

71-355-1

12/17/2010

1 of 7

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



Office of Pesticide Programs

Sally Hayes,  
Scientific & Regulatory  
Consultants, Inc.  
P.O. Box 1014,  
Columbia City, IN. 46725

DEC 17 2010

Product Name: Virocid  
EPA Reg. No.: 71355-1  
Notification Date: July 30, 2010  
Receipt Date: August 2, 2010  
Submission #: 879635

Dear Ms. Hayes,

The following amendment, submitted in connection with registration under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable with comments.

**Proposed Amendment**

- Add new claims for human influenza A virus (H1N1).
- Upgrade label first aid statement, precautionary statements and storage and disposal language.
- Add data previously rejected to support organisms listed below.

- Human Influenza A (H1N1) (ATCC VR-1469)
- Swine Influenza A virus (H1N1) (ATCC VR-333)
- Campylobacter jejuni (ATCC 33560)
- Corynebacterium pseudotuberculosis (ATCC 19410)
- Avibacterium (Haemophilus) paragallinarum (ATCC 29975)
- Klebsiella pneumonia (ATCC 13883)
- Listeria monocytogenes (ATCC 19115)
- Mycoplasma gallisepticum (ATCC 19610)
- Mycoplasma synoviae (ATCC 25204)
- Ornithobacterium rhinotracheale (ATCC 51463)
- Pasteurella multocida (ATCC 6529)
- Salmonella enteritidis (ATCC 13076)
- Fusarium dimerum (ATCC 16553)
- Penicillium expansum (ATCC 7861)
- Bordetella avium (ATCC 35086)
- Salmonella enterica (pullorum) (ATCC 9120)

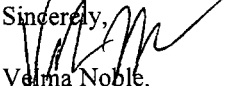
**Conclusions:**

- The CSF dated 09/228/10, for the basic formulation is acceptable.
- Please see the attached efficacy review.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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

Should you have any questions or comments concerning this letter, please contact Velma Noble PM Team 31 at (703) 308-6233.

Sincerely,  
  
Velma Noble,  
Product Manager, Team 31  
Regulatory Management Branch  
Antimicrobials Division (7510P)

Enclosure: Stamped Label

# VIROCID

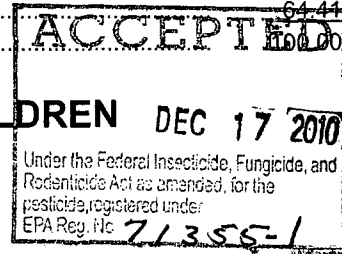
## CONCENTRATED BROAD SPECTRUM DISINFECTANT

**Active Ingredients:**

ALKYL *DIMETHYL BENZYL AMMONIUM CHLORIDE *(50% C <sub>14</sub> ; 40% C <sub>12</sub> ; 10% C <sub>16</sub> ) .....	17.060%
DIDECYL DIMETHYL AMMONIUM CHLORIDE .....	7.800%
GLUTARALDEHYDE.....	10.725%

**Other Ingredients:** .....

Total .....	64.415%
	100.000%



**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

VIROCID is effective against:

