

62432-1

8/1/2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

AUG - 1 2002

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. T. Jeffrey Jones
Delta Analytical Corporation
Agent for Antec International Ltd.
7910 Woodmont Avenue, Suite 1000
Bethesda, MD 20814

Subject: **Virkon S**
EPA Registration No. 62432-1
Application Dated June 17, 2002

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 the following comments:

Proposed Amendment

- Revised Labeling to incorporate changes made by notification

General Comments

1. Revise the statement, "For Use in Emergency Disease Control (OPT)" to read similar to the following:

"For use in the control of animal health pathogens listed on the label and emergency disease out break"

2. Please explain meaning of the abbreviation "OPT". I assume it means "optional".

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

CONCURRENCES

SYMBOL								
SURNAME								

23 11

If you have any questions 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 be 'AH' with a long horizontal stroke extending to the right.

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

Enclosure

Virkon® S
BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities (OPT.)

Effective against Viruses
(including CANINE PARVOVIRUS) • Bacteria • Fungi

For Use in Emergency Disease Control (OPT.)

For Use in Cleaning and Disinfecting Institutional Food Processing and Service Facilities including food handling and food preparation areas of restaurants and food processing plants, stores, hospitals, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses (OPT.)

For Use in Emergency Response and On-site Cleaning to meet emergency calls, crime scenes, traffic accidents, fires, flood, natural and other emergencies, cars, trucks, ambulances, and similar emergency apparatus, tires, wheels, floors, walls, ceilings, pavements, and equipment such as Stetson coats, boots, hats, masks, gloves, axes, jaws of life and similar emergency equipment (OPT.)

For Use in Greenhouses, Horticulture, and Aquaculture (OPT.)

ACTIVE INGREDIENTS:

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
OTHER INGREDIENTS.....	78.1%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER

See [Back] [Side] Panel[s] [Inside Booklet] for Additional Precautions

ACCEPTED
with COMMENTS
EPA Letter Dated:

AUG - 1 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 62432-1

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.

___ lbs. (___) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

Antec
International
LEADERS IN BIOSECURITY

Manufactured By:

ANTEC INTERNATIONAL LTD.
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England

Virkon[®] S is a registered trademark of and manufactured by Antec International Limited
US Patent No. 4822512

[Comment: The list of claims (sites) under "EFFECTIVE AGAINST" may be placed in any order as long as each subheading and its contents remains intact.]

EFFECTIVE AGAINST FOLLOWING ANIMAL HEALTH PATHOGENS:

EQUINE BACTERIA

Clostridium perfringens
Fistulous withers (Poll Evil)
Taylorella equigenitalis
Streptococcus equi (Strangles)
Pseudomonas mallei
(Glanders)
Bordetella bronchiseptica

EQUINE VIRUSES

African Horse Sickness
Equine Viral Arteritis
[Pink Eye]
Coital Exanthema
Myeloencephalopathy
Rhinopneumonitis
Equine Infectious Anemia
(Swamp Fever)
Equine papillomatosis
Equine Contagious Abortion
Adenovirus Pneumonia
Equine Influenza (The Cough)

EQUINE FUNGI

Trichophyton spp.
(Ringworm)
Trichophyton spp.
(Mud Fever)
Fusarium moniliforme

BOVINE BACTERIA

Moraxella bovis
Mycobacterium bovis
Haemophilus somnus

BOVINE VIRUSES

Calf rotavirus
Infective Bovine
Rhinotracheitis

Bovine Adenovirus Type 4

Pseudorabies
Foot & Mouth Disease

BOVINE FUNGI

Fusarium moniliforme

POULTRY BACTERIA

Streptococcus pyogenes
Campylobacter pyloridis
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum
Clostridium perfringens
Bordetella avium

POULTRY VIRUSES

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease
Avian Laryngotracheitis
Avian Influenza
Marek's Disease
Egg Drop Syndrome
Adenovirus

Turkey Herpes Virus

Duck Herpes Virus
Duck Viral Enteritis

POULTRY FUNGI

Aspergillus flavus
Aspergillus fumigatus
Candida albicans

SWINE BACTERIA

Bordetella bronchiseptica
Pasteurella multocida
Actinobacillus
pleuropneumonia
Treponema hyodysenteriae
Clostridium perfringens
SWINE VIRUSES

Hog Cholera
Swine Influenza
Porcine parvovirus
Rotaviral diarrhea
Vesicular stomatitis
Pseudorabies
Porcine Reproductive and
Respiratory Syndrome
(PRRS)
African Swine Fever
Foot and Mouth Disease

SWINE FUNGI

Fusarium moniliforme

COMPANION ANIMALS

BACTERIA

Staphylococcus aureus
Streptococcus pyogenes
Klebsiella pneumoniae
Pseudomonas aeruginosa

VIRUSES

Canine Parvovirus
Distemper
Leptospira canicola
Feline parvovirus
Feline herpes
Feline calicivirus

FUNGI

Microsporum canis

EFFECTIVE AGAINST THE FOLLOWING HUMAN HEALTH PATHOGENS

Human Immuno-Deficiency Virus (HIV), Streptococcus pyogenes, Campylobacter pyloridis, klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans.

