

70627-36

03/28/2001

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H-505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

70627-36

Date of Issuance:

MAR 28 2001

NOTICE OF PESTICIDE:
X Registration
Reregistration

(under FIFRA, as amended)

Term of Issuance:

CONDITIONAL

Name of Pesticide Product:

Easy Paks® 4-Shot™
Disinfectant Cleaner

Name and Address of Registrant (include ZIP Code):

S.C. Johnson Commercial Markets, Inc.
8310 16 th Street, MS 675
Sturtevant, WI 53177-0902

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 is conditionally 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 reregistration of your product under FIFRA section 4.

2. Add the phrase EPA Registration Number "EPA Reg. No. 70627-36".

Signature of Approving Official:

Handwritten signature of Velma Noble

Velma Noble
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Date:

MAR 28 2001

EPA Form 8570-6

CONCURRENCES

Table with columns for SYMBOL, SURNAME, DATE, and multiple empty columns for CONCURRENCES. Handwritten entries: SYMBOL 7510C, SURNAME J. Lantz, DATE 3/28/01.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

page 2
EPA Reg. No. 70627-36

3. Revise the "Precautionary Statement" such that the first statement reads as follows: "Causes irreversible eye damage and skin burns." Delete the word "concentrate" as it appears twice in the "Precautionary Statement".

4. Revise the "Environmental Hazards" statement to include the following statement: "This product is toxic to fish."

5. Revise the "First Aid" statements to agree with PR Notice 2001-1 as follows:

"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 Swallowed:

- Call a 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 a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If Inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice."

6. On page 3 in the "Disinfection" section, delete the brackets associated with the statements "For heavily soiled areas, a pre-cleaning step is required. OR Remove gross filth or heavy soil prior to application of the product." The "or" statement may be retained but one of these two statements must be included on the final printed label for this product. Also delete the brackets associated with the statements "(Remove excess liquid) OR (Wipe off with a clean cloth, sponge, or paper towel.)" The "or" statement may be retained but one of these two statements must be included on the final printed label for this product.

7. On page 3 revise to state as follows: "Use only with the ~~EASY PAKS 4 SHOT Disinfectant Cleaner~~ ^{CONCURRENCES} Use Solution Trigger Bottle."

SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

page 3
EPA Reg. No. 70627-36

8. On page 4 in the food processing plant directions delete the brackets associated with the statements "For heavily soiled areas, a pre-cleaning step is required. OR Remove gross filth or heavy soil prior to application of the product." The "or" statement may be retained but one of these two statements must be included on the final printed label for this product.

9. On page 6 revise to state as follows: "See outer carton for complete instructions, precautionary and first aid information, and storage and disposal."

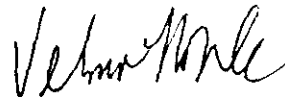
10. The following alternate brand names are approved for this product: "Don-O-Mite Plus Bathroom Deodorizing Cleaner/Disinfectant," "Disinfectant Cleaner PC Cartridge," and "CREW Restroom Disinfectant Cleaner SC."

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

If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosure (stamped label)

~~7510C:T.Lantz:3/20/01:70627-36~~

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

(Note to Agency: Text appearing in parenthesis or brackets is intended to show optional text.)

Johnson Wax PROFESSIONAL

EASY PAKS® 4-SHOT™ Disinfectant Cleaner

(CONCENTRATE)

- Cleaner • Deodorizer • Disinfectant • *Virucide
- Fungicide (against pathogenic fungi) • Mildewstat (on hard non-porous inanimate surfaces)

For (Hospital,) (Food Service,) (Food Plant) (Commercial) (Industrial) (&) (Industrial) Use Only

ACTIVE INGREDIENTS:	
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides.....	4.50%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	4.50%
INERT INGREDIENTS:	91.00%
TOTAL:	100.00%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 28 2001

EPA Reg. No. 70627-GA
EPA Est. No.
Lot number suffix (A) or (B) indicates
Appropriate establishment number.

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

70627-36

See additional precautionary statements on back (side) (left) (right) (panel) label below.
(See outer carton for complete instructions, precautionary and storage and disposal statements.)

NET CONTENTS:

(Product of USA)

(Note to Agency: Text appearing in parenthesis or brackets is intended to show optional text.)

(MARKETING CLAIMS): (Note to EPA - This text will only appear on the appropriate container.)

