

10190-14

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Bob MacDonald,
Scientific & Regulatory
Consultants, Inc.
P.O. Box 1014
Columbia City, In 46725

FEB -3 2010

Subject: Penetone XF-7117
EPA Reg. No.: 10190-14
Notification Date: January 4, 2010
EPA Receipt Date: January 4, 2010
Submission #: 865863

Dear Mr. MacDonald,

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

Proposed notification for alternative brand name spelling correction:

- Correction of alternative brand name from Penequat FD to Penquat FD
- Misspelling of "Porcine Circovirus Type 2" on the product's master label

General Comments

Based on a review of the submitted materials, your notification for the product "Penetone XF-7117" is acceptable. A copy of your notification has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

Velma Noble,
Product Manager -31

Regulatory Management Branch
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98



United States
Environmental Protection Agency
Washington, DC 20460

 Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 10190-14	2. EPA Product Manager V. Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PENETONE XF-7117	PM # 31	
5. Name and Address of Applicant (Include ZIP Code) Penetone Corporation 700 Gotham Parkway Carlstadt NJ 07072 <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 of ABN and correct misspelling per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Metal	<input checked="" 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
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container			4. Size(s) Retail Container 1,5,30,55,250,330,345,350,478,500,550		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product		
6. Manner in Which Label is Affixed to Product				<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
				<input type="checkbox"/> Other _____			

Section - IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Bob MacDonald	Title Agent for Penetone Corporation	Telephone No. (Include Area Code) 260-244-6270
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 or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Brooke Buchanan for</i>	3. Title Agent for Penetone Corporation	
5. Typed Name Bob MacDonald	5. Date 4 JAN 2010	

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Scientific & Regulatory
Consultants, Inc.

January 4, 2010

Ms. Velma Noble, PM-31
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: PENETONE XF-7117
EPA Reg. No. 10190-14

Dear Velma:

On behalf of our client Penetone Corporation (Penetone) enclosed is a notification for an Alternate Brand Name for subject product. This submission is a notification per PR Notice 98-10 therefore **no PRIA fees are applicable.**

The Alternate Brand Name (ABN) for the above subject product is **PENQUAT FD**. The notification dated December 28, 2009, had a misspelling of the ABN as Peneguat FD. In addition to the ABN notification, a misspelling of Porcine Circovirus Type 2 has been corrected. The organism change has been highlighted in red on the attached label.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 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.

Please contact me at 260-244-6270 for questions or concerns regarding this action.

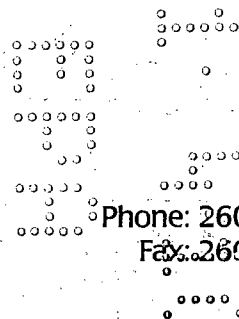
Sincerely,



Bob MacDonald
Agent for PENETONE CORPORATION

P.O. Box 1014
Columbia City, IN 46725

www.srcconsultants.com



Phone: 260-244-6270
Fax: 260-244-6273

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FIRST AID
Have the product container or label with you when calling the poison control center or doctor, or going for treatment.
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 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 the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF SWALLOWED: Call a poison control 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 a 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.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER Keep Out of Reach of Children. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. Harmful if swallowed. Harmful if inhaled. Avoid breathing spray mist. Do not get into eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

{If container is 5 gallons or larger the following statement MUST appear on label}

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water. 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.

PHYSICAL OR CHEMICAL HAZARDS

Do not mix with oxidizers, anionic soaps and detergents.

STORAGE AND DISPOSAL

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

Pesticide Storage: Open dumping is prohibited. Store only in original container. Do not reuse empty container. Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use. Keep from freezing. Contain and cleanup any product leaks or spills promptly. See pesticide and container disposal sections below for guidance.

Pesticide Disposal: Pesticide wastes are acutely 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.