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 thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. **Corrosive statement refers to powder only not in use solution.**

[Comment: The instructions under "DIRECTIONS FOR USE" may be placed in any order as long as they remain a continuous section on the label.]

BROAD SPECTRUM DISINFECTANT

Virkon_® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material. Virkon_® S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. **Apply a 0.5% (1:200) solution for routine sanitation.**

DIRECTIONS FOR USE

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

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
 2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
 3. Empty all troughs, racks, and other feeding and watering appliances.
 4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
 5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
 6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
 7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
 8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.
- This powder formula is easily diluted for use in manual or machine operations.

Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder to achieve recommended solution concentration.

Quantity of Water	0.5% Solution	1% Solution	2% Solution
1 Quart	0.15 ounces	0.3 ounces	0.7 ounces
1 Gallon	0.65 ounces	1.3 ounces	2.7 ounces
10 Gallons	6.7 ounces	13.4 ounces	26.7 ounces
50 Gallons	33.4 ounces	66.8 ounces	133.5 ounces

~~1.3 oz. measuring scoop is provided. Measuring cup provided.~~

Add ~~[1.3 oz. (1 scoop) of Virkon® S [the contents of one Virkon® S packet] to one gallon of warm water.~~ Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

POULTRY [PRODUCTION] [AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - Aspergillus flavus, Aspergillus fumigatus and Candida albicans. Bacteria - Streptococcus pyogenes, Campylobacter pyloridis, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella avium and Mycoplasma gallisepticum.]

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatches, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus).

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

SWINE PRODUCTION

[CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.]

Follow General Instructions to remove swine and pre-clean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants (use a 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus), and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

[CONTROLS: Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.]

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES:

Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

[CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies and Foot and Mouth Disease; Bacteria of *Maraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.]

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon[®] S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

[CONTROLS: Viruses Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*.]

[APPLICATIONS] A 1% solution of Virkon[®] S is recommended as a "one step" cleaning and disinfecting procedure for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon[®] S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon[®] S is intended to disinfect or maintain environmental surfaces, glasshouse structures, equipment, utensils, trays, containers, and vehicles in greenhouses and other horticultural settings prior to introduction or redistribution of plants, seeds or soil. It is not intended to directly affect horticultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

Remove all dirt, debris, slimes and other deposits from structures, empty trays and pots. Power wash all the dust off the covering and superstructure and let dry. Using a sprayer or fogger saturate all surfaces with a 1% solution of Virkon[®] S. Let air dry.

Virkon[®] S may also be used to disinfect irrigation tanks and lines. Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon[®] S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog

(wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Virkon[®] S is intended to disinfect/inactivate environmental surfaces associated with aquaculture including vehicles, nest boxes, waders, dive suits, hoses, brushes and other similar equipment. Virkon[®] S may also be used in foot dips. Virkon[®] S must not be applied directly to water.

Equipment used in separate fish tanks, ponds or aquaculture settings should be disinfected before reuse by soaking for 40-60 minutes in 1% Virkon[®] S solution followed by a water rinse.

Virkon[®] S at 1% solution is recommended for use in treating foot and mouth operations of at symptomatic animals prior to or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacture's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANTHRAZIS PREVENTION)

CONTROL OF ORBIS A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (CSFV), Cholera Virus, African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus.

A 1% solution of Virkon[®] S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon[®] S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon[®] S for long periods - 10 minutes is maximum contact time.

INSTITUTIONAL FOOD PROCESSING AND SERVICE FACILITIES (HUMAN HEALTH)

CONTROLS: Human Immuno-Deficiency Virus (HIV), Streptococcus pyogenes, Campylobacter pyloridis, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, and Candida albicans.

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

Do Not Use Virkon S on acid sensitive surfaces, surfaces made of acid metal, stainless steel, copper, brass or aluminum. Avoid splashing Virkon S solution on clothes or children. Virkon S 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 excess dirt and prepare a 2.0% solution according to the Dilution Chart. 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 excess dirt and use a 2.0% Virkon S solution prepared according to the Dilution Chart. Apply to surface using a mop, sponge, brushes, or spray device until the surface is visibly clean. Also dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon S solution.

Sanitizing Toilet Bowls: After flushing, sprinkle 1 oz. Virkon S powder around the bowl, scrub with a brush, and leave for 10 minutes. Flush.

Cleaning and Disinfecting Mantles Used in CPE Training: Mantles should be cleaned as soon as possible at the end of each class to avoid the risk of contamination on surfaces. Disassemble the mantles as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable moisture proof fields with a brush using a 2% Virkon S solution. Let stand for 10 minutes and rinse with potable water.

EMERGENCY RESPONSE AND GROSS CLEANUP

Cover heavy spillage of body fluids with Virkon S powder. Let stand for 10 minutes, and then scoop into plastic bag. Treat bag and its contents as infectious medical waste.

Prepare 2% Virkon S solution according to the Dilution Chart. Apply to surface to be treated using a mop, sponge, brush or spray device until the surface is visibly clean. Air dry.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.