

# Controlling the Safety Hazards of Disinfectants

*Presented to*

## *Conference on Protecting Avian Influenza Responders*

Sponsored by

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# OVERVIEW

- Background
- Disinfectant Data Requirements
- Disinfectant Labeling Requirements
- Final Points



# BACKGROUND

- **Substances used in or on living humans or animals:**
  - Are Drugs or Medical Devices
  - Are regulated by the Food and Drug Administration under the **Federal, Food, Drug and Cosmetic Act (FFDCA)**
- **Substances used in or on inanimate surfaces:**
  - Are pesticide products or devices
  - Are regulated by EPA under the **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**



# Antimicrobial Pesticides



- Under FIFRA, an **antimicrobial pesticide** is defined as a substance intended to **disinfect, sanitize, reduce or mitigate microbiological organisms on inanimate surfaces** (other than those on or in living humans or animals).



# EPA Approvals Under FIFRA

- EPA approval for a pesticide under FIFRA is either by registration (i.e., license) or by exemption (i.e., temporary approval).
- FIFRA's standard for registration is that the product may not cause "unreasonable adverse effects" when used according to the label.
- *Registrations:*
  - Section 3 registration (Federal): registrant submits required data and labeling to EPA for approval.
  - Section 24(c) registration (State): registrant submits required data and labeling to the state, which issues a "special local needs" registration. EPA has 90 days to accept or reject it.

# DISINFECTANT DATA REQUIREMENTS

- **Active ingredient data (for risk assessment):**
  - product chemistry
  - environmental fate
  - fish and wildlife
  - acute/chronic toxicity data
- **Product specific data (for labeling):**
  - Chemistry (ingredients, physical/chemical characteristics)
  - Acute toxicity (“six pack”)
  - Efficacy (product performance testing required for all public health products)

# Efficacy Data and Public Health Product Categories

- ❖ Efficacy test methods and public health claim categories:
  - ❖ Sanitizers
  - ❖ **Disinfectants**
  - ❖ Virucides
  - ❖ Sterilants/sporicides
- ❖ For guidance on tests, see:  
[www.epa.gov/oppbead1/methods/atmpa2z.htm](http://www.epa.gov/oppbead1/methods/atmpa2z.htm)



# Efficacy Tests for Disinfectants

- Disinfectants must pass either the **AOAC Use Dilution Test** or **Germicidal Spray Products Test** (see [http://www.epa.gov/oppad001/dis\\_tss\\_docs/dis-01.htm](http://www.epa.gov/oppad001/dis_tss_docs/dis-01.htm))

- Tests may include:

1. *Salmonella choleraesuis* (Limited Disinfectant—1 or 2)
2. *Staphylococcus aureus* (Broad-spectrum Disinfectant—1 and 2)
3. *Pseudomonas aeruginosa* (Hospital Disinfectant—1, 2 and 3)



# Efficacy Testing for Avian Influenza A

- To claim inactivation of avian influenza A, a disinfectant must be successfully tested against it using one of the above tests.
- If EPA reviews and accepts the test results, the claim may be approved, and the product may be sold/distributed legally for that purpose.

# Registered Disinfectants for AI virus

- 100 disinfectants are registered for AI virus
- Use is limited to poultry houses, farm premises, and farm equipment
- Disinfectants are tested and registered for use on precleaned, hard, nonporous surfaces
- Must follow label directions to be effective
- See list of AIV products on EPA's Website
  - [www.epa.gov/pesticides/factsheets/avian.htm](http://www.epa.gov/pesticides/factsheets/avian.htm)
  - Linked to Federal Pandemic Flu Strategic Plan Website: [www.pandemicflu.gov](http://www.pandemicflu.gov)

# DISINFECTANT LABELING REQUIREMENTS

- EPA regulations specify label format and content
- EPA stamps the label “Accepted” when it registers a new product or approves an amendment
- You may obtain labels by inserting EPA Reg. No. at <http://www.epa.gov/pesticides/pestlabels/>
- **“The Label is the Law”** —Users must obey the Misuse Statement: “It is a violation of federal law to use this product inconsistent with its labeling.”

