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US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

NOTICE OF PESTICIDE: ☐ REGISTRATION ☐ REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

EPA REGISTRATION NO. 7078-17

DATE OF ISSUANCE MAY 10 1996

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT

CIDEX O.P.A. ANTIMICROBIAL

NAME AND ADDRESS OF REGISTRANT *(Include ZIP code)*

Johnson & Johnson Medical Inc.
P.O. Box 90130
Arlington, TX 76004

NOTE: Changes in labeling formula 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 U.S. 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.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this 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 is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration No. 7078-17".

b. Include the appropriate EPA Est No. onto the label.

c. Include the the main heading : "Storage and Disposal" to appear above all the directions for storage and disposal.

d. Move the referral statement to appear directly below the Note to Physican section.

☐ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL | DATE

EPA Form 8570-6 (Rev. 5-76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

e. Revise the statement:

Do not discharge effluent containing this product into into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified addressed in NPDES permit.

to read:

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.

f. Since the accepted chemical name for this product is 1,2-Benzenedicarboxaldheyde, it is preferred that this name be declared as the primary name in the ingredient section. The chemical name: ortho-Phthalaldehyde could be referenced via an asterick to appear directly below the ingredient section.

g. Include the heading: Net Contents

h. Delete the statement: May cause skin sensitization. NOTE: The data you submitted does not support this claim.

i. Revise the statement: "Maybe harmful or fatal if swallowed" to read: Harmful or fatal if swallowed.

3. Inform the end-use formulators that at this time, exposure data will be required from end-use formulators to support their individual product registrations.

4. Even though at the onset of the review of this product it was determined that the avian dietary study will be waived for this product, now this data requirement is being imposed as a condition of this registration. The time frame established will be nine months from the date of this registration.

5. At the onset of the review of this product, it was determined that the hydrolysis study will not be imposed on indoor products. Todays data requirements are requiring a minimum of an hydrolysis study for all products which includes indoor products, especially for formulating and manufacturing use products. The time frame established will be nine months from the date of this registration.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

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.

Submit one (1) copy of the final printed label prior to release of the product for shipment.

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

Sincerely,

Marion Johnson
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosures

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

CIDEX* O.P.A. ANTIMICROBIAL

Active Ingredient:

ortho-Phthalaldehyde (1,2-Benzenedicarboxaldehyde)	99.7%
Inert Ingredients	0.3%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See back panel for additional precautionary statements.

STATEMENT OF PRACTICAL TREATMENT

If swallowed: **DO NOT INDUCE VOMITING.** Give at least two glasses of water: Seek medical advice with urgency. Do not give anything by mouth to an unconscious person.

If on skin: Wash with plenty of soap and water. Get medical attention.

If in eyes: Immediately flush with plenty of water for at least 15 minutes. Get immediate medical attention.

If inhaled: Remove to fresh air. If breathing is difficult, administer oxygen. If symptoms persist, call a physician.

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

Imported by
Johnson & Johnson
MEDICAL INC.
ARLINGTON, TEXAS 76004-0130

EPA Reg. No. 7078-
EPA Est. No.

* Trademark

5946

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER

KEEP OUT OF REACH OF CHILDREN

Corrosive. Causes burns. Causes severe eye and skin damage. May cause skin sensitization. Avoid breathing dust. May be harmful or fatal if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles, protective clothing, and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

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

For use by manufacturers only in formulating Sterilants and Disinfectants (Indoor Use Only). Forumulators using this product are responsible for providing data for the EPA registrations for their formulated products.

DISPOSAL

PESTICIDE DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Pesticide wastes are toxic. 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 the label instructions, contact your State Pesticide or your Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Plastic Containers: 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.

PHYSICAL PROPERTIES

Melting Point..... 55-56° C Solubility in Water at 20° C..... 5 % (w/w)

STORAGE AND HANDLING

In its crystalline solid form, CIDEX* O.P.A. Antimicrobial can be stored in high density polyethylene drums at 20-25° C (68-77° F) with no significant oxidation from air. This product melts at 55-56° C (131-133° F). Exposure to elevated temperatures in the presence of air should be avoided. For short storage times (up to one month), temperatures up to 40° C (104° F) can be tolerated if the product is blanketed with an inert atmosphere of nitrogen or argon. Since this product is light-sensitive, it must be stored in opaque containers.

CIDEX O.P.A. Antimicrobial can be transferred with any solids handling equipment with appropriate precautions to avoid prolonged exposure to heat, light, and/or air as described above.

LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonably fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible experts' evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all forms of the active or under all conditions. THE MANUFACTURER NEITHER MAKES NOR INTENDS, NOR DOES IT AUTHORIZE ANY AGENT OR REPRESENTATIVE TO MAKE, ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, AND IT EXPRESSLY EXCLUDES AND DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. This warranty does not extend to, and the Buyer shall be solely responsible for, any and all losses or damages which result from the use of this product in any manner which is inconsistent with the label directions, warnings, and indications.

BUYER'S EXCLUSIVE REMEDY AND MANUFACTURER'S OR SELLER'S EXCLUSIVE LIABILITY FOR ANY AND ALL CLAIMS, LOSSES, DAMAGES, OR INJURIES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT WHETHER OR NOT SUCH LIABILITY IS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY IN TORT OR OTHERWISE, SHALL BE LIMITED, AT THE MANUFACTURER'S OPTION, TO REPLACEMENT OF, OR THE REPAYMENT PURCHASE PRICE FOR, THE QUANTITY OF PRODUCT WITH RESPECT TO WHICH DAMAGES ARE CLAIMED. IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

NET WT. 55 LBS (25 KG)

* Trademark