

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

April 19, 2018

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Ellen M. Baldassare Regulatory Affairs & Product Stewardship Consultant Lanxess Corporation 111 RIDC Park West Drive Pittsburg, PA 15275

Subject: Label Notification per PRN 98-10 –Minor Label Changes are listed below:

- Addition of pictograms/visuals on how to make VirkonTM S solution according to already approved directions and at already approved dilutions and volumes
- Addition of optional marketing claims
- > Addition of optional pictograms and language describing (already approved) product use sites
- Addition of optional distributor address information
- Minor corrections to punctuation and brackets
- > Updated year to include 2018 on copyright statements
- In addition, registrant also requesting to add a claim for disinfection of the non-OIE list pathogen, Porcine Rotavirus. The claim is supported by efficacy data, but not submitted because FIFRA 2(ee) claims are not subject to data review. Chapter 4 of the pesticide registration manual guidance that animal disease and zoonotic micro-organisms not on the OIE list are not public health pathogens and do not require submission of efficacy data to support label claims.

Product Name: VirkonTM S

EPA Registration Number: 39967-137 Application Date: March 16, 2018

Decision Number: 540012

Dear Ms. Baldassare:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition,

Page 2 of 2 EPA Reg. No. 39967-137 Decision No. 540012

regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Srinivas Gowda at 703-308-6354 or via email at gowda.srinivas@epa.gov.

Sincerely,

Sounda for Jacqueline Hardy

Product Manager – Team 34

Regulatory Management Branch II

Antimicrobials Division (7510P)

Enclosure: "Notification" Stamped EPA Label

TEXT IN {BRACES} ARE COMMENTS TO REVIEWER

Alternate Brand Names: [Virkon™ S Disinfectant and Virucide – ABN]

[VirkonTM Aquatic Disinfectant and Virucide – ABN] [trifectantTM Broad Spectrum Disinfectant – ABN]

[VirkonTM VC Disinfectant and Virucide for Veterinary-use-ABN]

{deletion/correction to remove word "use" made in order to match PPLS listing}

VirkonTM S

[Disinfectant and Virucide]

[BROAD SPECTRUM DISINFECTANT,][FUNGICIDE] [& ALGAECIDE]

[Fragrance Free] [and] [Reduced Dye] [Fragrance and Dye Free]

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

[For Use in Emergency Disease Control]

Effective against Viruses*

Bacteria

Fungi

[Including Canine Parvovirus*]

ACTIVE INGREDIENTS:

Potassium peroxymonosulfate Sodium Chloride OTHER INGREDIENTS

TOTAL

NOTIFICATION

39967-137

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/19/2018

[Equivalent to 9.75% Available Chlorine]

KEEP OUT OF REACH OF CHILDREN DANGER/PELIGRO

[See [Inside Booklet][back panel] [side panel] for [Additional Precautions] [and] [Directions for Use and Disposal instructions

21.41% 1.50%

77.09%

100.00%

[See [side]]/][back] panel for additional precautions and leaflet for additional directions for use] [See Side Panel for Precautionary Statements]

[Refer to accompanying labeling for additional precautions and complete directions for use] [See leaflet for additional directions for use [and * explanatory notes.]]

EPA Reg. No. 39967-137

EPA Est. No. XXXXX-YY-ZZZ

<Lot or batch #> [Product Code#]

[Net Contents: XXX [(X-containers)] [(tablets)][see individual container]

[POWDER FORM]

[TABLET FORM] [TABLETS]

[SACHET FORM] [INDIVIDUAL SACHETS]

Revision Submission Date: March 16, 2018

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{deletion/correction to remove word "use" made in order to match PPLS listing}

Front Panel Continued

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[©[2017][2018] LANXESS. trifectant™ is a registered trademark of Antec International Ltd.]

FIRST AID		
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 or Clothing:	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.	
If Swallowed:	Call a 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	
HOTEL BUT MAN (DED		

HOT LINE NUMBER

For 24-hour emergency information on this product, call 866-673-6350. 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.

