphic >>



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