BACTERIA	DILUTION
<i>Salmonella Choleraesuis</i> (ATCC 10708) enterica (formerly <i>S. choleraesuis</i> )*	1:400
<i>Staphylococcus aureus</i> (ATCC 6538)*	1:400
<i>Pseudomonas aeruginosa</i> (ATCC 15442)*	1:400
<i>Campylobacter jejuni</i> *	1:400
<i>Corynebacterium pseudotuberculosis</i> *	1:400
<i>Avibacterium paragallinarum</i> (formerly <i>H. paragallinarum</i> )*	1:400
<i>Klebsiella pneumoniae</i> *	1:400
<i>Listeria monocytogenes</i> *	1:400
<i>Mycoplasma gallisepticum</i> *	1:400
<i>Mycoplasma synoviae</i> *	1:400
<i>Ornithobacterium rhinotracheale</i> *	1:400
<i>Salmonella enterica</i> (formerly <i>S. enteritidis</i> )*	1:400
<i>Mycoplasma hyopneumoniae</i> **	1:400
<i>Streptococcus suis</i> *	1:400
<i>Salmonella enterica choleraesuis, serotype typhisuis</i> (ATCC 8324) (formerly <i>S. typhisuis</i> )*	1:400
<i>Escherichia coli</i> *	1:400
<i>Bordetella avium</i> *	1:256
<i>Salmonella enterica</i> (formerly <i>S. pullorum</i> )*	1:256
<b>FUNGUS (on environmental surfaces)</b>	
<i>Fusarium dimerum</i> *	1:400
<i>Penicillium expansum</i> *	1:400
<i>Trichophyton mentagrophytes</i>	1:400
<b>VIRUS (on environmental surfaces)</b>	
Porcine circovirus, type II [PCV, PT-1 cell]*	1:200
Pseudorabies [American BioResearch Laboratories]*	1:400
Porcine Respiratory and Reproductive Syndrome [Arko Laboratories]*	1:400
Avian Reovirus [Spafas Strain]*	1:256
Marek's Disease [Spafas Strain]*	1:400
Newcastle Disease [Spafas Strain]*	1:400
Avian Influenza [Turkey/Wis/66 strain-H9N2]*	1:400
Human Influenza A (H1N1)*	1:400
Swine Influenza A (H1N1)*	1:400
Avian Infectious Laryngotracheitis [Charles River Laboratories]*	1:400
Infectious Bursal Disease [Spafas Strain 2512]*	1:400
<b>Algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers</b>	<b>25-50 ppm</b>
*in the presence of 400 ppm AOAC synthetic hard water and 5% soil load	
**in the presence of 400 ppm AOAC synthetic hard water and 25% soil load	

Note: Bracketed [ ] information is optional text. Text separated by a comma (,) denotes—and/or-options. {Bracketed Text} is for administrative purposes only and will not appear on the printed label.

4097

FIRST AID STATEMENTS	
<b>IF IN EYES</b>	<ul style="list-style-type: none"> <li>• Hold eyelids open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing-eyes.</li> <li>• Call a poison control center or doctor for 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 treatment advice.</li> </ul>
<b>IF SWALLOWED</b>	<ul style="list-style-type: none"> <li>• Call a 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>IF INHALED</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<p>[For emergency information on [product, use, etc.], call the <b>National Pesticides Information Center</b> at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.]</p> <p><b>NOTE TO PHYSICIAN:</b> Probable mucosal damage may contraindicate the use of gastric lavage. Have a product container or label with you when calling the poison control center, doctor, or going for medical treatment.</p>	

**APPLICATION:**

**Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:**

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings)
2. Hatchers, setters, and chick processing facilities
3. Food processing plants (slaughterhouses)
4. Trucks and other vehicles
5. Veterinary hospitals

**Sanitizing hatchery rooms, incubators, and hatchers, poultry houses and livestock buildings by fogging.**  
**Control of algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers.**

**DIRECTIONS FOR USE:**

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

**Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:**

1. **Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):**  
 For disinfection of hard, non-porous surfaces: stainless, galvanized and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, sealed brick walls, aluminum sandwich panels and feeding/drinking equipment:
  - A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
  - B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the appropriate disinfection solution<sup>†</sup> by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
  - C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.
  - D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with portable water before reuse.

Note: Bracketed [ ] information is optional text. Text separated by a comma(,)denotes-and/or-options. {Bracketed Text}is for administrative purposes only and will not appear on the printed label.

5067

- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution<sup>†</sup> for 10 minutes. Allow to air dry.
- F. Fresh disinfection solution should be made daily or if visibly soiled.

**2. Hatcheries:**

Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with the appropriate disinfection solution<sup>†</sup> by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfection solution ~~should~~ must be made daily or if visibly soiled.

**3. Food processing plants (including Chicken Processing Facilities):**

Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Disinfect hard, non-porous surfaces by applying the appropriate disinfection solution<sup>†</sup> with a coarse spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

**4. Trucks and other vehicles:**

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the appropriate disinfection solution<sup>†</sup> to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

**5. Veterinary hospitals:**

For disinfection of the following hard non-porous surfaces: floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Saturate surfaces with the appropriate disinfection solution<sup>†</sup> by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Immerse all leashes, muzzles, ropes or other types of equipment used to restrain or handle animals as well as shovels, scrapers, and forks used to remove manure and litter. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfection solution ~~should~~ must be made daily or if visibly soiled.