Manufactured for: Lanxess Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275 [Distributed by: Vetoquinol USA Inc. 4250 N. Sylvania Ave Fort Worth, Texas 76137]

For information: US/Canada (800) LANXESS International +1 412 809 1000

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EFFECTIVE AGAINST THE FOLLOWING [PATHOGEN[S]]:

[ANIMAL AND ZOONOTIC PATHOGENS]

BACTERIA

[Actinobacillus pleuropneumoniae]

[Bacillus cereus]

[Brucella abortus]

[Campylobacter jejuni]

[Clostridium perfringens]

[Dermatophilus congolensis]

[Escherichia coli]

[Klebsiella pneumoniae]

[Mycoplasma gallisepticum]

[Mycoplasma hyopneumonia]

[Pasteurella multocida]

Pseudomonas aeruginosa

Salmonella enterica

Salmonella typhimurium

[Shigella sonnei]

[Staphylococcus aureus]

[Staphylococcus epidermidis]

[Streptococcus pyogenes]

[Streptococcus suis]

[Not approved in California for use against the following bacteria]

[Bordetella avium]

[Bordetella bronchiseptica]

[Fistulous withers (Poll Evil)]

[Haemophilus somnus]

[Helicobacter pylori]

[Leptospira canicola]

[Listeria monocytogenes]

[Moraxella bovis (Pink Eye)]

[Mycoplasma mycoides]

[Pseudomonas mallei (Glanders)]

[Pseudomonas vulgaris]

[Streptococcus equi (Strangles)]

[Taylorella equigenitalis]

[Treponema hyodysenteriae]

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VIRUSES*

Avian Influenza Virus

[Avian Laryngotracheitis Virus]

[Bovine Adenovirus Type 4]

[Canine Adenovirus (Canine Hepatitis)]

[Canine Parvovirus]

[Equine Herpes Virus (Type 1)]

[Equine Herpes Virus (Type 3)]

[Equine Influenza Virus (Type A)]

[Feline Calicivirus]

[Feline Panleukopenia Virus]

[Feline Rhinotracheitis Virus]

[Foot and Mouth Disease Virus]

[Newcastle Disease Virus]

[Simian Virus (SV40 Virus)]

[Not approved in California for use against the following viruses*:]

[Adenovirus Pneumonia]

[African Horse Sickness Virus]

[African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)]

[Bovine Polyoma Virus]

[Bovine Pseudocowpox Virus]

[Bovine Viral Diarrhea Virus (no hard water)]

[Calf Rotavirus (no hard water)]

[Canine Coronavirus]

[Canine Parainfluenza Virus]

[Chicken Anemia Virus]

[Coital Exantherma Virus]

[Distemper Virus]

[Duck Adenovirus (no hard water)]

[Duck Enteritis Virus]

[Egg Drop Syndrome Adenovirus]

[Equine Infectious Anemia Virus (Swamp Fever)]

[Equine Arteritis Virus (no hard water)]

[Equine Contagious Abortion Virus]

[Equine Papillomatosis Virus]

[Equine Influenza Virus (The Cough)]

[Feline Herpes Virus]

[Feline Infectious Peritonitis Virus]

[Feline Parvovirus]

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[Hog Cholera Virus]

[Infectious Bronchitis Virus]

[Infectious Bursal Disease Virus]

[Infectious Canine Hepatitis Virus]

[Infectious Pancreatic Necrosis Virus]

[Infectious Salmon Anaemia Virus]

[Infective Bovine Rhinotracheitis Virus (no hard water)]

[Maedi- Visna Virus]

[Marek's Disease Virus]

[Mouse Parvovirus]

[PCV2 Virus (PMWS)]

[Porcine Epidemic Diarrhea Virus]

[Porcine Parvovirus]

[Porcine Reproductive and Respiratory Syndrome Virus (PRRS)]

[Porcine Rotavirus]

[Pseudorabies Virus (Aujesky's Disease) (no hard water)]

[Rotaviral Diarrhea Virus]

[Snakehead Rhabdovirus]

[Swine Influenza Virus]

[Swine Vesicular Disease Virus]

[Transmissible Gastroenteritis Virus (TGE) (no hard water)]

[Turkey Herpes Virus (no hard water)]

[Turkey Rhinotracheitis Virus]

[Vesicular Stomatitis Virus]

[FUNGI]

[Trichophyton mentagrophytes (2%)]

[Not approved in California for use against the following fungi:]

[Aspergillus flavus]

[Aspergillus fumigatus]

[Fusarium moniliforme]

