

9150-7

9/18/2009

1/11



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

SEP 18 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Bonnie J. Bieber
Regulatory Coordinator
International Dioxide, Inc.
40 Whitecap Dr.
North Kingstown, RI 02852

FILE COPY

Subject: Adox 3125
EPA Registration No. 9150-7
Application Date: July 30, 2009
Receipt Date: July 31, 2009

Dear Ms. Bieber:

The following amendments, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with the comments listed below:

Proposed Amendment:

- Revision of precautionary statements to include "explosive hazard" language
- Revisions to "Food Processing Plants" uses

Comments:

1. You must revise the first aid statement so the routes of exposure are in the following order: "If in eyes", "If on skin or clothing", "If swallowed", "If inhaled".
2. You must correct the misspelling in the "Note to Physician" to read, "...the use of *gastric* lavage."

General Comments:

A stamped copy of the labeling accepted with conditions is enclosed. Submit one (1) copy of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Wanda Henson at (703) 308-6345.

Sincerely,

Emily H. Mitchell
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

[0001] – MASTER LABEL

ADOX® 3125

25% AQUEOUS SODIUM CHLORITE SOLUTION

[0002]

PRECURSOR FOR CHLORINE DIOXIDE AND ACIDIFIED CHLORITE SOLUTIONS FOR INDUSTRIAL USE ONLY

[0003]

Active Ingredients

Sodium Chlorite ----- 25%

Inert Ingredients ----- 75%

Total: 100%

ACCEPTED
with COMMENTS
EPA Letter Dated:

SEP 18 2009

[0004]

KEEP OUT OF REACH OF CHILDREN

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
amended for the pesticide,
registered under EPA Reg. No. 9150-7

[0005]

DANGER

[0006]

See Side Panels for Additional Precautionary Statements

[0007]

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 by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

If swallowed: Call 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.

For 24 hour emergency information on this product, call Chemtrec at 1-800-424-9300 (US, Canada, Puerto Rico, Virgin Islands) 1-703-527-3887 (All Other Areas). Medical Emergency 1-800-441-3637 (outside U.S. 302-774-1000)

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

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

[0008]
EPA Reg. No. 9150-7

[0009]
EPA Est. No. XXXXXX-YYY-ZZZ

[0010]
NET CONTENTS _____ GAL.

ACCEPTED
with COMMENTS
EPA Letter Dated:
SEP 18 2009

[0011]
Manufactured For:
INTERNATIONAL DIOXCIDE, INC.
40 Whitecap Drive
North Kingstown, RI 02852

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
amended for the pesticide
registered under EPA Reg. No. 9150-7



ANSI/NSF 60
DRINKING WATER
TREATMENT ADDITIVES
3R80
Max. Use Level 28 mg/L

[0012]
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[0013]
ADOX® is a registered trademark of International Dioxide Inc., a DuPont Company.

[0014]
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMAN & DOMESTIC ANIMALS

[0015]
DANGER. This product becomes a fire or explosive hazard if allowed to dry. Highly corrosive, causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or clothing. May be fatal if swallowed. Do not get on bare hands. Wear goggles or face shield and neoprene gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing at once to avoid fire and wash separately before reuse. Avoid breathing fumes.

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[0016]

ENVIRONMENTAL HAZARDS

This product is toxic to fish and other aquatic organisms. 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 Eliminations 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.

[0017]

PHYSICAL AND CHEMICAL HAZARDS

DANGER: This product becomes a fire or explosive hazard if allowed to dry. Strong oxidizing agent. Mix or dilute into water only. Mixing with acids, or alcohol, or other chemicals may cause evolution of chlorine and chlorine dioxide gas which is toxic and may be explosive. Combustible materials contaminated with ADOX® 3125 may burn rapidly. Keep handling areas and equipment clean and free of oils, greases, combustibles, and dust. Do not contaminate this product with garbage, dirt, organic matter, paint products, solvents, acids, vinegar, beverages, oils, pine oils, dirty rags, or other foreign matter. Do not expose to hot surfaces, sparks or open flame.