# Label Elements

- Product Name
- Company Name and Address
- Net Contents
- EPA Reg No. and Est. No.
- Ingredients Statement
- Child Hazard Warning
- **Signal Word**
- **First Aid**
- **Precautionary Statements**
- **Environmental Hazards**
- **Physical/Chemical Hazards**
- **Directions for Use and Misuse Statement**
- Storage and Disposal Instructions

# Sample Label

# DREWCHLOR® 3004

FOR USE IN THE MECHANICAL GENERATION OF CHLORINE DIOXIDE AS A DISINFECTANT, SANITIZER, AND MOLLUSK CONTROL AGENT IN RECIRCULATING AND ONCE-THROUGH WATER SYSTEMS, OR FOR MICROORGANISM CONTROL AS A CHEMICAL OXIDANT IN AQUATIC SYSTEMS.

ACTIVE INGREDIENTS: SODIUM CHLORITE\* ..... 25%  
INERT INGREDIENTS: ..... 75%  
TOTAL ..... 100.0%

(\*AVAILABLE CHLORINE - 39%)

CONTAINS 2.58 LBS. SODIUM CHLORITE PER GALLON AT 70°F.

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER

Highly corrosive. Causes eye damage and skin burns. May be harmful if inhaled. May be fatal if swallowed. Irritating to nose and throat. Avoid breathing vapor. Do not get in eyes, on skin, on clothing. Do not handle with bare hands. Wear protective eyewear (goggles or face shield), clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

## ENVIRONMENTAL HAZARDS

This product 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 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. Do not contaminate water by cleaning of equipment or disposal of waste. Apply this pesticide only as specified on this label.

## PHYSICAL AND CHEMICAL HAZARDS

Dry DREWCHLOR 3004 is a strong oxidizing agent. Mix only into water. Contamination may start a chemical reaction with generation of heat, liberation of hazardous gases (chlorine dioxide - a poisonous explosive gas), and possible fire and explosion. Do not contaminate with garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, pine oil, dirty rags or any other foreign matter.

## EMERGENCY HANDLING

In case of contamination or decomposition, do not re-seal container. If possible, isolate container in open and well ventilated area. Flood with large volumes of water. If fire occurs, extinguish fire by applying large volumes of water. Any uncapped drums near the fire should be cooled by spraying with water.

## KEEP OUT OF REACH OF CHILDREN DANGER 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 the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for 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 treatment advice.

### 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 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 a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label and MSDS with you when calling a poison control center or doctor, or going for treatment.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 1757-96

EPA Est. No. 1757-TX-1  
1757-NJ-1



Ashland Chemical Company  
Division of Ashland Inc.

One Drew Plaza  
Boonton, New Jersey 07005  
Phone (201) 283-7600  
24 Hour Emergency Telephone Number  
1-800-274-5283 or 1-800-ASHLAND  
™ Trademark and © Registered trademark of Ashland Inc.

\* KYNAR is a registered trademark of E.I. duPont de Nemours & Co.  
† TEFLON is a registered trademark of E.I. duPont de Nemours & Co.

## DIRECTIONS FOR USE

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

**FEED REQUIREMENTS:** Feed rates of DREWCHLOR 3004 will depend on the severity of contamination and the degree of control desired. The exact dosage will depend on the size of the system and residual necessary for effective control. Approximately one pound of chlorine dioxide is generated from 6.8 pounds of DREWCHLOR 3004 and an aqueous solution of chlorine.

**METHOD OF FEED:** Large amounts of chlorine dioxide can be generated using ASHLAND'S GENEROX™ generator by two common methods: 1.) the chlorine method which utilizes DREWCHLOR 3004 and chlorine gas, or 2.) the hypochlorite method which utilizes DREWCHLOR 3004, a hypochlorite solution and an acid. Your Ashland representative can guide you in the selection, installation and operation of the GENEROX™ feed system. Consult Product Bulletin and also the instructions on the GENEROX™ generation system before using DREWCHLOR 3004.

