

14 JUN 1991

West Agro, Inc.
11100 North Congress Avenue
Kansas City, MO 64153

Attention: Richard Beach
Regulatory Specialist

Gentlemen:

Subject: ZZZ Disinfectant
EPA Registration No. 4959-16
Your Submission Dated March 20, 1991

This is in response to your submission dated March 20, 1991 regarding the revised Confidential Statement of Formula and labeling for the subject product.

The revised Confidential Statement of Formula and proposed alternate source of supply for the active ingredient are acceptable. This submission satisfactorily fulfills our requirement in that regard.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

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CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Note that the preferred declaration for the active ingredient is now Iodine*. When new labels are printed, you should delete "Titratable" from the ingredient statement on the label.

Sincerely yours,



Ruth G. Douglas
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

BEST AVAILABLE COPY

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY
ZZZ DISINFECTANT

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Authorized by USDA for use in federally inspected meat, poultry and egg processing plants.

CONCENTRATED BROAD SPECTRUM IODOPHOR FOR USE AS A ONE-STEP CLEANER-DISINFECTANT AND NO-RINSE SANITIZER

Hospitals and Clinics Food Processing Plants Dental Offices Hand Sanitizing in Food Plants Schools and Institutions
Nursing Homes Kitchens and Lunch Rooms Restrooms

Used as directed ZZZ DISINFECTANT is effective against *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Mycobacterium tuberculosis*, Pathogenic fungi and kills the HIV-1 Virus on pre-cleaned environmental surfaces and objects previously soiled with blood or other body fluids.

ACTIVE INGREDIENTS:

Titrateable Iodine* 1.75%
INERT INGREDIENTS: 98.25%
Total 100.00%

*From alpha-(p-nonylphenyl)-omega-hydroxypoly(oxyethylene)-iodine complex

PRECAUTIONARY STATEMENTS: HAZARD TO HUMANS AND DOMESTIC ANIMALS

KEEP OUT OF THE REACH OF CHILDREN

DANGER. CORROSIVE. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wear goggles or face shield. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge into lakes, streams, ponds or public waters unless in accordance with a NPDES permit. For guidance, contact the regional office of EPA.


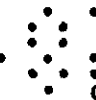
STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. If swallowed, promptly drink a large quantity of water. Do not induce vomiting. Avoid alcohol. Get medical attention. Remove and wash contaminated clothing before reuse.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsions may be needed.

EPA Reg. No. 4959-16

EPA Est. No. _____ State-01

Sold by:  company logo  company name

address

0005-F1190

DIRECTIONS FOR USE:

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

Not for Residential Use.

The color of a ZZZ DISINFECTANT solution is proportional to the iodine concentration. Prepare a fresh solution daily, or whenever a noticeable change in its rich amber color, or more often if the solution becomes diluted or soiled. Used as directed, ZZZ DISINFECTANT is effective in hard water (up to 400 ppm CaCO₃) and in 5% or more organic load against listed bacteria and pathogenic fungi.

ONE-STEP CLEANING AND DISINFECTING:

This product may be used to clean and disinfect operating areas, rooms, floors, walls, counter tops, rest rooms, shower areas, containers, bed frames, morgues, laboratories, cafeterias, freezers, animal rooms, cages and other hard, non-porous surfaces. Before applying disinfecting solution, food products and packaging materials must be removed from the room or carefully protected. Remove deposits before applying the disinfecting solution. Using a solution of 6 ounces ZZZ DISINFECTANT per 5 gallons of warm water (68°F or warmer), immerse objects in disinfecting solution, or apply solution with a mop, sponge or brush. Where appropriate, use a mechanical brush. Allow a 10 minute contact time with disinfecting solution. All contact surfaces must be rinsed with potable water before reuse. Walls and all other non-food contact surfaces may drain after rinsing.

NOTE: When mixing ZZZ DISINFECTANT with cold water (as low as 5°C), increase use to 6 oz. per 5 gallons water.

ACCEPTED

14 JUN 1991

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 4959-16

ZZZ disinfectant and medical instruments, tubing, catheters, thermometers and rubber gloves follow the specific instructions listed below.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES AND OBJECTS PREVIOUSLY SOILED WITH BLOOD OR OTHER BODY FLUIDS:

PERSONAL PROTECTION: While handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings (goggles or glasses).

CLEANING PROCEDURE: Before applying disinfecting solution thoroughly clean blood and other body fluids from hard surfaces, interior and exterior surfaces of instruments and objects to be decontaminated. Thoroughly wet hard surfaces with a solution containing 3 ounces of ZZZ DISINFECTANT per 5 gallons of water. Completely immerse small objects and instruments in the disinfecting solution. Flush and fill tubing, catheters and the lumen of hollow instruments with the disinfecting solution; avoid entrapment of air bubbles. Allow at least 10 minutes of contact time.

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids should be autoclaved and disposed of according to Federal, State and Local regulations for infectious waste disposal.

TO CLEAN AND DISINFECT TOILET BOWLS AND URINALS: Flush toilet. Add 1 ounce of ZZZ DISINFECTANT directly to water in toilet bowl. Brush to cover all bowl surfaces including under the rim. Allow disinfectant to remain for at least 10 minutes. Flush toilet. Rinse metal parts with water after disinfecting to prevent corrosion.

SANITIZING PREVIOUSLY CLEANED FOOD CONTACT SURFACES:

Sanitize previously cleaned and rinsed hard, non-porous surfaces such as glass, metal, plastic, and porcelain, with a solution containing 1 ounce of ZZZ DISINFECTANT per 5 gallons of water. Spray or immerse equipment with sanitizing solution and allow 1 minute contact time. Drain solution from equipment; do not rinse. ZZZ DISINFECTANT used at 1 ounce per 5 gallons of water contains 25 ppm titratable iodine and does not require a final rinse with potable water in accordance with Federal Food Additive Regulation 178.1010.

HAND SANITIZING IN FOOD PROCESSING PLANTS: Thoroughly wash and rinse hands before sanitizing. Dip or rinse hands in a solution containing 1 ounce of ZZZ DISINFECTANT per 5 gallons of water. ZZZ DISINFECTANT may be injected directly into wash or rinse water at a rate of 1 ounce per 5 gallons of water. A final potable water rinse is not required.

USE DILUTION TABLE
ZZZ DISINFECTANT/ WATER TITRATABLE IODINE

1 oz to 5 gallons water	25 ppm
3 oz to 5 gallons water	75 ppm
6 oz to 5 gallons water	150 ppm

STORAGE AND DISPOSAL

Keep container closed when not in use. Do not store below 25°F or above 100°F for extended periods.

PROHIBITIONS: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

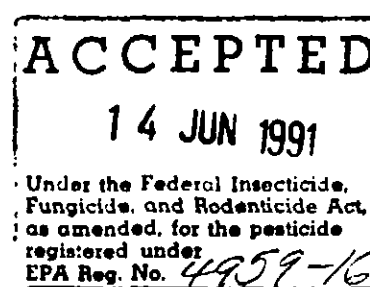
PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or, if allowed by State and local authorities, burn container. If burned, stay out of smoke.

NET CONTENTS:
LOT NO.:

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