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EPA Letter Dated:

SEP 18 2009
Under the Federal Insecticide,
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[0018]

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store upright in cool, dry and well-ventilated place. Avoid excessive heat or freezing. Protect from contact with other chemicals; avoid storage with organic chemicals, acids, reducers and combustible material. Keep container tightly closed when not in use. In case of spills, flush and drain promptly to sewer with large quantities of water. Do not allow liquid to dry out because this could present a fire hazard. If fire occurs, extinguish with large volume of water. Avoid exposure to high temperatures during storage. Store remote from other chemicals and combustible materials. Do not skid or slide drums.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or 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 directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative 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. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on it's side and roll back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip back and forth several times. Turn the container over onto its other end and tip back and forth several times. Empty the rinsate into 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, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

EMERGENCY HANDLING: In case of contamination or decomposition, do not reseal container. Isolate in an open, well-ventilated area. Flood with large volumes of water. Cool unopened drums in vicinity by water spray.

ACCEPTED
with COMMENTS
EPA Letter Listed

SEP 18 1991

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended by subsequent acts,
registered under EPA Reg. No. 9150-7

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[0019]

NOTICE: Seller expressly warrants that the product conforms to its chemical description. There are no warranties associated with the sale of the product either express or implied including, but not limited to, the warranties of fitness for a particular purpose or use.

[0020]

DIRECTIONS FOR USE

[0021]

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

[0022]

METHOD OF APPLICATION

Use ADOX® 3125 with a Chlorine Dioxide Generator to generate an aqueous chlorine dioxide solution. Alternatively, ADOX® 3125 can be used to form acidified sodium chlorite solutions by mixing the product with a Generally Recognized as Safe (GRAS) acid such as citric, phosphoric, hydrochloric or acetic acid.

Chlorine Dioxide Generators react ADOX® 3125 with either chlorine or a chlorine solution and hydrochloric acid. The generated chlorine dioxide solution can be added at a point in the system to be treated which ensures uniform mixing. Follow all instructions in the chlorine dioxide generator manual carefully. Always prepare and use chlorine dioxide solutions in a well-ventilated area.

[0023]

APPLICATIONS

[0024] – [OPT.]

POTABLE WATER AND WASTEWATER DISINFECTION: For most municipal and other potable water systems, a chlorine dioxide residual concentration up to 2.0 ppm is sufficient to provide adequate disinfection. Typically, the target residual concentrations range from 0.20 – 0.75 ppm. Monitor the distribution system to ensure that the chlorite concentration does not exceed its maximum contaminant level (MCL) of 1 mg/L and that chlorine dioxide does not exceed its maximum residual disinfection level (MRDL) of 0.8 mg/L. For wastewater and sewage applications, residual chlorine dioxide concentrations up to 5.0 ppm are generally adequate.

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[0025] – [OPT.]

POTABLE WATER SYSTEMS: Nitrification: to control the build up of nitrification in the water distribution system. Utilize a chemical metering system to add this product so that the resulting dose of chlorine dioxide or sodium chlorite to control nitrification does not exceed the MRDL of 0.8mg/L for ClO₂, or the MCL of 1.0 mg/L for chlorite ion.

Use of this product in public water systems (drinking water utilities) triggers monitoring and compliance requirements under 40 CFR 141. Among other requirements the user of this product is required to conduct daily monitoring for chlorine dioxide and chlorite at the point of addition and to comply with standards for chlorine dioxide and chlorite. The user of this product is required to contact State or primary drinking water programs to determine specific monitoring, compliance, reporting, and record-keeping requirements in order to avoid adverse human health effects and/or non-compliance with such requirements.”

[0026] – [OPT.]

FOOD PROCESSING PLANTS, DAIRIES, BOTTLING PLANTS AND BREWERIES, FOOD PLANTS PROCESS WATER. For microbial control in typical food processing water systems, such as flume transport, chill water systems, hydrocoolers, and retort cooling water, apply ADOX® 3125 through a chlorine dioxide generation system to achieve a chlorine dioxide residual concentration ranging from 0.25 to 5.0 ppm.

Residual concentrations of up to 5.0 ppm chlorine dioxide generated from ADOX® 3125 may also be used as a water sanitizer for fruit and vegetable washing and cut and peeled potato products followed by a subsequent potable water rinse.

ACCEPTED
with COMMENTS
EPA Letter Dated:

[0027] – [OPT.]

POULTRY PROCESSING WATER: Use ADOX® 3125 to generate chlorine dioxide for use as an antimicrobial agent in water used in poultry processing in an amount not to exceed 3 ppm residual chlorine dioxide as determined by an appropriate method.

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

[0028] – [OPT.]

