

46274-2

05-05-2011

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:
46274-2

Date of Issuance:
MAY - 5 2011

Term of Issuance:
Conditional

Name of Pesticide Product:
DAKIN'S SOLUTION
DISINFECTANT BY CENTURY

NOTICE OF PESTICIDE:
 Registration
 Reregistration

(under FIFRA, as amended)

FILE COPY

Name and Address of Registrant (include ZIP Code):

Century Pharmaceuticals, Inc.
10377 Hague Road
Indianapolis, IN 46256

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision No. D-430289) is registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
 - a. Revise the "EPA File Symbol to read, EPA Reg. No. 46274-2 "

Signature of Approving Official:

Wanda Y. Henson
Acting Product Manager Team (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date:

MAY - 5 2011

Page 1 of 2

b. Revise the "Hazards to Humans and Domestic Animals" statement as follows:

1. The Signal Word is "Caution", based upon the result of the acute dermal toxicity study.

2. The Precautionary Statements must state:

"Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse."

3. The First Aid statements must state:

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.

c. Revise the Ingredient statement as follows:

Active Ingredient: Sodium Hypochlorite.....	0.50%
Other Ingredients.....	<u>99.50%</u>
Total.....	100.00%

(equivalent to 0.48% available chlorine)

3. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Should you have any questions regarding this letter, please contact me either by phone at (703) 308-6345 or email at Henson.Wanda@epa.gov.

Sincerely,



Wanda Y. Henson
Acting Product Manager Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosures: (Stamped Label)

EPA Reg. No. _____

DAKIN'S SOLUTION® DISINFECTANT By CENTURY (5000 ppm NaOCl)

For Hospital / School / Home Use

- Clean and Disinfect in one step
- Stabilized, Ready-to-Use Bleach Solution
- For Use on Non-Porous Hard Surfaces
- Multipurpose, broad spectrum Disinfectant

Active ingredient: Sodium Hypochlorite.....0.50%
(equivalent to 0.48% available chlorine)
Inert ingredients.....99.50%

CAUTION

KEEP OUT OF REACH OF CHILDREN

Read complete warnings and directions prior to use

CENTURY PHARMACEUTICALS, INC.

INDIANAPOLIS, IN 46256

www.CenturyPharmaceuticals.com

Questions or Comments? 317-849-4210 or 1-866-343-2576
Monday - Friday 9 AM to 4 PM EST.

Item # 777-08

NET 237 ml (8 FL. OZ.)

Lot # _____

Not for sale or use after _____

1 Gallon
10 FL. OZ.

ACCEPTED
with **COMMENTS**
EPA Letter Dated:

MAY - 5 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide,
registered under EPA Reg. No. 46274-2

DAKIN'S SOLUTION® DISINFECTANT for Use on Hard Surfaces to eliminate germs including Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin Resistant *Enterococcus faecalis* (VRE), *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella enterica*.

SURFACES: May be used on all hard, non-porous surfaces such as floors, walls, tables, and chairs. May be used on glass, stainless steel, vinyl, and plastics.

DIRECTIONS FOR USE: It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Effective as a disinfectant in the presence of a 5% organic soil load. Heavily soiled surfaces must be pre-cleaned prior to disinfections.

Spray directly on hard surfaces until surface is completely wet. Allow 10-minute contact time. No rinsing is required. Wipe off the excess solution as needed.

NOTES: This product degrades with age. Discard the product after its expiration date.

PRECAUTIONARY STATEMENTS: It may produce chemical burns. Do not get on skin or in eyes. **Physical or chemical Hazards:** Mix with water only! Do not use this product with ammonia, acids or organic materials such as vinegar, rust removers, or toilet bowl cleaners. This product not intended for use on fabrics

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTIONS: Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or drinking. Remove and wash contaminated clothing before reuse.

FIRST AID:

External: If on skin or clothing: take off contaminated clothing, rinse skin immediately with plenty of water for 15-20 minutes. If skin irritation persists, call a poison control center or get medical attention. For eyes, hold eye open and rinse gently with water for 15-20 minutes and get immediate medical attention for further treatment advice.

Internal: Give milk, water or egg white. **Do not** induce vomiting. Call physician or poison control center immediately. **Inhalation:** Remove to fresh air. Get medical attention.

STORAGE AND DISPOSAL: Store this product in a cool, dry area, away from direct sunlight and heat to avoid deterioration. Non-Refillable container, do not reuse or refill this container. When discarding empty container, place in trash collection or take to recycling center. Do not contaminate water, food, or feed by storage and disposal.

Barcode

W/W