



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**August 11, 2004**

Jeff Jones, Agent for  
**Antec International, Ltd.**  
7910 Woodmont Ave., Suite 1000  
Bethesda, MD 20814

Subject: Notification Application Per PR Notice 98-10  
**Virkon**  
EPA Registration No. 62432-2  
Application Dated July 9, 2004

Dear Mr. Jones:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

**Proposed Notification:**

- Adding effluent discharge labeling statement

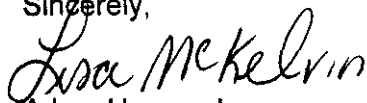
**General Comment:**

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Lisa McKelvin at (703) 308-7496.

Sincerely,

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

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United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number  
 295764

**Application for Pesticide - Section I**

1. Company/Product Number 62432-2	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. c/o Delta Analytical Corp. 7910 Woodmont Ave., Suite 1000 Bethesda, MD 20814  <input type="checkbox"/> Check if this is a new address	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. _____  Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

E. Notification: Use additional page(s) if necessary. (For section I and Section II.)

Notification pursuant to PR Notice 95-1 adding effluent discharge labeling statement.

I certify that this notification is consistent with PR Notice 95-1 and EPA regulations at 40 CFR 152.46 and that no other changes have been made to the labeling of this product. I further understand that if this notification is not consistent with the terms of PR Notice 95-1 and 40 CFR 152.46, then this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
* Notification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jeff Jones	Title Agent, Antec International Ltd.	Telephone No. (Include Area Code) 301 652 5495
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent, Antec International Ltd.	
4. Typed Name Jeff Jones	5. Date July 9, 2004	

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Duplicate  
Application  
Att 8/4/04  
No Reply  
Necessary

July 9, 2004

Document Processing Desk (NOTIF)  
Office of Pesticide Programs  
US EPA  
1801 Bell Street  
Arlington, VA 22202

Re: Virkon; EPA Reg. No. 62432-2; Notification of addition of effluent discharge labeling statement pursuant to PR Notice 95-1

Dear Sir or Madam:

I am notifying the Agency of the addition of the required effluent discharge labeling statement pursuant to PR Notice 95-1 to the Virkon label. Previously, Virkon has not been distributed in large containers, but it will be in the future. Accordingly I am adding the required effluent discharge statement. Attached please find the following documents supporting this notification:

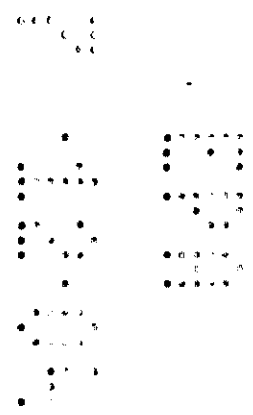
- Application for Pesticide Registration (EPA Form 8570-1)
- Proposed labeling (5 copies)
- Current stamped label

If you have questions regarding this submission, please contact me.

Sincerely,

T. Jeffrey Jones, Agent  
Antec International Ltd.

Attachments



4 8 8

**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, and 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.]

<b>ACTIVE INGREDIENTS</b>	
Potassium peroxymonosulfate	21.45%
Sodium chloride	1.50%
<b>OTHER INGREDIENTS</b>	<u>77.05%</u>
<b>TOTAL</b>	<b>100.00%</b>

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]

Front Panel Continued

**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.

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

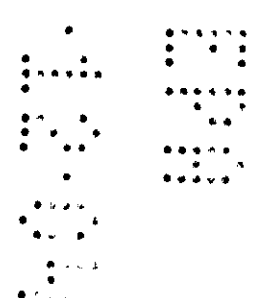
Sudbury, Suffolk, CO10 2XD, England

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



**DIRECTIONS FOR USE:**

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

***INSTITUTIONAL, FOOD PROCESSING, 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.

### 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.

[note to reviewer: Effluent discharge statement to be included for package sizes of greater than or equal to 5 gallons (liquid) or 50 pounds (solid, dry weight), in accordance with PR notice 95-1]

#### **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.

### **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.

<b>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.)</b>			
<b>VIRUCIDE, BACTERICIDE, FUNGICIDE</b>			
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 - 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	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.
<p>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.</p>			