AQUEOUS DISINFECTION SYSTEMS FOR CIP CLEANING: If the concentration of chlorine dioxide generated from ADOX® 3125 exceeds 5.0 ppm, a potable water rinse should follow treatment. Care should be taken to ensure the biological and chemical quality of the potable water.

[0029] – [OPT.]

GENERAL INDUSTRIAL PROCESS WATER TREATMENT (OILFIELD INJECTION WATER, WHITE WATER PAPER MILL SYSTEMS, AND RECIRCULATING COOLING TOWERS): For control of microbial slime, these systems will require a chlorine dioxide residual concentration ranging between 0.25 and 5.0 ppm.

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[0030] – [OPT.]

ONCE THROUGH COOLING WATER SYSTEMS: Control of mollusks can be effectively accomplished using ADOX® 3125 as directed in commercial and industrial once through cooling water systems. ADOX® 3125 may be fed on a continuous or slug basis depending on the degree of system fouling.

SLUG DOSE: Add 42 to 210 lbs. of chlorine dioxide per million gallons of water (5 to 25 ppm).

CONTINUOUS DOSE: Add 2 to 16 lbs. of chlorine dioxide per million gallons of water (0.25 to 2 ppm).

[0031] – [OPT.]

IN FOOD PROCESSING PLANTS, (POULTRY, MEAT FISH) DAIRIES AND BOTTLING PLANTS

For use as a terminal food contact surface sanitizing rinse conforming to 40 CFR 180.940 paragraph (b) and (c) not requiring a subsequent potable water rinse.

[0032] – [OPT.]

Direction For Use:

1. This solution is intended for use as a food contact surface sanitizer for dairies, ice cream factories and food processing plants.
2. This solution may be used on hard surfaces such as tables, trays, bins, etc. and the interior or exterior of food processing equipment.
3. All equipment should be thoroughly cleaned to remove gross food particles and soil by pre-flush or pre-scrape and where necessary, a pre-soak treatment. The surfaces or objects should then be cleaned with a detergent or cleaner followed by a potable water rinse before application of the sanitizing solution.
4. Add 6 oz. of ADOX® 3125 to 50 gallons of water and then acidify to pH 2.6 with organic or mineral acids or add 20 grams of Activator C or 175 grams of Activator K to the solution. Allow to stand for at least 15 minutes.
5. This solution should be allowed to contact all food processing equipment for at least 1 minute but preferably longer by transferring and/or spraying into each food-processing vessel. It is essential that the sanitizing solution contact all surfaces to be sanitized. Thus, hard to reach in place equipment, pipes, closed vessel, etc. should be filled with the solution to ensure contact of all surfaces with the sanitizing solution. Use suitable protective breathing apparatus when spraying this solution on external equipment.
6. After the required contact time or longer, the solutions are allowed to drain from all surfaces and air dried.
7. The above solution may not be reused for sanitizing but may be diluted to 1:5 with water and used for cleaning of walls, floors and drains of the plant.

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with COMMENTS
EPA Letter Dated:

SEP 18 2000

United States Environmental Protection Agency
Washington, DC 20460
EPA Region 7
Chicago, IL 60604

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[0033] – [OPT.]

Chlorine dioxide generated from ADOX® 3125 may also be used as a water sanitizer for fruit and vegetable washing and cut and peeled potato products without a subsequent potable water rinse requirement, provided that the concentration of total residual oxidants meet the residual limitations of < 1.0 ppm.

[0034] – [OPT.]

Residual concentrations up to 5.0 ppm chlorine dioxide in process water may be used for washing whole uncut and unpeeled fruits and vegetables although a final potable water rinse is required if the residual exceeds 1 ppm.

[0035] – [OPT.]

Potatoes including those which have been peeled or cut, may be treated with sufficient chlorine dioxide to produce a residual concentration of up to 5.0 ppm provided this is followed by a potable water rinse.

[0036] – [OPT.]

USE OF ACIDIFIED SODIUM CHLORITE SOLUTIONS

Pursuant to 21 C.F.R. Part 173.325, the Food and Drug Administration (FDA) has approved the use of acidified sodium chlorite solutions as antimicrobial agents for poultry, meat, and raw agricultural commodities. Specific use-instructions for these applications are listed below.

[0037] – [OPT.]

