



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**August 12, 2003**

Jeff Jones  
Agent for Antec International Ltd.  
c/o Delta Analytical Corp.  
7910 Woodmont Avenue, Suite 1000  
Bethesda, MD 20814

Subject: **Virkon®**  
EPA Registration No. 62432-2  
Your application dated May 19, 2003

Dear Mr. Jones:

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

- Response to PR Notice 2001-1

**General Comment:**

The following labeling corrections must be made:

1. Last page, bottom box, delete the statement "Preventing the spread of infection and contamination" because the statement is not an acceptable efficacy claim. Historically, the Antimicrobials Division (AD) has not allowed any claim that a disinfectant will promote infection control, reduce-contamination, or the like. AD admitted having erroneously approved the following statement that currently appears on the label under OPT "Preventing the spread of infection and contamination." AD requested that you remove this statement.
2. In addition, the word "INFECTIOUS/INFECTION" is not an acceptable term on pesticide product labeling for the same reasons as stated above, and therefore must be deleted wherever it appears on the label. You may consider proposing alternative language for AD's consideration.

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

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,

A handwritten signature in black ink, appearing to read 'AH', with a long horizontal line extending to the right.

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

enclosure:

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**Antec International**  
**[Virkon logo]**  
**Virkon®**  
**Broad Spectrum Disinfectant**

**[With Virkon only one product is needed to clean and disinfect all surfaces]**

[FOR USE IN: Cleaning and disinfecting institutional, commercial, residential and public service facilities including hospitals and nursing homes; medical and dental offices; clinics and other health-care facilities; laboratories; food processing plants, equipment and warehouses; food service and preparation areas including commercial and institutional kitchens, restaurants and cafeterias; restrooms; retail stores including supermarkets, florists, barbers, and beauty salons; factories; schools and daycare centers; hotels; offices; correctional facilities; funeral parlors and mortuaries; gymnasiums, stadiums and health spas; transportation terminals and vehicles including ships, planes, automobiles, trucks, trains, EMS; and homes and residences.]

[EFFECTIVE AGAINST A WIDE RANGE OF VIRUSES, BACTERIA AND FUNGI INCLUDING:

Streptococcus pyogenes, Campylobacter pyloridis, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans.]

**ACTIVE INGREDIENTS**

Potassium peroxymonosulfate .....	21.45%
Sodium chloride .....	1.50%
OTHER INGREDIENTS .....	77.05%
TOTAL .....	100.00%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See [Back Panel][Box] for Additional Precautions  
[See product insert for Directions for Use]

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
**AUG 12 2003**

Under the Federal Insecticide,  
Fungicide and Rodenticide Act  
as amended by the FIFRA  
Amendments of 1996, EPA Reg. 40.62432-2

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**FIRST AID**

**Have the product container or label with you when calling a poison control center or doctor, or going for treatment.**

**If Swallowed:**

- Call 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 the poison control center or doctor
- Do not give anything by mouth to an unconscious person

**If Inhaled:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a Poison Control Center or doctor for further treatment advice.

**If in Eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

**If on Skin:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for further treatment advice.

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage. [Front panel continued]

Net Contents: [0.35 oz. (10 grams), 1.75 oz. (50 grams), 1.1 lbs. (500 grams), 2.2 lbs. (1 kilogram), 11 lbs. (5 kilograms)] [See individual product]

[When dissolved in lukewarm water forms [1 quart][1.3 gallons][13 gallons][26 gallons][132 gallons] of 1% solution]

Manufactured by Antec International LTD

Leaders in Biosecurity

Windham Road, Chilton Industrial Estates

Sudbury, Suffolk, CO10 2XD, England

Tel: 011441787377305 Fax: 011441787310846

EPA Reg. No. 62432-2

EPA Est. No. 62432-EN-001

Virkon is a registered trademark of and manufactured by Antec International Ltd US Patent No. 4822512

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
AUG 12 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 62432-2

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## DIRECTIONS FOR USE:

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

### ***INSTITUTIONAL, FOOD PROCESSING, RESIDENTIAL AND SERVICE FACILITIES***

With VIRKON, only one product is needed to clean and disinfect all surfaces.

**Do Not Use Virkon on acid-sensitive surfaces such as marble or soft metals such as copper, brass, or aluminum. Avoid splashing VIRKON solution on textiles or carpets. Virkon may be used on carpeting or other textiles only if area is tested for color fastness before use and treated area vacuumed when dry.**

**Cleaning and Disinfecting Food Contact Surfaces:** Remove gross dirt and prepare 1.0% solution according to the table below. Apply to surface using a sponge, brush, or spray device until the surface is visibly clean. Let stand for 10 minutes and rinse with potable water.

**Cleaning and Disinfecting Non-Food Contact Surfaces:** Remove gross dirt and use 1.0% Virkon solution prepared according to the table below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Let stand 10 minutes and air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon solution.

This product is not to be used 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.

**Sanitizing Toilet Bowls:** After flushing, sprinkle VIRKON powder around the bowl, scrub with a brush, leave for 10 minutes. Flush.

**Cleaning and Disinfecting Manikins Used in CPR Training:** Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon solution. Let stand for 10 minutes and rinse with potable water.

