

675-1

08/23/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

August 23, 2005

Mary C. Pisculli  
Regulatory & Registration Compliance Associate  
Reckitt Benckiser, Inc.  
Morris Corporate Center IV  
399 Interpace Parkway  
Parsippany, NJ 07054-0225

Subject: Vani-Sol Bowl Cleanse  
EPA Registration Number 675-1  
Application Date: May 20, 2005  
EPA Received Date: May 25, 2005

Dear Ms. Pisculli:

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

**Proposed Amendment**

- Revised Basic Confidential Statement of Formula (see CSF dated 5/20/05)
- Revised Alternate Confidential Statement of Formula (see CSF dated 5/20/05)
- Revised labeling
- Child Resistant Packaging Certification Statement

**Product Chemistry**

The certified limits for water, for the basic formulation, must be updated from 23.69% to 22.57% for the upper certified limit and from 22.31% to 21.25% for the lower certified limit.

**Labeling Deficiencies**

1. Delete the term "New (Improved)" from the product label.

CONCURRENCES

YMBOL	JRNAME	DATE					
7510C							

- 2. Delete the claim for the microorganisms "Rotavirus WA", "Enterococcus (Streptococcus) faecalis", "Poliovirus Type 1", "Hepatitis A", "Enterobacter aerogenes", and "Klebsiella pneumoniae" from the product label. Efficacy data must be submitted to support the claim for these microorganisms. The product you cited is not similar or identical to the subject product.

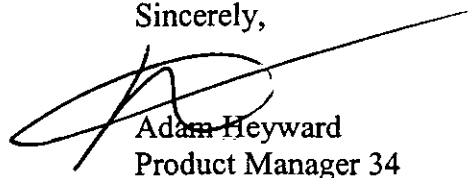
**General Comments**

The revised basic Confidential Statement of Formula, dated May 20, 2005, supersedes all previously accepted basic formulas.

The proposed label amendment will be acceptable when the above deficiencies are addressed and the revised label is submitted.

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

Sincerely,



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

<< Front Panel >>

**ACTIVE INGREDIENT:**

Hydrogen Chloride .....	23.0%
<b>OTHER INGREDIENTS:</b> .....	<u>77.0%</u>
<b>TOTAL:</b> .....	100.0%

KEEP OUT OF REACH OF CHILDREN

**DANGER:** CORROSIVE. Contains Hydrogen Chloride.  
See back (side) panel for additional precautionary statements.  
Use only in well ventilated areas.

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

<< Front or Back Panel >>

EPA Reg. No.: 675-1  
EPA Est. No.: 777-NJ-2  
55179-IN-1  
See bottom or side (for Lot/Date code)

<< Back Panel >>

**Questions? Comments? Call: (1-800-228-4722) (1-800-677-9218)**  
(or) Visit us at (www.lysol.com) (www.reckittprofessional.com)  
Made in U.S.A. © RBI (year)  
Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054 (-xxxx)  
Contains no phosphates (Phosphate free)

<< Back Panel-Optional text >>

Monday – Friday, 8:45 a.m. – 4:30 p.m. (Eastern time)  
Company Logo (Reckitt Benckiser Professional)  
Recycle Symbol  
Important facts (about this product)  
This (bottle) (container) is made of x% post-consumer recycled plastic.  
Encourage your local authorities to establish a program to recycle this (bottle) (container).

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

AUG 23 2005

Under the Federal Insecticide,  
Fungicide and Rodenticide Act as  
registered for the pesticide,  
registered under EPA Reg. No. 675-1

**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

<< Front or Back Panel – use as bullet point or in paragraph format with Marketing / Product Performance claims >>  
NOTE: The term "This product" may be stated before any claim.

<< Marketing / Product Performance claims >>

(Antibacterial) (Antifungal) (Antimicrobial) (Antiviral) (Bactericidal) (Deodorizes) (Disinfectant) (Disinfects)  
(Fungicidal) (Sanitizer) (Sanitizes) (Toilet Bowl Cleaner) (Virucidal)  
New (Improved) (Formula)  
(Clean) (Fresh) (Minty) (Spearmint) (Wintergreen) Scent  
(Complete) (Comprehensive) (Easily) (Effectively) (Quickly) (Thoroughly) (Cleans) (Shines) (Whitens)  
(toilet bowls) (and urinals)

