

FEB 10 1989

Dufois Chemicals, Inc.
3650 East Kemper Road
Sharonville, OH 45241

Gentlemen:

Subject: Response to Tuberculocidal Data Call-In Notice
Iodet Bactericidal Liquid Detergent
EPA Registration No. 5736-3
Your Submission Dated July 20, 1988

This is in response to your resubmission in regard to the Tuberculocidal Data Call-In (TB DCI) Notice for the subject product.

The submitted tuberculocidal data meet the requirements of the TB DCI Notice to support effectiveness of the product as a tuberculocide against Mycoadacterium tuberculosis var bovis (BCG) when used at a 1:171 dilution (3/4 oz/gal; 75 ppm titrable iodine) in the presence of 408 ppm hard water (as CaCO₃) on precleaned, hard, nonporous surfaces for a contact time of 10 minute at 20 °C.

The labeling (label and Technical Data Sheet), submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable in support of the TB DCI Notice provided that you:

1. Make the following revisions before you release the product for shipment bearing the amended labeling.
 - a. Include the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling" immediately under the Use Directions heading on the Technical Data Sheet also.
 - b. Delete "Only for sale to use and storage by service persons."
 - c. Revise "See Technical Data Sheet for use directions for tuberculocidal disinfection" to read "See Technical Data Sheet for additional instructions and use directions for tuberculocidal disinfection."

57158:I:Douglas:K-10:KENCO:2/2/89:2/13/89:AS:VO:AS

CONCURRENCES

SYMBOL								1 of 6
SURNAME								
DATE								

2. Submit the final printed labeling for inclusion in the product file.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions in this regard, please contact Ms. Ruth Douglas at (703) 557-3842.

Sincerely yours,



Jeff Kempter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (TS-767C)

Enclosure

20/6

ONE GALLON (3.785 liters)
U.S. MEASURE

See label for
Additional Use

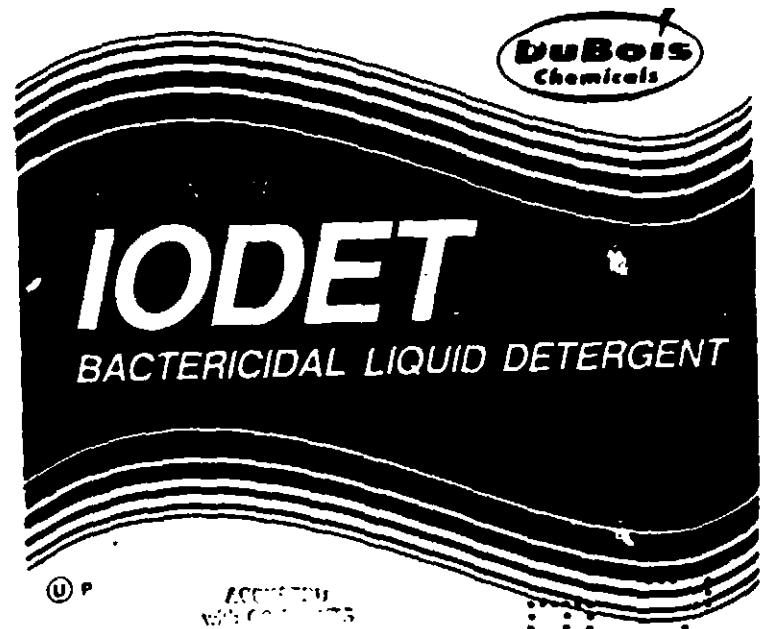
DuBOIS CHEMICALS
IODET®
BACTERICIDAL LIQUID
DETERGENT

ACTIVE INGREDIENTS:
OK (p-nonylphenyl)-omega-hydroxypoly
oxyethylene-iodine complex (supplying
1.265% Titerable iodine by weight) 6.33%
OK (p-nonylphenyl)-omega-
hydroxypoly (oxyethylene) condensate 7.24%
Phosphoric acid 15.00%
INERT INGREDIENTS: 71.43%
100.00%

KEEP OUT OF
REACH OF CHILDREN

DANGER:
SEE PRECAUTIONARY STATEMENT
ON SIDE OF CONTAINER

Made in U.S.A. P.D. 415-487



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5736-3

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FOR HOSPITAL USE/BACTERICIDAL LIQUID DETERGENT

TECHNICAL DATA

GENERAL DESCRIPTION:

GENERAL DESCRIPTION. IODET® iodophoric, acidic, bactericidal liquid detergent is designed to clean and disinfect ~~in one operation~~ without the need of heat. IODET detergent can be used in water of any hardness level.