[Microsporum canis]

[Trichophyton spp. (Ringworm)]

[Trichophyton spp. (Mud Fever)]

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[PLANT PATHOGENS]

[Not approved in California for use against plant pathogens]

[Alternaria solani]

[Botrytis cinera]

[Colletotrichum coccodes]

[Didymella bryoniae]

[Fusarium oxysporum]

[Fusarium solani]

[Penicillium oxalicum]

[Phomopsis sclerotioides]

[Pyrenochaeta lycoopersici]

[Pythium aphanidermatium]

[Rhizoctonia solani]

[Sclerotinia sclerotiorum]

[Thielaviopsis basicola]

[Verticillium dahliae]

[Xanthomonas axonopodis]

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Corrosive statement refers to powder only not in use-diluted solution.

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.

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BROAD SPECTRUM DISINFECTANT

VirkonTM S is effective against numerous microorganisms affecting animals: viruses*, gram positive and gram negative bacteria, fungi (molds and yeasts – Not Approved for this use in California), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses* was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution."

[Respiratory illnesses attributable to Pandemic 2009 H1N1are caused by influenza A virus. VirkonTM S [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses* including Pandemic 2009 H1N1 (formerly called swine flu).]

[This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus*.]

[This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses* including Pandemic 2009 H1N1 (formerly called swine flu).]

[Kills Pandemic 2009 H1N1 influenza A virus* (formerly called swine flu).]

[Kills Pandemic 2009 H1N1 influenza A virus*.]

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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

[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 use-diluted 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.]

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deletion/correction to remove word "use" made in order to match PPLS listing

[Fogging (Wet Misting) Instructions –

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

Close room off, so fog is confined to room to be treated.

Prepare a VirkonTM S dilution of 0.5% to 2.0% in water (1:200 to 1:50) - (refer to specific directions for Poultry, Swine, Bovine, Greenhouse and Aquaculture uses.).

Apply use-diluted solution at an application rate of 1 gallon per 430 ft² of floor space. Use a mechanical or plumbed in misting system designed for water-based applications with a droplet size of greater than 50 microns, or a pressure washer/knapsack or tank sprayer to deliver fine mist. Insert the nozzle of the fogging device through a suitable opening in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Do not house animals or use equipment until treatment has dried. Rinse waterers and feeders with potable water before reuse. Rinse foggers and sprayers with potable water following use.

Note: Individuals must avoid entering the building or room during fogging. If the building or room must be entered, then individuals entering must wear a NIOSH/MSHA approved respirator, plus goggles, long sleeve shirts and pants.]

[Virkon™ S DILUTION CHART

To achieve the appropriate use-diluted VirkonTM S concentration, fill container with the volume of water and quantity of powder or tablet(s) found in the following table. [For a 1% solution, add one (1) tablet to one pint of water.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water.] .

[Powder

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

Measuring cup provided.]

]

Note to reviewer: TEXT IN [BRACKETS] IS OPTIONAL

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[Tablet

Quantity of Water	0.5% Solution†‡	1% Solution	2% Solution
1 Pint	-	1 tablet	2 tablets
1 Quart	1 tablet	2 tablets	4 tablets
1 Gallon	4 tablets	8 tablets	16 tablets

[Sachet

Quantity of Water	0.5% Solution††	1% Solution	2% Solution
1 Gallon	-	1 Sachet	2 Sachets
2 Gallons	1 Sachet	2 Sachets	4 Sachets

†† The 0.5% solution currently is not approved for use in California.

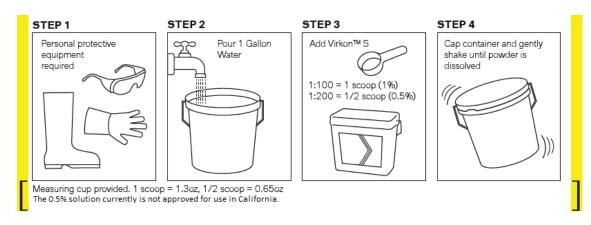
Solutions are stable for 7 days. Do not soak metal objects in VirkonTM S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations.]