A great toilet bowl disinfectant and sanitizer for use in: {insert use site}  
All the power you need to clean your toilet bowl  
Brightens as it cleans  
Cleans and disinfects (toilet bowls) (and urinals)  
Confidence of Lysol®  
(Contains a) High level dissolving ingredient  
Contains Hydrogen Chloride to remove rust and lime scale  
Contains no phosphates and is germicidal when used as directed for disinfecting  
Deep Down Clean!  
Disinfectant Power of Lysol®  
Easily (and) (Effectively) disinfects toilet bowls (and urinals)  
Easy under-the-rim cleaning  
Extra strength (Powerful) cleaner  
Formulated especially for hard water mineral deposits, limescale and rust  
Frequent use (Regular use) helps prevent build-up of (lime scale) (rust) (stains) (mold & mildew)  
(in the toilet bowl) (plumbing pipes)  
Great for everyday (cleaning), (deodorizing) (and) (disinfecting)  
Great for heavy-duty cleaning  
Hard water (cleaner) formulation  
Heavy-duty Cleaner  
Keep your toilet looking new  
Leaves (Restores) a sparkling shine  
Leaves (your) toilet bowl(s) sanitary  
Meets AOAC Use-Dilution efficacy test standards for Hospital (type disinfection) (Disinfectants)  
Mineral dissolving action  
More than clean  
Powerful cleaner (for the toilet bowl)  
Powerful stain fighting  
Powers out rust stains  
Prevents the build-up of limescale and mineral deposits in the 's' bend and pipes to help water flow  
optimally  
Recommended for use in (hospitals) (nursing homes) (dental offices) (and other) (commercial) (public)  
(facilities)  
Strong enough for the dirtiest toilet bowl  
Strong enough to clean the dirtiest toilet bowl  
Use in toilets (and urinals) located in: {insert use site}  
Use regularly for maximum home hygiene  
Use regularly to maintain a clean, fresh & shiny toilet bowl (even under the rim)  
Used by professionals  
Used in Hospitals. (Institutional and Industrial Facilities.)

(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. Harmless to plumbing and septic tanks.

<<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)

<< Front or Back Panel – use as bullet point or in paragraph format with Marketing / Product Performance claims >>

<< Cleaning claims >>

( A ) professional strength toilet bowl cleaner  
Cleaning strength used in (places like) hospitals  
Cleans and (&) (Disinfects) (Deodorizes)  
Cleans everyday dirt and grim (in toilet bowls)  
Destroys (dissolves) toilet bowl rings  
Dissolves the toughest hard water deposits  
(Easily) Breaks down stains without heavy (hard) brushing or scrubbing  
Fast-Acting Cleaning Formula  
High strength cleaning for your toilet bowl and trap  
Hospital strength cleaning  
Hospital strength toilet bowl cleaning  
Starts to (lift) (dissolve) (remove) stains on contact  
The professional strength cleaning power leaves the bowl sanitary  
Tough cleaning power

<< Disinfecting/Deodorizing claims >>

An effective disinfectant (sanitizer) for use in the toilet  
Disinfects above and below the waterline  
Disinfects, (sanitizes) (deodorizes) and (kills) (eliminates) odor-causing germs  
Even mold isn't too tough for Lysol®  
For maximum cleaning and germ\*\* kill, let stand for at least 10 minutes  
Kills Escherichia coli (E. coli) 0157:H7, Salmonella choleraesuis and Shigella dysenteria  
Kills (Eliminates): {insert organisms}  
Kills (household) Germs\*\* (above and below the waterline)  
Kills (household) (bathroom) (bacteria\*) (fungi\*) (mold) (viruses†) (germs\*\*) in the toilet  
Kills odor causing germs\*\*  
Kills the following (bacteria) (fungi) (viruses) (germs) (microorganisms): {insert organisms}  
Kills the germs\*\* that cause (bad) odors  
Kills viruses† and bacteria\*  
On hard, non-porous surfaces, this product kills the following (bacteria) (virus) (and fungi): {insert organisms}  
Penetrates to (kill) (eliminate) and destroy tough (stains) (mold & mildew) and bacteria  
Proven to kill: Staphylococcus aureus (a leading cause of skin infections, boils, food poisoning, blood infections)  
Salmonella choleraesuis (a fecal/orally transmitted bacterial which may lead to food borne disease, food poisoning, diarrhea, dehydration, stomach cramps, fever and vomiting.)  
Rotavirus WA (the leading cause of infectious diarrhea in children)  
Shigella dysenteriae (leading cause of bloody diarrhea, breaks down intestinal lining.)  
Human Immunodeficiency Virus Type 1 [HIV-1][AIDS virus] (cause of AIDS virus)  
Enterococcus faecalis (leads to blood infections)  
Escherichia coli (leading cause of diarrhea, vomiting, food poisoning and bloody diarrhea)  
Escherichia coli 0157:H7 (leading cause of diarrhea, vomiting, food poisoning and bloody diarrhea)  
Klebsiella pneumoniae (leading cause of pneumonia and lung illnesses)  
Pseudomonas aeruginosa (cause of skin ulcers, blood infections, pneumonia hospital grade)  
Reduces odor-causing (bacteria) (fungi) (germs) in toilets  
This product is (Bactericidal) (Fungicidal) (Virucidal) in killing: {insert organisms}