PROPERTIES:

PROPERTIES:	
State	Mobile liquid
Color	Brown
Solubility	Instant, with water, at all proportions
Odor	Slight indous, evanescent
Foam	Suited to recommended usage
pH	2.7 at 1/4 oz per gallon of water
Stability	Excellent under 125°F
Biodegradable	Contains biodegradable surfactants
KEEP FROM FREEZING	If frozen, return to producing

EPA Registration No.

5736.3

INGREDIENTS:

(p-nonylphenyl) omega-hydroxypoly	
(oxyethylene) iodine complex (supplying	
1.265% titratable iodine by weight)	6.33%
(p-nonylphenyl) omega-hydroxypoly	
(oxyethylene) condensate	7.24%
Phosphoric Acid	15.00%
Inert Ingredients	71.43%

DIRECTIONS FOR USE:

For General Cleaning: IodET is to be used at a concentration of 3/4 oz. per gallon of water (75 ppm available iodine). If surfaces are heavily soiled use two containers.

For Disinfecting: Recommended for use on preformed, hard, nonporous, inanimate surfaces. Apply IODET at a concentration of 3/4 oz. per gallon of water (75 ppm titratable iodine). Allow 10 minute contact time and follow by a water rinse. Rinse soil from washing

cloth in rinse compartment before redipping in wash solution to avoid weakening solution

For laboratory glassware, thermometers, and surgical instruments: Immerse items in ¼ oz per gallon of water solution of IODET detergent (75 ppm titratable iodine) immediately after use for presoaking before hand washing or machine washing to soften blood and soils

Heat sensitive items: Items that cannot be autoclaved will be disinfected by soaking for 15 minutes in a ¾ oz. per gallon of water solution of IODET detergent (75 ppm titratable iodine)

Physical therapy equipment: Whirlpool baths, etc., will be cleaned, disinfected, and mineral scale controlled ~~continuously~~ by regular cleaning with a ¾ oz per gallon of water solution of IODET detergent (75 ppm liberatable iodine).

Mopping: A ¼ oz per gallon of water solution of IODET detergent (75 ppm titratable iodine) may be used in conventional mopping procedure. Follow the double bucket method recommended by DuBois for mopping.

Sprayer, wet-vacuuming: Follow DuBors procedure for sprayer wet vacuuming with a 1/4 oz per gallon of water solution of IODET detergent (75 ppm titratable iodine) on tile and resilient flooring in laboratories, kitchen, halls and patient rooms.

Third sink sanitizing: Ware should be completely cleaned and rinsed before being immersed in the sanitizing rinse. The correct amount of IOET detergent to use is ¼ oz. per gallon of water (25 ppm titratable iodine).

Brush-type cold water glass washer: Adjust machine in accordance with machine manufacturer's directions if necessary. A solution of ¼ oz. of IODET detergent per gallon of water provides 25 ppm titratable iodine.

FOR HOSPITAL DISINFECTION:

Thoroughly clean surface to remove heavy soil or gross filth prior to disinfecting. Use $\frac{3}{4}$ oz. of IODET per gallon of cold water (75 ppm titratable iodine) for disinfecting rubber, plastic, stainless and glass equipment against *Staphylococcus aureus*, *Salmonella choleraesuis* and *Pseudomonas aeruginosa*. Allow a minimum of a 10 minute contact time and follow by a water rinse.

For disinfection against tuberculosis (*Mycobacterium tuberculosis* var *Bovis* B6C), thoroughly pre-clean surface to remove heavy soil or gross silt before disinfecting. Use 3 1/4 ounce of IODET per gallon of cold water (75 ppm titratable iodine). Allow a contact time of 10 minutes at 20°C on hard, nonporous environmental surfaces and follow by a water rinse.

