

62432-1

9/19/2001

Page 1 of 9

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY


 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 WASHINGTON, DC 20460

SEP 19 2001

 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: Amendment for Additional Use Sites
 Virkon S
 EPA Registration No. 62432-1
 Amended Application Dated April 25, 2001

Dear Mr. Jones:

This letter acknowledges receipt of your application for amendment for adding additional use sites to the label.

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable with the following comments.

I. FARM PREMISES:

The following label directions are required for farm premises disinfectants to permit their classification as non-food use products:

\ Directions for Use

1. Do not use in milking stalls, milking parlors, or milk houses (for phenolics, cresylic acid, and pine oils).
2. Remove all animals and feed from premises, vehicles, and enclosures.
3. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

4. Empty all troughs, racks, and other feeding and watering appliances.
5. Thoroughly clean all surfaces with soap or detergent and rinse with water.
6. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
7. 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.
8. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

II. POULTRY HOUSE:

Directions for Use

The following label directions are required for poultry house disinfectants to permit their classification as non-food use products:

1. Remove all poultry and feeds from premises, trucks, coops, and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
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. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

A stamped copy is enclosed for your records.

If you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely yours,



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

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4 8 9
Page 1

VIRKON-S®
BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

ACTIVE INGREDIENTS:

Potassium peroxymonosulfate..... 20.4%

Sodium Chloride..... 1.5%

INERT INGREDIENTS..... 77.1%

TOTAL..... 100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER

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

___ lbs. (___) Net Weight

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

ANTEC INTERNATIONAL LTD.
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England
Tel: (1787) 77305 Telex: 987495 Fax: (1787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited
US Patent No. 4822512

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

EFFECTIVE AGAINST:

EQUINE BACTERIA

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

EQUINE VIRUSES

African Horse Sickness
African 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
Rhinothraeitis
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 choleaesuis
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

POULTRY FUNGI

Turkey Herpes Virus
Duck Herpes Virus
Duck Viral Enteritis
Aspergillus flavus
Aspergillus fumigatus
Candida albicans

SWINE BACTERIA

Bordetella bronchiseptica
Pasteurella multocida
Actinobacillus
pleuropneumonia
Treponema hyodysenteria
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

Streptococcus aureus
Streptococcus pyogenes
Klebsiella pneumoniae
Pseudomonas aeruginosa

VIRUSES

Canine Parvovirus
Distemper
Leptospira canicola
Feline parvovirus
Feline herpes
Feline calicivirus

FUNGI

Microsporium canis

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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.

FIRST AID

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.
IF INHALED: If symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.
IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.
NOTICE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling

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.

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Quantity of Water	Amount of Powder for 1% Solution	Amount of Powder for 2% Solution
1 Quart	0.3 ounces	0.7 ounces
1 Gallon	1.3 ounces	2.7 ounces
10 Gallons	13.4 ounces	26.7 ounces
50 Gallons	66.8 ounces	133.5 ounces

1.3 oz. measuring scoop is 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 for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

POULTRY [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 choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

HATCHERIES: VIRKON-S at 1% solution can be used for cleaning and disinfecting hatchers, 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: Remove chickens [birds], feed, and water troughs, then remove manure and litter. 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 1-2% 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*.

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, water-proof footwear (rubber boots), and associated livestock equipment and instruments.

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VIRKON-S at 1-2% 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.

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.

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COMPANION ANIMALS

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9 3 9
Page 6

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,] [infections 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.

EMERGENCY DISEASE CONTROL

(²) **CONTROLS:** Foot and Mouth Disease 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.

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

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