<< Organisms >>

<< Bacteria >> (Enterococcus (Streptococcus) faecalis) (Escherichia coli) (Escherichia coli 0157:H7)  
(Klebsiella pneumoniae) (Mycobacterium bovis BCG) (Pseudomonas aeruginosa)  
(Salmonella choleraesuis) (Shigella dysenteriae) (Staphylococcus aureus)

<< Viruses >> (Hepatitis A) (Human Immunodeficiency Virus Type 1 [AIDS virus]) (Poliovirus Type 1)  
(Rotavirus WA) ...

<< Fungi >> (Aspergillus niger (mold & mildew)) (Trichophyton mentagrophytes (Athlete's Foot Fungus))

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 bactericidal, fungicidal, and virucidal claims.

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<< Front or Back Panel – use as bullet point or in paragraph format with Marketing / Product Performance claims >>

<< Sanitizing – Hard non-porous, non-food contact surface claims >>

(front / back panel claim)

Fast acting (sanitizer)

Kills 99.9% of (household) (bacteria) (virus) (germs)\*\*\*

Kills (bacteria) (virus) (germs) on hard, non-porous surfaces in seconds\*\*\*

Kills (Eliminates) 99.9% of (bacteria) (virus) (germs) in 30 seconds\*\*\*

Kills (Eliminates) 99.9% of (bacteria) (virus) (germs) on hard, non-porous surfaces in 30 seconds\*\*\*

Leave in (at least) 30 seconds to sanitize 99.9% of bacteria in your bowl\*\*\*

Leaves (your) toilet bowl(s) sanitized

Sanitizes after 30 seconds\*\*\*

(back panel qualifiers)

\*\*\*Kills (Eliminates) 99.9% of (Enterobacter aerogenes) (Escherichia coli 0157:H7) (Staphylococcus aureus) and Rotavirus WA inside the toilet (above and below the waterline) in 30 seconds.

\*\*\*(This product) kills 99.9% of Enterobacter aerogenes, Escherichia coli 0157:H7, Staphylococcus aureus and Rotavirus WA inside the toilet (above and below the waterline) after 30 seconds.

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**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, or fungi used

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<< Back Panel >>

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

<< Advisory statements - IMPORTANT: Advisory statements must be included where appropriate >>

**Apply Carefully - Contains 23% Hydrogen Chloride**

Use only on vitreous china toilet bowls (and urinals).  
Do not use on porcelain sinks, washbowls or bathtubs.  
Do not use with chlorine bleach or any other chemical product.  
Clean up spills and drips immediately.  
Will not harm plumbing or septic systems

(This product) has been specially formulated for use only in toilet bowls. It should not be used or placed on toilet bowl lids, vanities, sinks, bathtubs, cabinets, countertops, rugs, etc.

<< Operation directions >>

**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. **AVOID SQUEEZING BOTTLE WHEN OPENING.** To reseal, turn (twist) cap clockwise until tightly closed.

**To Open Child Resistant Cap:** Hold bottle firmly with one hand on a flat surface. With other hand, squeeze sides of cap where symbols indicate and turn counterclockwise. **AVOID SQUEEZING BOTTLE WHEN OPENING.** To reseal, turn (twist) cap clockwise until tightly closed.

<< Cleaning directions >>

**To Remove Tough Stains:**

1. Apply a generous amount of liquid directly onto the tough stains. For severe rust stains, if possible, remove water from bowl before applying liquid.
2. Let soak for 15 minutes. **Do not close toilet bowl lid.**
3. Brush entire bowl thoroughly with a bowl brush (or bowl mop) and repeat if necessary.

<< Disinfecting directions >>

**To Clean (Deodorize) and Disinfect (Toilet Bowls) (and Urinals):**

1. Flush first and remove excess dirt and grime before cleaning.
2. Wet all surfaces of bowl interior, including sides of bowl and under the rim, with at least 4 oz. of liquid [squeeze bottle approximately 15 seconds]. Replace cap securely.
3. Let soak for at least 10 minutes. **Do not close toilet bowl lid.**
4. Brush entire bowl thoroughly with a bowl brush and flush.
5. Rinse brush in fresh water after use.