Do not mix with soap or alkaline materials

PACKAGING:

Packed 4 1-gal (3 785 liters) plastic containers per case

TITRATION:

Use IODET detergent Sanitation Test Kit

GERMICIDAL TESTS:

Method: AOAC Use Dilution Confirmation Method, 13th Edition, 1997, page 68

Results: *Staphylococcus aureus* (ATCC No 6538) 75 ppm
titratable iodine

Salmonella choleraesuis (ATCC No 10708) 75 ppm titratable iodine

Pseudomonas aeruginosa (ATCC No 15442) (PRD 10) 75 ppm
titratable iodine

75 ppm titratable iodine is equivalent to 3/4 ounces of IODET detergent per gallon of water

KEEP OUT OF REACH OF CHILDREN.

DANGER:

Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing when handling. Protect skin and eyes when handling. Harmful or fatal if swallowed. Avoid contamination of food.

First Aid: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. For eyes call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsions may be needed.

ACCEPTED
FOR COMMENTS
in the following order:

Statement of Practical Treatment

FEB 10 1989

TNC.

DuBOIS CHEMICALS, ~~GENERAL CHEMICALS CORPORATION~~
GENERAL OFFICES DuBOIS TOWER • CINCINNATI, OHIO 45202 • PHONE (513) 762-6000

57 ~~SECRET~~ It is to be understood that the use of this product rather than that containing a dye indicated on the label implies accuracy of test of and under conditions

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GERMICIDAL LIQUID DETERGENT

DIRECTIONS FOR USE

Do not use this product in a manner inconsistent with its labeling. IODET is an iodophoric acidic sanitizer-detergent for use with brush type, cold water glass for final sanitizing rinsing of utensils or food contact surfaces.

Utensils and Glasses in Hand Washing Operations:

Pre-scrub utensils and glasses to remove gross food particles. Pre-soak if necessary.

In a DuBois detergent

potable water

In a solution of 1/4 oz. to one gallon of cold water (25 ppm titratable iodine). Immerse for at least 2 minutes or for contact time specified by governing sanitary code.

Rinsed utensils on a rack or drainboard to air dry.

On all surfaces before contact with food.

operations. Fresh sanitizing solution must be prepared at least daily. Prepare more often if becomes diluted or soiled.

During glassware and final sanitizing rinsing of food utensils, use 1/4 ounce per gallon

(25 ppm titratable iodine). Let glasses and utensils drain and air dry. Acceptable under

FDIC Food Additive Law for final sanitizing rinses of food equipment.

Titratable iodine, where required by health authorities, use 1/4 ounce per two gallons

minimum exposure time of two minutes.

Use: DuBois IODET at 25 ppm of titratable iodine (1/4 ounce per gallon of water) is

200 ppm of available chlorine derived from sodium hypochlorite.

See Germicidal Equivalent Concentration Method, A.O.A.C. 13th Edition, 1980, page 59.

KEEP OUT OF REACH OF CHILDREN

DANGER

Corrosive: Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing when handling. Protect eyes and skin when handling. Harmful or fatal if swallowed. Avoid contamination of food.

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. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

Rinse empty containers thoroughly with water and discard them.

Notes to Physicians: Probable mucosal damage may contraindicate the use of gastric lavage. Measure against circulatory shock, respiratory depression and convulsion may be needed.

STORAGE AND DISPOSAL:

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

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture or residue 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 incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

KEEP FROM FREEZING. IF FROZEN RETURN TO PRODUCING PLANT.

U.S. Pat. 2,931,777; 2,977,315; 3,028,299

EPA Registration No. 5736-3 EPA EST. No. 5736-NJ1

ONLY FOR SALE TO, USE & STORAGE BY SERVICE PERSONS

DUBOIS CHEMICALS, A DIVISION OF DOW CORP. • GENERAL OFFICES: DUBOIS TOWER • CINCINNATI, OHIO 45202

I.N.C.

Disinfecting *Tuberculocidal*
Treat *disinfecting* *tuberculocidal* *surface* to remove heavy soil or gross filth
- *disinfecting* *tuberculocidal* *use* 1/4 ounce IODET per gallon of cold water
25 ppm titratable iodine for disinfecting, rubber, plastic, stainless
glass equipment, against *Staphylococcus aureus*, *Salmonella*
typhimurium and *Pseudomonas aeruginosa*. Allow a minimum of
minute contact time and follow by a water rinse. AOAC Use-Dilution
Titration Method, 14th Edition, 1984.

Technical Data sheet for use directions for *disinfecting* *tuberculocidal*

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