**Preparation table:**

Dilution	Preparation Method
1:400	1/3 fluid ounce per gallon of water
1:256	1/2 fluid ounce per gallon of water
1:200	2/3 fluid ounce per gallon of water

<sup>†</sup> See organism and preparation table to determine the appropriate disinfection solution.

**Sanitizing hatchery rooms, incubators and hatchers, poultry houses and livestock buildings by fogging:**

**A. Hatchery rooms:**

Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

**Note:** The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves, and pants.

0097

**B. Incubators and hatchers:**

Prepare a stock solution of one (1) part of VIROCID to four (4) parts water. Fog 3 ounces of solution per 100 cubic feet of this into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog.

It is also satisfactory to fog setters and hatchers with a 1:1000 solution of VIROCID. If this is done, fog for 30-90 seconds once per hour or once every two hours.

**C. Poultry houses and livestock buildings:**

After the house has been depopulated and cleaned as in 1. A to F under "Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as tight as possible.

Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Place the fogger ~~itself may be placed~~ just inside the door of the building to be treated, or insert ~~the nozzle of the fogger may be inserted~~ through a suitable opening in the door or building. The opening must ~~should~~ be just large enough to accommodate the nozzle.

After fogging, the building must ~~should~~ be kept closed for twenty-four hours. After twenty-four hours, ~~the fog should have settled and~~ open the house ~~can now be opened~~ and aired. ~~The house should be opened~~ for a minimum of twenty-four hours before it is repopulated with poultry or livestock.

**Note:** The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completed settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves and pants. If feeders and waterers were not removed from the premise during treatment, or were not adequately covered to prevent contact with treatment, they must ~~should~~ be washed with detergent and water before use for poultry or livestock.

**Control of algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers:**

- A. VIROCID must ~~should~~ be added in the system directly at a point where uniform mixing and even distribution will occur. Do ~~and~~ not mixed with any other chemicals or additives; ~~it should be added~~
- B. Severely fouled systems must ~~should~~ be chemically and/or manually cleaned before adding VIROCID treatment. If algae/slime growth is absent or minimal, proceed with the initial dose.
- C. **Initial Dose:** 2.5 fluid ounces of VIROCID per 100 gallons of water (50 ppm) in the system. Repeat treatment until algae/slime growth is controlled.

**Maintenance Dose:** After algae control is evident/achieved, apply 1.25 fluid ounces of VIROCID per 100 gallons of water (25 ppm) in the system every 7 days (weekly). Repeat treatment as needed to maintain algae/slime control.

**STORAGE AND DISPOSAL:**

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

**Storage:** Store in a cool, dry place in tightly closed container away from children. Avoid temperatures below 23°F and above 113°F.

**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 representatives at the nearest EPA Regional Office for guidance.

**Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. *{Insert applicable triple rinse instruction for container size below}* Offer for recycling if available. ~~Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.~~

7097

{For containers equal to or less than 5 gallons}

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. 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.

{For containers greater than 5 gallons}

Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container over on its end and tip it back and forth several times. Empty rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

### **PRECAUTIONARY STATEMENTS:**

Hazards to humans and domestic animals

**DANGER.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves. Harmful if inhaled. Avoid breathing vapor. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet. ~~Remove contaminated clothing and wash before reuse.~~ Remove and wash contaminated clothing before reuse.

### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to fish. 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 into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact our State Water Board or Regional Office of the EPA.

#### **LIMITED WARRANTY AND DISCLAIMER:**

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort or otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

EPA Reg. No. 71355-1

EPA Est. No. 71355-BEL-001

Batch No: See top/bottom

Expiry Date: See top/bottom

Net Contents: See top/bottom

{net contents will appear on front panel; registration numbers, batch no. and expiry date may appear on any panel}



Produced by :  
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