**IMPORTANT NOTICE:** Seller warrants that the product conforms to its chemical description and is responsible fit for the purposes stated on the label under normal conditions of use. THE FOREGOING WARRANTIES ARE EXCLUSIVE AND ARE IN LIEU OF ALL OTHER WARRANTIES, WHETHER WRITTEN, ORAL OR IMPLIED. THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, IN OTHER RESPECTS THAN AS EXPRESSLY SET FORTH HEREIN, ARE EXPRESSLY EXCLUDED AND DISCLAIMED.

NOTE: Buyer assumes all responsibility for safety and use not in accordance with directions.

## FOR INDUSTRIAL USE ONLY

BATCH NO.

GAL. NET CONTENTS

## STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE:** Keep product dry in tightly closed container when not in use. Do not drop, roll or acid drum. Keep upright. Always replace cover. Store in a cool, dry, well-ventilated area away from heat or open flame. Do not reuse empty container.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide 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.

### CONTAINER DISPOSAL:

**METAL CONTAINERS:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**PLASTIC CONTAINERS:** Triple rinse (or equivalent). 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.

ACCEPTED

JUN 23 2003

Under the Federal Insecticide, Fungicide, and  
Rodenticide Act as amended, for the  
pesticide, registered under  
EPA Reg. No. 1757-96



# Child Hazard Warning and Signal Word

- Child Hazard Warning is on all labels
- Signal work is derived from tox studies
  - Category I            Danger
  - Category II          Warning
  - Category III/IV      Caution

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

# First Aid Statement

- Std. statements for Tox. Category I, II or III  
Note to Physician for Cat I (skin/eye) or contains 10% petroleum distillates

## 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 the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for 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 treatment advice.

### 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 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 a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label and MSDS with you when calling a poison control center or doctor, or going for treatment.

# Hazards to Humans and Domestic Animals

- Consequences of unprotected exposure
- Personal Protective Equipment (PPE)
- Reentry interval or exposure level

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

Highly corrosive. Causes eye damage and skin burns. May be harmful if inhaled. May be fatal if swallowed. Irritating to nose and throat. Avoid breathing vapor. Do not get in eyes, on skin, on clothing. Do not handle with bare hands. Wear protective eyewear (goggles or face shield), clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

# Environmental Hazards

- Toxicity to fish or birds
- Keep out of lakes, streams or ponds
- No effluent discharge without NPDES permit or approval of waste treatment plant

## **ENVIRONMENTAL HAZARDS**

**This product 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 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. Do not contaminate water by cleaning of equipment or disposal of waste. Apply this pesticide only as specified on this label.**

# Physical/Chemical Hazards

- Flammability
- Shock Hazard
- Explosive Potential

## PHYSICAL AND CHEMICAL HAZARDS

Dry DREWCHLOR 3004 is a strong oxidizing agent. Mix only into water. Contamination may start a chemical reaction with generation of heat, liberation of hazardous gases (chlorine dioxide - a poisonous explosive gas), and possible fire and explosion. Do not contaminate with garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, pine oil, dirty rags or any other foreign matter.

# Use Directions

- **Directions for Use must specify:**
  - The surfaces, objects or inanimate environments intended for treatment (floors, walls bathroom surfaces, etc.)
  - The major areas in which the product is intended for use (hospitals, restaurants, homes, schools).
  - The level of activity (e.g., Sanitizer, Disinfectant, Sporicide)
  - Pathogens against which product is effective

# Use Directions (cont'd.)

- How the product must be applied:
  - Pre-cleaning step
  - Recommended use dilution and provide instructions for preparing it including the units of measure (ounces, quarts).
  - Method of application
  - Contact time
  - How to remove the product from the surface after the recommended exposure time

## BROAD SPECTRUM DISINFECTANT

Virkon<sup>®</sup> S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution was determined in the presence of 400 ppm AOAC hard water and 5% organic material. Virkon<sup>®</sup> S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water. Apply a 0.5% (1:200) solution for routine sanitation.

### 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.
- This powder formula is easily diluted for use in manual or machine operations.

# FINAL POINTS

- Disinfectants are registered and explicitly labeled based on safety and efficacy data.
- To maximize safety and effectiveness, follow all label directions exactly.
- Questions about finer points of using the product should be directed to the registrant.
- Questions about regulations or policies may be directed to EPA.