

71654-6

12/2/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

DEC 2 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Thomas C. McEntee  
Product Registration Manager  
E.I. du Pont de Nemours and Company  
DuPont Chemical Solutions Enterprise  
Experimental Station (ESL402/3224A)  
P.O. Box 80402  
Wilmington, DE 19880-0402

**FILE COPY**

Subject: Notification Application per PR Notice 95-2  
**Virkon® S**  
EPA Registration Number: 71654-6  
Application Date: November 11, 2009  
Receipt Date: November 12, 2009

Dear Mr. McEntee:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 95-2.

**Proposed Notification:**

Addition of Influenza A virus (H1N1) label claim

**General Comment:**

Based on a review of the material submitted, the following comment applies:

The notification is acceptable.

Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email address at [garvie.heather@epa.gov](mailto:garvie.heather@epa.gov).

Sincerely,

ShaRon Carlisle  
(Acting) Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)



20116



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 71654-6	2. EPA Product Manager Sharon Carlisle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon(R) S	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) E.I. du Pont de Nemours and Company Dupont Chemical Solutions Enterprise, P. O. Box 80402 Experimental Station (ESL 402/3442A) Wilmington, DE 19880-0402  <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.

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

Notification - Label claims in accordance with Pandemic 2009 H1N1 Influenza Policy October 21, 2009. <http://www.epa.gov/oppad001/h1n1-guide.html>

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, 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 checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 10 lb., 1lb., 9 oz., 1.3 oz.		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> 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 Thomas C. McEntee		Title Product Registration Manager		Telephone No. (Include Area Code) 302 695 6856	
Certification 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 both under applicable law.					6. Date Application Received (Stamped) 
2. Signature 		3. Title Product Registration Manager			
4. Typed Name Thomas C. McEntee		5. Date November 11, 2009			



**Virkon® S**  
Disinfectant and Virucide

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

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] {OPT}

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities  
For Use in Emergency Disease Control [OPT]

Effective against  
•Viruses  
Including Canine Parvovirus [OPT]  
•Bacteria  
•Fungi

**NOTIFICATION**  
Date Reviewed: 1/21/09  
Reviewed By: A. Barrese

**ACTIVE INGREDIENTS:**

Potassium peroxymonosulfate.....	21.41%
Sodium Chloride.....	1.50%
<b>OTHER INGREDIENTS.....</b>	<b>77.09%</b>
<b>TOTAL.....</b>	<b>100.00%</b>

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER/PELIGRO**  
See Inside Booklet for Additional Precautions

POWDER FORM [OPT]

TABLET FORM [OPT]

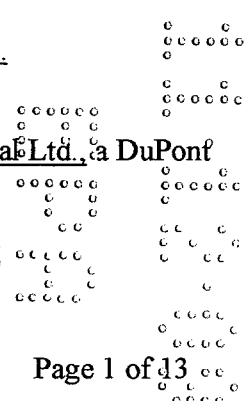
SACHET FORM [OPT]

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Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

EPA Reg. No. 71654-6

EPA Est. No. XXXXX-YY-ZZZ

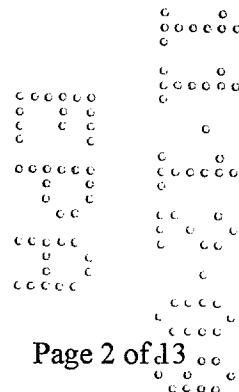


Front Panel Continued

<b>FIRST AID</b>	
<b>If in Eyes:</b>	<ul style="list-style-type: none"> <li>● Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>● Remove contact lenses, if present after 5 minutes, then continue rinsing eye.</li> <li>● Call a Poison Control Center or doctor for further treatment advice.</li> </ul>
<b>If on Skin or Clothing:</b>	<ul style="list-style-type: none"> <li>● Take off contaminated clothing.</li> <li>● Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>● Call a Poison Control Center or doctor for further treatment advice.</li> </ul>
<b>If Swallowed:</b>	<ul style="list-style-type: none"> <li>● Call Poison Control Center or doctor immediately for treatment advice.</li> <li>● Have Person sip a glass of water if able to swallow.</li> <li>● Do not induce vomiting unless told to do so by the poison control center or doctor</li> <li>● Do not give anything by mouth to an unconscious person</li> </ul>
<b>HOT LINE NUMBER</b>	
For 24-hour emergency information on this product, call 1-800-3637 (US & Canada) or 1-302-774-1100 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>Note to Physician:</b> Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufactured for:  
E.I. DuPont de Nemours and Company  
 PO Box 80023  
 Wilmington, DE 19880-0023  
 Questions? Call 1 800 441-7515

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

### 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.

#### Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT]

#### 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.

#### 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

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

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 is currently not approved for use in California.

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. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]

POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of Streptococcus pyogenes, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, 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, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts) Aspergillus flavus, Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium, Helicobacter pylori .

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatching, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

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 pre-clean 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. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* 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:** Bacteria of *Actinobacillus Pleuropneumoniae* and *Clostridium perfringens*; *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of *Fusarium moniliforme* Foot and Mouth Disease and Bacteria of *Treponema hyodysenteriae*.

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended 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.

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. *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.

### EQUINE PRODUCTION

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

**CONTROLS:** *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 Exanthema, 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: 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: *Not an approved use in California:* 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: *Not an approved use in California:* 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:** Bovine Adenovirus Type 4; *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, Foot and Mouth Disease and Bacteria of Haemophilus somnus.

Follow General Instructions to remove livestock and pre-clean 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 of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. *Not approved in California for use against the following organisms:* Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.

**APPLICATIONS:** A 1% solution of Virkon® S is recommended 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 [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 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 pre-cleaned 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 removed organic deposits.*



AQUACULTURE

*Not approved for this use in California*

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, 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 sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

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 manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

*Not approved for this use in California*

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

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.

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**DISINFECTANT LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS**

*Not approved for this use in California*

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

Disease Organism	Dilution rate	Oz./Gal.
PCV2 Virus (PMWS)	1:200	0.7

**USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS**

A 1% solution of Virkon® S is recommended 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 Virkon® 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, Virkon® S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

**STORAGE AND DISPOSAL**

**PESTICIDE STORAGE** Store out of reach of children.

**CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container.** 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.

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