

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 09 2005

Ms. Olivia Laird
Agent for Virocid
Laird's Regulatory Consultant, Inc.
7804 Braemar Place
Leesburg, VA 20175

Subject: Virocid
EPA Registration No. 71355-1
Amendment Date: August 11, 2004
EPA Receipt Date: August 13, 2004

Dear Ms. Olivia Laird,

The following amendment submitted in connection with registration under FIFRA 3(c)(7)(A) is acceptable.

- Addition of microorganisms

Conditions

Revise the label as follows:

1. Based on the Agency letter dated February 2, 2004, the following organisms were unacceptable and must be deleted from the label:

Campylobacter jejuni, Cornebacterium pseudotuberculosis, Klebsiella pneumoniae, Listeria monocytogenes, Orithobacterium rhinotracheale, Salmonella choleraesuis serotype enteritidis, Haemophilus paragallinarum, Mycoplasma synoviae, Mycoplasma gallispecticum, Mycoplasma hyopneumoniae, Streptococcus suis, escherichia coli, Bordetella avium, Salmonella choleraesuis serotype pulorum, Salmonella choleraesuis subsp. Choleraesuis, serotype typhisuis, Fusarium dimerum, Pencillium expansum, Pseudorabies, Porcine Respiratory and Reproductive Syndrome, Avian Reovirus, Marek's Disease, Newcastle Disease, Avian Influenza, and Avian Infectious Laryngotracheitis .

2. Under "Farm equipment and animal housing building," revise step F by stating, "Fresh disinfection solution should be made daily *or if visibly soiled.*"

3. Under "Storage and Disposal" instructions, bold the subheading, **Storage, Pesticide Disposal, and Container Disposal** .

CONCURRENCES

SYMBOL	SURNAME	DATE					

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Acceptable Data

Data Requirement	Means of Support	Status
Virucidal Effectiveness Test - Porcine Circovirus Type 2	Submitted study, MRID 463414-01	Acceptable in 1:200 dilution for 10 min. in 5% soil

General Comments

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

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

for

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Efficacy Data Evaluation
Stamped Label

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

New label & correct use
directions

3/7

VIROCID®

CONCENTRATED BROAD SPECTRUM DISINFECTANT

Active ingredients :

ALKYL* DIMETHYL BENZYL AMMONIUM CHLORIDE *(50% C14;40% C12;10% C16) 17.060 % (by wt)
 DIDECYL DIMETHYL AMMONIUM CHLORIDE 7.800 %
 GLUTARALDEHYDE 10.725 %
Inert ingredients 64.415 %
 100.000 %

**KEEP OUT OF REACH OF CHILDREN
DANGER**

VIROCID is effective against :

BACTERIA	Dilution
<i>Salmonella Choleraesuis</i> (ATCC 10708)* ✓	1:400
<i>Staphylococcus aureus</i> (ATCC 6538)* ✓	1:400
<i>Pseudomonas aeruginosa</i> (ATCC 15442)* ✓	1:400
FUNGUS (on environmental surfaces) :	
<i>Tricophyton mentagrophytes</i> (ATCC 9533)	1:400
VIRUS (on environmental surfaces) :	
<i>Porcine circovirus, type II</i> (PCV, PT-1 cell)* ✓	1:200
Infectious Bursal Disease of Chickens (SPAFAS Strain 2512)* ✓	
Algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers	25-50 ppm

*in the presence of 400 ppm AOAC synthetic hard water and 5% soil load

RECORDED
with GCM/1/1/05
in LPA/1/1/05
FEB 09 2005

Under the Food and Drug Administration
Regulation for Disinfectants
and Antiseptics
71355-1

FIRST AID STATEMENTS	
Have product container with you when calling the poison control center, doctor, or going for medical treatment.	
IF IN EYES	<ul style="list-style-type: none"> • Hold eyelids 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 eyes. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • 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 SWALLOWED	<ul style="list-style-type: none"> • 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.
IF INHALED	<ul style="list-style-type: none"> • 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 advice.
NOTE TO PHYSICIAN :	
Probable mucosal damage may contraindicate the use of gastric lavage.	

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, aluminium 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 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.

FEB 09 2005

* see table top of label to determine the appropriate disinfection solution

- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
- 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* for 10 minutes. Allow to air dry.
- F. Fresh disinfection solution should be made daily.

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* 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 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* 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* 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* 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 be made daily or if visibly soiled.

Preparation table :

dilution	Preparation method
1:1000	
1:400	1/8 fluid ounce per gallon of water
1:256	1/2 fluid ounce per gallon of water
1:200	3/8 fluid ounce per gallon of water

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 09 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No. 71355-1

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.

B. Incubators and hatchers :

Prepare a stock solution of one (1) part VIROCID to four (4) parts water. Fog 3 ounces for 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. The fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening should be just large enough to accommodate the nozzle. After fogging, the building should be kept closed for twenty-four hours. After twenty-four hours, the fog should have settled and 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 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. If feeders and waterers were not removed from the premise during treatment, or were not adequately covered to prevent contact with treatment, they 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 should be added in the system directly and not mixed with any other chemicals or additives ; it should be added at a point where uniform mixing and even distribution will occur.
- B. Severely fouled systems 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 (50ppm) 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 (25ppm) in the system every 7 days (weekly). Repeat treatment as needed to maintain algae/slime control.

FFR 0 9 2005

71355-1

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.

Disposal of pesticide : 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.

Disposal of container : 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.

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 your State Water Board or Regional Office of the EPA.

PRECAUTIONARY STATEMENTS

Hazard 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.

Remove contaminated clothing and wash before reuse.

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. N° : 71355-1 EPA Est. N° : 71355-BEL-001
BATCH N° : see top / bottom EXPIRY DATE : see top / bottom
Net contents : see top / bottom

Produced by :

CID LINES NV/SA - Waterpoortstraat 2 - B 8900 IEPER - BELGIUM - EUROPE

Phone: 011-32-57-217877 - Fax: 011-32-57-217879

<http://www.cidlines.com> - info@cidlines.com



ACCEPTED
with COMMENTS
in EPA Register Data:

FEB 09 2005

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
amended, and under the
Federal Food, Drug and
Cosmetics Act, Reg. No.

71355-1