TO CONTROL THE MICROBIAL POPULATION OF POULTRY PROCESSING CHILLER WATER:

Prepare a solution having a concentration of sodium chlorite between 50 and 150 ppm. Dilute 1 gallon of ADOX® 3125 to 5000 gallons with water for 50 ppm or 1 gallon of ADOX® 3125 to 1666 gallons with water for 150 ppm. Lower the pH of this solution to between 2.8 and 3.2 with any GRAS acid. This solution is used in a pre-chiller or chiller for chicken carcasses and carcass parts.

[0038] – [OPT.]

TO CONTROL THE MICROBIAL POPULATION OF CHICKEN CARCASSES:

Prepare a solution having a concentration of sodium chlorite between 500 and 1200 ppm. Dilute 1 gallon of ADOX® 3125 to 500 gallons with water for 500 ppm sodium chlorite or 1 gallon ADOX® 3125 to 208 gallons with water for 1200 ppm. Lower the pH of this solution to between 2.3 and 2.9 with any GRAS acid. Spray or dip the carcass parts in this solution or use as a component of a post chill carcass spray or dip solution when applied to poultry meat, organs or related parts or trim.

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EPA Letter Dated:

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[0039] – [OPT.]

TO CONTROL THE MICROBIAL POPULATION IN THE PROCESSING OF RED MEAT, RED MEAT PARTS AND ORGANS:

Prepare a solution having a concentration of sodium chlorite between 500 and 1200 ppm. Dilute 1 gallon of ADOX® 3125 to 500 gallons with water for 500 ppm sodium chlorite or 1 gallon of ADOX® 3125 to 208 gallons with water for 1200 ppm. Lower this solution to between pH 2.5 to 2.9 with any GRAS acid. The red meat parts are sprayed or dipped into the solution.

[0040] – [OPT.]

TO CONTROL THE MICROBIAL POPULATION IN PROCESSED, COMMINUTED OR FORMED MEAT (UNLESS SUCH USE IS PRECLUDED BY THE USDA STANDARDS OF IDENTITY IN 9 CFR PART 319):

This additive is used at levels between 500 and 1200 ppm of sodium chlorite to control the microbial population on processed, comminuted, or formed meat products (unless precluded by standards of identity in 9 CFR Part 319) prior to packaging of the food for commercial purposes, in accordance with current industry standards of good manufacturing practice. Dilute 1 gallon of ADOX® 3125 to 500 gallons with water for 500 ppm sodium chlorite or 1 gallon of ADOX® 3125 with 208 gallons for 1200 ppm sodium chlorite. Lower the pH of this solution to between 2.5 to 2.9 with any GRAS acid. This solution is applied as a spray or dip.

[0041] – [OPT.]

TO ELIMINATE THE GROWTH OF MICROORGANISMS, IN FOOD PROCESSING FACILITIES, THAT CAUSE SPOILAGE ON RAW AGRICULTURAL COMMODITIES SUCH AS FRUITS AND VEGETABLES:

Prepare a solution having a concentration of between 500ppm and 1200 ppm of sodium chlorite. Dilute 1 gallon of ADOX® 3125 diluted to 500 gallons (500 ppm) or 208 gallons (1200 ppm), with water. Lower the pH of the solution to between 2.3 and 2.9 with any GRAS acid. The raw agricultural products are spray or dipped into this solution. This treatment must be followed by a potable water rinse or by blanching, cooking or canning.

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with COMMENTS
EPA Letter Draft

SEP 18 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registered under EPA Reg. No. 9150-7

- Changed [0012] – Changed 2008 to 2009
- Changed [0015] – Changed to reflect language on 9150-8; ADOX® 750
- Changed [0017] – Changed to reflect language on 9150-8; ADOX® 750
- Changed [0015] – Changed
 - Storage - to reflect language on 9150-8; ADOX® 750
- Changed [0026] – Changed
 - Application/Use Header to reflect language on 9150-8; ADOX® 750
 - Added language reflect language on 9150-8; ADOX® 750
- Changed [0029] – Changed Application/Use Header to include the word “Water”
- Added [0031]
 - Updated the CFR from 21 CFR 178.1010 to 40 CFR 180.940
 - Currently approved on 9150-8; ADOX® 750
- Added [0032] – Currently approved on 9150-8; ADOX® 750
- Changed [0039] – Added “between” to reflect language on 9150-8; ADOX® 750

ACCEPTED
with COMMENTS
EPA Letter Dated:
SEP 18 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 9150-7