{Dilution tables specific to each product form are optional and will appear on the appropriate form's label}

{Optional pictograms for making an in-use solution, using select volumes from the dilution chart. }

[How to make a ready-to-use VirkonTM S disinfectant solution:]

{From powder instructions:}



Revision Submission Date: March 16, 2018 Page 10 of 25

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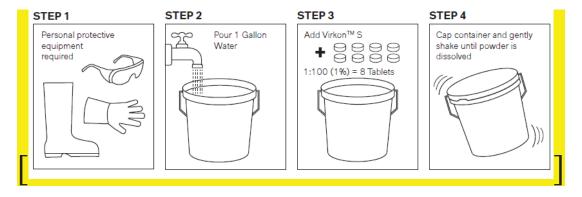
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[How to make a ready-to-use VirkonTM S disinfectant solution:]

{From tablet instructions:}



[POULTRY PRODUCTION AND RATITE PRODUCTION]

[CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis virus and Avian Influenza virus; Bacteria of Streptococcus pyogenes, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella enterica, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Mycoplasma gallisepticum. Not approved in California for use against the following organisms: Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease virus, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts – Not Approved for this use in California) Aspergillus flavus, Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium, Helicobacter pylori.]

[HATCHERIES: VirkonTM 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. Saturate surfaces with a 1% solution of VirkonTM S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

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[Fogging (Wet Misting) Instructions – Poultry and Ratite Production

Follow General Instructions to remove poultry and/or animals from room to be treated.

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

Close room off, so fog is confined to room to be treated.

Prepare a VirkonTM S at dilution of 1.0% to 2.0% in water (1:100 to 1:50).

Apply at an application rate of 1 gallon per 430 ft² of floor space. Use a mechanical or plumbed in misting system designed for water-based applications with a droplet size of greater than 50 microns, or a pressure washer/knapsack or tank sprayer to deliver fine mist. Insert the nozzle of the fogging device through a suitable opening in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Do not house animals or use equipment until treatment has dried. Rinse waterers and feeders with potable water before reuse. Rinse foggers and sprayers with potable water following use.

Note: Individuals must avoid entering the building or room during fogging. If the building or room must be entered, then individuals entering must wear a NIOSH/MSHA approved respirator, plus goggles, long sleeve shirts and pants.]

[BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with VirkonTM S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VirkonTM S. After contact for 10 minutes, rinse with potable water. Do not house poultry or use equipment until treatment has dried.]

[PROCESSING PLANTS: Spray Virkon™ S at 1% solution to disinfect and clean walls, ceilings and floors. Saturate surfaces for a period of 10 minutes. Allow surfaces to air dry.]

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[SWINE PRODUCTION].

[CONTROLS: Bacteria of; Actinobacillus Pleuropneumoniae and Clostridium perfringens; Foot and Mouth Disease virus, Fungi of Trichophyton mentragrophytes (2%). Not approved in California for use against the following organisms: Viruses of Hog Cholera, Swine influenza virus, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS), Porcine Rotavirus, Pseudorabies virus, Rotoviral Diarrhea virus falready included in approved pathogen list on page 5, adding to also appear in this section], African Swine Fever virus, Fungi of Fusarium moniliforme, and Bacteria of Treponema hyodysenteriae.]

[Follow General Instructions to remove swine and preclean area to be treated. Use a 1% solution of VirkonTM S for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments. Saturate surfaces with a 1% solution of VirkonTM S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[Fogging (Wet Misting) --- Swine

Follow General Instructions to remove poultry and/or animals from room to be treated.

Use a 0.5% -1.0% solution of VirkonTM S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%*. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)].

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[EQUINE PRODUCTION] [BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES AND EQUIPMENT]

[CONTROLS: Viruses of Equine herpes Type 1 and Type 3 and Equine Influenza. Bacteria of; Brucella abortus, Clostridium perfringens, Dermatophilus congolenisis (at 2%), Pseudomonas aeruginosa, Salmonella typhimurium and Staphylococcus aureus. Fungi of Trichophyton mentagrophytes (at 2%). Not approved in California for use against the following organisms: Fungi of Fusarium moniliforme, Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).]

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

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Follow general instructions to remove animals from area to be treated. Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% VirkonTM S solution, saturating surfaces for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[To Clean Blankets, Saddle Pads and Rugs: *Not an approved use in California*: Using a 1% solution of VirkonTM S, shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.]