{If container is 5 gallons or less use the following container disposal statements}

Container Disposal: Nonrefillable Container. Do not refill or reuse container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Drain for 10 seconds after flow begins to drip. Fill container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

{If container is 5 gallons or more use the following container disposal statements}

Container Disposal: Nonrefillable Container. Do not refill or reuse container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into the application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

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[PENETONE XF-7717] [This product] is a multi-purpose disinfectant-cleaner for Animal and Poultry Housing facilities. [PENETONE XF-7717] [This product] provides effective one step cleaning and disinfecting against Gram negative and positive bacteria and viruses.

At use dilution, [PENETONE XF-7717] [This product] may be used on acrylic, aluminum, brass, chrome, ethylene propylene, galvanized metal, steel, stainless steel, glass, glazed ceramic and tile surfaces, hard non-porous surfaces, nitrile, polyethylene, polypropylene, polyurethane, PVC (polyvinyl chloride), tin, vinyl, viton, sealed fiberglass, and zinc.

DIRECTIONS FOR USE

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

Registered for cleaning and disinfecting hard non-porous surfaces. Not for use on feed, food or litter.

USE DIRECTIONS

To clean and disinfect hard nonporous surfaces [of floors, garbage cans, tables, walls, refrigerator exteriors, sinks, and telephone booths in non-animal areas associated with the sites noted above]. Remove gross filth and heavy soil from surfaces prior to disinfecting. Apply a solution of 1 ounce [PENETONE XF-7717] [product] per gallon of water (diluted 1:128) to hard non-porous surfaces. Apply with cloth, sponge mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surface to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse. [Do not use in any application involving direct or indirect food or drinking water contact.]

BOOT/SHOE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Remove as much soil as possible by scraping waterproof shoes or boots or by precleaning and place in 1 ounce of [PENETONE XF-7717] [product] per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

HATCHERIES: Use 1 ounce of this product per gallon of water to treat the following hard, non-porous surfaces: hatcher, setters, trays, racks, carts and sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more. Rinse with potable water before reuse. Then allow to air dry.

VEHICLES: Clean all vehicles including mats, crates, cabs, and wheels with high-pressure water and this product. To disinfect the hard non-porous surfaces of vehicles use a solution of 1 ounce [PENETONE XF-7717] [product] per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

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POULTRY (AND SWINE) PREMISE SANITATION

Site Preparation: The first step in any on-going sanitation program should be the removal of gross contamination and debris. This may be accomplished using a shovel, broom, or vacuum depending on the area to be disinfected. The efficacy of even the most efficient germicidal cleaner is reduced in the presence of heavy organic matter. Once the heavy debris is eliminated, thoroughly clean all surfaces with soap or detergent and rinse with water.

DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES

1. Remove all animals and feed from premises, vehicles, coops, crates and enclosures.
2. Remove all gross soil, litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by hogs 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. Thoroughly saturate all surfaces with a solution of 1 oz. [PENETONE XF-7717] [product] per gallon of water (1:128), using conventional spraying methods.
6. Allow all treated areas to remain in contact with this solution for at least 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 in removing litter and manure in [PENETONE XF-7717] [product] at a dilution of 1:128. Allow to remain in contact for at least 10 minutes.
8. Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
9. Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains, waterers and other equipment which may come in contact with food or water with soap or detergent, and rinse with potable water before reuse.

{Alternate Text Format as opposed to numbered steps}

DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES

Remove all animals and feeds from premises, vehicles, coops, crates and enclosures. Remove all gross soil, litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by hogs or other animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Thoroughly saturate all surfaces with a solution of 1 oz. [PENETONE XF-7717] [product] per gallon of water (1:128), using conventional spraying methods. Allow all treated areas to remain in contact with this solution for at least 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used in removing litter and manure in [PENETONE XF-7717] [product] at a dilution of 1:128. Allow to remain in contact for at least 10 minutes. Ventilate buildings, coops and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains,

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waterers and other equipment which may come in contact with food or water with soap or detergent, and rinse with potable water before reuse.

DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNES, RATITE OR ANIMAL HOUSING FACILITIES, CALF PENS AND VEHICLES

1. Do not use in milking stalls, milking parlors, or milk houses.
2. Remove all animals and feed from premises, vehicles and enclosures.
3. Remove all gross soil, litter, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceilings of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by hogs or other animals.
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. Thoroughly saturate all surfaces with a solution of 1 oz. [PENETONE XF-7717] [product] per gallon of water (1:128) (or equivalent dilution), using conventional spraying methods. Allow to remain in contact with this solution for at least 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 manure in a solution of 1 oz. [PENETONE XF-7717] [product] per gallon of water (1:128). Allow to remain in contact for 10 minutes.
8. 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.
9. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

{Alternate Text Format as opposed to numbered steps}

DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNES, RATITE OR ANIMAL HOUSING FACILITIES, CALF PENS AND VEHICLES

Do not use in milking stalls, milking parlors or milk houses. Remove all animals and feed from premises, vehicles and enclosures. Remove all gross soil, litter, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces and from walls to ceilings of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Thoroughly saturate all surfaces with a solution of 1 ounce [PENETONE XF-7717] [product] per gallon of water (1:128) (or equivalent dilution) using conventional spray methods. Allow to remain in contact with this solution for at least 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used in removing litter and manure in a solution of 1 oz. [PENETONE XF-7717] [product] per gallon of water (1:128). Allow to remain in contact for 10 minutes.

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Ventilate buildings, cars, trucks, boats and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

DIRECTIONS FOR USE IN POULTRY HOUSE

1. Remove all poultry and feed 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 1 ounce [PENETONE XF-7717] [product] per gallon water (dilute 1:128) 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, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

{Alternate Text Format as opposed to numbered steps}

DIRECTIONS FOR USE IN POULTRY HOUSE

Remove all poultry and feed from premises, trucks, coops and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with 1 ounce [PENETONE XF-7717] [product] per gallon water (dilute 1:128) for a period of 10 minutes. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

DIRECTIONS FOR DISINFECTION/VIRUCIDE OF POULTRY/TURKEY EQUIPMENT, SWINE QUARTERS, ANIMAL QUARTERS AND KENNELS

Remove all animals and feeds from premises, vehicles and enclosures such as coops and crates. 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 animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with 1 ounce [PENETONE XF-7717] [product] per gallon water (dilute 1:128) for a period of 10 minutes. 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.

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After application, ventilate buildings, coops and other closed spaces. Do not house poultry or other animals or employ equipment until treatment has been absorbed, set or dried.

All treated equipment that will contact feed or drinking water (racks, troughs, and automatic feeders, fountains and waterers) must be thoroughly scrubbed with soap or detergent, then rinsed with potable water before reuse.

DIRECTIONS FOR USE (FOGGING)

Prior to fogging setters or hatcher facilities, food products and packaging must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart per 1000 cubic feet of room area with a product solution containing 1½ ounce product to 1 gallon of water (or equivalent use dilution) (1,300 ppm). Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus. Vacate area of all personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before reuse.

*NOTE: The fog generated is irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of actual fogging and a minimum of 4 air exchanges (ACH) per hour in the facility. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

PENETONE CORPORATION
700 Gotham Parkway
Carlstadt, NJ 07072

phone - (201) 567-3000
website – www.west-penetone.com

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Optional Claims:

Kills [Reduces][Effective Against][Eliminates][Controls] {*Insert organism name from page 1*} [in 10 minutes][in Animal & Poultry Facilities]

Kills [Reduces][Effective Against][Eliminates][Controls] [bacteria] [and] [viruses] [in 10 minutes] [in Animal & Poultry Facilities]

Helps reduce [bacterial][and][viral]cross contamination [transfer] between [equipment][facilities][in Animal & Poultry Facilities]

For [cleaning][and] disinfection of [farm][animal][poultry] facilities [and equipment] to aid in the control of [key][important][viruses][and][bacteria]

Kills [Reduces][Effective Against][Eliminates][Controls] bacteria and viruses on environmental surfaces

Concentrated [Broad Spectrum] [Bactericidal][Virucidal][Shoe Bath] Disinfectant

One Step [Labor saving][Multi-Purpose]Disinfectant [Cleans][disinfects][and] [Deodorizes]

Effective against common poultry bacteria and viruses

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