<< Sanitizing / Deodorizing directions >

**To Clean (Deodorize) and Sanitize (Toilet Bowls) (and Urinals):**

1. Flush first and remove excess dirt and grime before cleaning.
3. Wet all surfaces of bowl interior, including sides of bowl and under the rim, with at least 4 oz. of liquid [squeeze bottle approximately 15 seconds]. Replace cap securely.
3. Let stand for 30 seconds. **Do not close toilet bowl lid.**
4. Brush entire bowl thoroughly with a bowl brush and flush.
5. Rinse brush in fresh water after use.

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<< Back Panel >>

<< IMPORTANT: All organisms must be identified by genus & species.  
Abbreviations may be included but must appear in (parens). >>

<< Hard Non-porous Surfaces >>

<< Disinfection against Bacteria >>

Enterococcus (Streptococcus) faecalis  
Escherichia coli (E. coli)  
Escherichia coli 0157:H7 (E. coli 0157:H7)  
Klebsiella pneumoniae  
Mycobacterium bovis BCG  
Pseudomonas aeruginosa (Pseudomonas)  
Salmonella choleraesuis (Salmonella)  
Shigella dysenteriae  
Staphylococcus aureus (Staph)

<< Disinfection against Viruses >>

Hepatitis A  
Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS virus]  
(tested in 10% fetal bovine serum)  
Poliovirus Type 1  
Rotavirus WA

<< 30-second Disinfection against Virus >>

Rotavirus WA -

<< Disinfection against Fungi >>

Aspergillus niger (mold & mildew)  
Trichophyton mentagrophytes (Athlete's Foot Fungus)

<< Hard Non-porous, Non-food Contact Surfaces >>

<< Sanitization against Bacteria >>

Enterobacter aerogenes  
Escherichia coli 0157:H7 (E. coli 0157:H7)  
Staphylococcus aureus (Staph)



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<< Back Panel >>

<< IMPORTANT: The following is required for professional use products making claims against: >>

<< Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus] >>

**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 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 or 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 should be autoclaved and disposed of according to local regulations for infectious waste disposal.

<< Terminal Sterilant Statement – qualified metal surfaces >>

**This product is not for use on critical & semi-critical medical devices or medical equipment surfaces.**

<< Terminal Sterilant Statement – unqualified metal surfaces >>

**This product is not to be used as a terminal sterilant / high level disinfectant** on any surface that <sup>(1)</sup> is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body; or <sup>(2)</sup> contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enters normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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<< Back Panel >>

**PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals**

**DANGER: CORROSIVE – Contains Hydrogen Chloride.**

Causes irreversible eye damage or skin burns. Harmful if swallowed or 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	
<b>If in eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a Poison Control Center or doctor for treatment advice.</li></ul>
<b>If swallowed</b>	<ul style="list-style-type: none"><li>• Call a Poison Control Center or doctor immediately for treatment advice.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told by a Poison Control Center or doctor.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a Poison Control Center or doctor for treatment advice.</li></ul>
<b>If inhaled</b>	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible.</li><li>• Call a Poison Control Center or doctor for further treatment advice.</li></ul>
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 Hazard language >>

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

<< Storage and Disposal language – Household containers >>

**STORAGE AND DISPOSAL:** Store in cool, well-ventilated area, inaccessible to small children. Do not reuse empty container. Rinse empty container thoroughly and discard in trash or recycle.

<< Storage and Disposal language – Professional containers 1 gallon or less >>

**STORAGE AND DISPOSAL:**

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

**STORAGE:** Store in cool, well-ventilated area, inaccessible to small children.

**DISPOSAL:** Do not reuse empty container. Rinse empty container thoroughly and discard in trash or recycle.

**Note:** Bracketed information is denoted as: <<directive>>, {insert as noted}, (optional text), [required qualifier].  
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The product label must identify the specific bacteria, virus, fungus & mold.

<< Storage and Disposal language – Professional containers greater than 1 gallon >>

**STORAGE AND DISPOSAL:**

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

**STORAGE:** Store in original container in areas inaccessible to small children. Keep securely closed.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes can not be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

**CONTAINER DISPOSAL:** Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

<< Environmental Hazards – Professional containers 5 gallon or greater >>

**ENVIRONMENTAL HAZARDS:**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other water 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 sewage systems without previously notifying the local sewerage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.