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[Virkon™ Aquatic Disinfectant and Virucide – ABN] [trifectant™ Broad Spectrum Disinfectant – ABN]

[VirkonTM VC Disinfectant and Virucide for Veterinary-use-ABN]

{deletion/correction to remove word "use" made in order to match PPLS listing}

[BOVINE PRODUCTION]

[CONTROLS: Bovine Adenovirus Type 4, Foot and Mouth Disease virus; Fungi of Trichophyton mentragrophytes(2%). Not approved in California for use against the following organisms: Bacteria of Moraxella bovis and Fungi of Fusarium moniliforme. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, and Bacteria of Haemophilus somnus.]

[Follow General Instructions to remove livestock and preclean area to be treated. Use a 1% solution of VirkonTM S 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. Saturate surfaces with a 1% solution of VirkonTM S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[Fogging (Wet Misting) --- Bovine

Follow General Instructions to remove poultry and/or animals from room to be treated.

Use a 0.5% -1.0% solution of Virkon™ S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)].

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[COMPANION ANIMALS]

[CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. Fungi of Trichophyton mentragrophytes(2%). Not approved in California for use against the following organisms: Viruses of Distemper, Feline parvovirus, Feline herpes; Bacteria of Leptospira canicola; Fungi of Microsporum canis.]

[APPLICATIONS: Use a 1% solution of VirkonTM S as a "one step" cleaning and disinfecting procedure (Remove gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems]within or [associated with]Veterinary Medical Hospitals, animal infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles. Saturate surfaces with a 1% solution of VirkonTM S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

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

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[GREENHOUSES AND HORTICULTURE]

[VirkonTM S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. Not approved in California for use on ventilation and other equipment and water systems. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.]

[For surfaces and equipment

- 1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.
- 2) Use a dilution of 1:100 or 1.3 oz. Virkon™ S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been precleaned with water to remove organic deposits. Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to remove organic deposits.
- 3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.
- 4) Heavy growth of algae or fungi may have to be scrubbed off following application.
- 5) Reapply as often as needed for control. For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of VirkonTM S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of VirkonTM S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.]

[For evaporative coolers: Not approved use in California: Treat existing algae and slime-contaminated surfaces with a 1:100 dilution of VirkonTM S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of VirkonTM S for every gallon of cooler water.]

[VirkonTM S may also be used to disinfect irrigation tanks and lines. Not approved use in California: 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.]

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Note to reviewer: TEXT IN [BRACKETS] IS OPTIONAL

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{deletion/correction to remove word "use" made in order to match PPLS listing}

[Fogging (Wet Misting) Instructions – Greenhouse/Horticulture

[Use a 0.5% -1.0% solution of VirkonTM S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%*. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)].

[AQUACULTURE].

[Not approved for this use in California]

[VirkonTM S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. VirkonTM S may also be used in foot dips. VirkonTM S must not be applied directly to water.]

[Equipment used in separate sites, tanks, ponds in aquaculture settings must be disinfected before each new use by soaking for 20-30 minutes in a 1% VirkonTM S solution followed by a water rinse.]

[Fogging (Wet Misting) Instructions -- Aquaculture

Use a 0.5% -1.0% solution of VirkonTM S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%*. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use. Refer to Fogging (Wet Misting instructions)].

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[EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)]

[Disinfection helps to control and prevent the cross-contamination of OIE List A organisms including; Newcastle Disease Virus, Foot and Mouth Disease Virus, African Horse Sickness Virus†, Vesicular Stomatitis Virus†, Classical Swine Fever Virus†, (Hog Cholera virus†), African Swine Fever Virus†, Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus†, and Mycoplasma mycoides† (Contagious Bovine Pleuropneumonia†). †Not approved for this use in California.]

[Use a 1% solution of VirkonTM S 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 VirkonTM 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. Saturate surfaces for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

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

[DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISM PCV2 VIRUS*

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection. However, VirkonTM S is an effective disinfectant for all hard, non-porous surfaces against the following organism at the dilution rates specified below. If the threat is known and limited to one of the organism below, VirkonTM S may be used at the following dilution rates:

Organism	Dilution Rate	Oz./Gallon	
PCV2 virus* (PMWS)	1:200	0.7]

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[USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS]

[Use a 1% solution of Virkon™ S to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon™ S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that VirkonTM S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, VirkonTM S may only be applied using hand-held sprayers, sponges or other absorbent materials. Do not allow VirkonTM S to pool on surfaces that may be within reach of animals. Do not allow VirkonTM S to come into direct contact with people. Allow VirkonTM S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.]