ACCEPTED  
WITH COMMENTS  
in EDA Letter Dated:  
AUG 12 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for use as a disinfectant,  
registered under EPA Reg. No. 62432-2

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## DILUTION CHART

To this much water:	1.0% solution add this much Virkon (1000 ppm available Chlorine)	2.0% solution add this much Virkon (2000 ppm available Chlorine)
<b>American</b>		
1 quart	0.33 ounces	0.66 ounces
1 gallon	1.3 ounces	2.6 ounces
10 gallons	13.4 ounces	26.4 ounces
50 gallons	66.8 ounces	133.6 ounces
<b>Metric</b>		
1 liter	10 grams	20 grams
5 liters	50 grams	100 grams
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2000 grams	4000 grams

[diagrams of measuring cup and measuring cap]

For Disinfecting use a rate of 7.5 gallons/1,000 sq. ft.

For Cleaning and Disinfecting use a rate of 15 gallons/1,000 sq. ft.

## PRECAUTIONARY STATEMENTS

### **Hazards to Humans and Domestic Animals**

**DANGER:** Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only, not in-use solution.

## **STORAGE AND DISPOSAL**

Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash. Do not mix this product with other chemicals.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
AUG 12 2003  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, and under the Federal  
Registration Act...

62432-2

AUG 12 2003

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Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,

**VIRKON FOR THE PROTECTION OF  
HOTEL GUESTS AND SHIP PASSENGERS (opt.); MEDICAL AND DENTAL STAFF (opt.); CATERING AND FOOD  
SERVICE STAFF (opt.); CPR STUDENTS (opt.); SERVICE PERSONNEL (opt.)**

62432-2

VIRUCIDE, BACTERICIDE, FUNGICIDE

INFECTIOUS SOURCE	THE DANGERS	CONTROL	VIRKON
PEOPLE - from saliva	Transmits bacteria and viruses including staphylococci and streptococci.	Clean and disinfect all crockery, cutlery and drinking glasses with Virkon solution. Also containers in which crockery etc. is transported. <u>Change frequently</u>	Use 1.0% Virkon to clean and disinfect. Rinse in water
PEOPLE - from poor personal hygiene and from surfaces in toilets, wash basins, etc.	Transmits bacteria and viruses causing enteritis and typhoid.	Clean and disinfect all surfaces in the bathroom twice daily with Virkon.	Use 2.0% Virkon to clean and disinfect. Rinse in water
PEOPLE - fungal foot infections	Organisms causing foot infections in swimming pool changing areas, bathroom floors.	Clean and disinfect floors daily with Virkon.	Use 1.0% Virkon to clean and disinfect.
PEOPLE - nursery play areas	From young children where personal hygiene is poor - contaminating equipment and play areas.	Clean and disinfect play areas and equipment twice daily with Virkon.	Use 1.0% Virkon to clean and disinfect.
PEOPLE - Blood, body fluids, vomit	All blood should be treated as HIV positive; vomit and body fluids are also highly infective.	Cover heavy blood spillage with Virkon powder. Leave for 10 minutes, then scoop into plastic bag.	Use 2.0% Virkon to clean and disinfect area.
FOOD PREPARATION AREA - from poultry, meat, fish, cheese.	From contamination by Salmonella, Escherichia coli and Campylobacter	Clean and disinfect all surfaces on which food is prepared with Virkon 3 or 4 times daily. Clean and disinfect cheese boards, containers regularly.	Use 1.0% Virkon to clean and disinfect. Let stand 10 minutes and rinse with potable water.
VEGETABLE PREPARATION AREA -	From vegetables contaminated with soil containing organisms of human and animal fecal origin.	Clean and disinfect all surfaces in this area - including sinks, work benches, floors, containers in which vegetables pass to kitchen.	Use 1.0% Virkon to clean and disinfect. Let stand 10 minutes and rinse with potable water.
FOOD - Preparation in the kitchen	Infection from all surfaces: benches, mixing bowls, equipment used for preparing cold items, cream, mayonnaise and cutting meat for cold buffet etc. Contamination as above	Clean and disinfect with Virkon solution regularly - several times daily and between different foods.	Use 1.0% Virkon to clean and disinfect. Let stand 10 minutes and rinse with potable water.
WASTE FOOD BINS	Contamination as above.	Clean and disinfect with Virkon solution.	Use 1.0% Virkon to clean and disinfect. Rinse in water.
BARS/RESTAURANTS - Crockery, cutlery, drinking glasses in restaurants and bars and in the trays in which they are transported.	From people who transmit viral and bacterial contaminants from saliva and hands.	Clean and disinfect. Wash all glasses etc. in Virkon solution.	Use 1.0% Virkon to clean and disinfect. Let stand 10 minutes and rinse with potable water. Change Virkon solution daily or more frequently if solution is cloudy or dirty.

N.B. Where dishwashing/pot washing machines are available, if properly operated, the items should be sterile when they leave this machine. At this stage they are open to contamination from people and surfaces; for this reason all surfaces and equipment in the known food processing zone should be washed with Virkon. This single operation will clean and disinfect thus preventing the spread of infection and contamination which occurs when cleaning is done using a detergent only.