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

For pails, [jugs], [bottles]: Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. [Retain desiccant canister with product during storage.] Do not mix this product with other chemicals.

For [sachet] [pouch] [packet] [bag]: Store in a cool dry place. Keep out of reach of children. [Retain desiccant canister with product during storage.] Do not mix this product with other chemicals.

[For spray bottle with in-use solution: Store in a cool dry place. Keep out of reach of children. Do not mix this product with other chemicals.]

PESTICIDE DISPOSAL: Pesticide wastes may be hazardous. [Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot 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.] [1] [-refer to product [leaflet] [insert] [booklet] [label] for pesticide disposal instructions]

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. [Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment.] [Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.] [1-refer to product [leaflet] [insert] [booklet] [label] for container disposal instructions]

{\(^1\)}Note to reviewer: When the size of container prohibits fitting full statement on the container, the text in brackets denoted in [\(...\)] \(^1\)above will be replaced with the below statement in red:

[-refer to product [leaflet] [insert] [booklet] [label] for pesticide disposal instructions]

Please note this will only occur when the full statement (denoted in $[...]^l$) instead appears on additional labeling accompanying or included with each container of product.}

 2 Note to reviewer: When the size of container prohibits fitting full statement on the container, the text in brackets denoted in [...] 2 above will be replaced with the below statement in red:

[-refer to product [leaflet] [insert] [booklet] [label] for pesticide disposal instructions]

Please note this will only occur when the full statement (denoted in $[...]^2$) instead appears on additional labeling accompanying or included with each container of product.}

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{Optional company logo-may appear in color, black only, or grey scale}



[LANXESS] [LANXESS = Energizing Chemistry

{Optional Product Specific Branding/Marketing Logos- may appear in color, black only, or grey scale}

>> Virkon™

» Virkon™

>> Virkon[™]

S

S

li S

[>> Virkon™ S{][}>> Virkon™ S_{][}>> Virkon™ S_]



>Virkon™ AQUATIC **≫Virkon**™ AQUATIC









{←These brand logos are specific to

the tablet form of the product only and will only appear on the appropriate form's labeling}

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{Pictograms optional for use on Front panel of label}





{Pictograms optional for use on Front panel of label when label contains aquaculture instructions}



only of trifectantTM}

Optional tablet picture to be used on insert/leaflet for tablet form

{Additional Marketing Claims}

[Will not harm most surfaces upon incidental contact]

[Will not harm most hard non-porous surfaces]

[Compatible with most surfaces upon incidental contact]

[Compatible with most hard non-porous surfaces]

[Non-damaging to most surfaces upon incidental contact]

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[Non-damaging to most hard non-porous surfaces]

[Made][Manufactured] in the USA]{Optional logo to appear on back or side panel. May



appear in color or black and white: [MADE IN THE USA] [This text and/or logo will only appear on product manufactured in the US (at an EPA Registered Establishment, located in the USA) [MADE IN THE USA]

[A key component to a successful [aquaculture, swine, poultry, dairy, equine, animal farm] biosecurity program.]

[Destroys bacteria, fungi, viruses* on hard non-porous surfaces found in [swine], [poultry], [diary], [equine]; [farms] and [animal holding facilities]]

[Destroys bacteria, fungi, viruses* on hard non-porous surfaces found in [shelters] and/or [vet] [clinics] [practices]]

[Biosecurity disinfectant]

[Safe to use on floors, equipment, cages and kennels, when used as directed]

[Cleans [mineral deposits associated with] hard water scale]

[Cleans stains from algae]

[Cleans hard water stains]

[Cleans mineral deposits]

[Compatible with most metals in [vehicle construction,] [vehicle disinfection,] [hog][/][swine][/][poultry] [transporter vehicle] [disinfectant] [or] [disinfection,] [hog][/][swine][/][poultry] [trailer vehicle] [disinfectant] [or] [disinfection].]

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{Optional pictograms and text for marketing pamphlets}

[VirkonTM S in-use solutions can be used for:]