J-SPRAY™ DISPENSING SYSTEM - For use with (Johnson Wax Professional) (Prism) (Drackett) (J-Spray) (EASY PAKS 4- SHOT) brand dispensing equipment. Eliminates mixing. The Accurate Solution to Cleaner Dilution. Disinfectant Cleaning With The Convenience of (J-Spray) (EASY PAKS 4- SHOT). (J-Spray) (EASY PAKS 4- SHOT) (This package offers) Reduced exposure To Concentrate Due To Closed Transfer System. Solutions To Go! Concentrate. Makes XX bottles. Each compartment of a J-Spray cartridge produces XX oz. (XX mL) ready-to-use product. Four concentrate cartridges makes xx gallons (xx L) of ready-to-use product.

(FEATURES, CLAIMS & USES:)

EASY PAKS 4-SHOT Disinfectant Cleaner is a phosphate free formulation designed to provide effective cleaning, deodorizing, and disinfection specifically for hospitals, nursing homes, schools and colleges, (medical) offices, food processing plants, food service establishments (restaurants), hotels, motels, and restrooms where housekeeping is of prime importance in controlling the hazards of cross contamination on treated surfaces.

This product, when used as directed, is formulated to disinfect inanimate, hard non-porous surfaces: walls, floors, tables, chairs, and telephones. For larger areas: operating rooms, patient care facilities and restrooms, this product is designed to provide both general cleaning and disinfecting.

This product deodorizes those areas, which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, basements, restrooms and other areas, which are prone to odors caused by microorganisms.

(CLAIMS:)

Efficacy tests have demonstrated that **EASY PAKS 4-SHOT** Disinfectant Cleaner is an effective **BACTERICIDE, FUNGICIDE, AND VIRUCIDE** in the presence of **ORGANIC SOIL (5% BLOOD SERUM)**. The use dilution yields 703 ppm of active quaternary germicide.

Bactericidal Activity - When used as directed on hard non-porous inanimate surfaces, this product exhibits effective disinfectant activity against the organisms: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Brevibacterium ammoniagenes*, *Enterobacter aerogenes*, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Salmonella typhi*, *Shigella dysenteriae*, *Streptococcus faecalis*, *Streptococcus pyogenes*, *Streptococcus salivarius*, and meets the requirements for hospital use.

***Virucidal Activity** - This product when used as directed on hard non-porous inanimate surfaces, this product exhibits effective virucidal activity against HIV-1 (associated with AIDS), Adenovirus Type 2 (causative agent of upper respiratory infections), Influenza A/Brazil, Influenza A2/Japan (representative of the common flu virus), Herpes simplex virus type 1 (causative agent of fever blisters and mononucleosis) and Vaccinia virus (representative of the pox virus group).

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 28 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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registered under EPA Reg. No. 70627-36

(Note to Agency: Text appearing in parenthesis or brackets is intended to show optional text.)

DIRECTIONS FOR USE:

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

Not to be used as a terminal sterilant-high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or contact with the blood stream or normally sterile areas of the body or, (2) Contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product maybe used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Disinfection - [For heavily soiled areas, a pre-cleaning step is required. or Remove gross filth or heavy soil prior to application of the product.] To disinfect inanimate, hard non-porous surfaces, add 1 oz. per gallon of water. Apply with mop, cloth, sponge or mechanical sprayer so as to wet all surfaces thoroughly. Allow surfaces to remain wet for 10 minutes. [(Remove excess liquid) or (Wipe off with a clean cloth, sponge or paper towel.)] After use, all food contact surfaces must be thoroughly rinsed with potable water. This product must not be used to clean the following surfaces: utensils, glassware, and dishes. Prepare fresh solution for each use.

(Note to EPA: The directions that appear for specific container sizes will be substituted for the specific container size.)

J-SPRAY™ DISPENSING SYSTEM

Each compartment of an **EASY PAKS 4- SHOT** Disinfectant Cleaner concentrate cartridge can be diluted to produce XX fl. oz. (xx mL) of ready to use product. Four concentrate cartridges make a total of XX gallons (XX L) of ready-to-use **EASY PAKS 4- SHOT** Disinfectant Cleaner. The use dilution yields 700 ppm of active quaternary germicide. Use only with the **EASY PAKS 4- SHOT** Disinfectant Cleaner Use Trigger Bottle. *Read instructions before use.* Do not mix with other chemicals. Do not put any other product in spray bottle.

(Cartridge Placement Instructions:)

1. Remove side cap, and fill bottle with water to line. Replace cap.
2. Open bottle top by removing (black) (grey) neck ring. Remove snap cap from cartridge and insert **EASY PAKS 4- SHOT** Disinfectant Cleaner concentrate cartridge into neck of bottle. Replace (black) (grey) neck ring.
3. Insert trigger spray dip tube into center cartridge hole, and gently push plastic plunger down through one of the sealed foil compartments. Then continue to push until top and bottoms seals are broken. **DO NOT PIERCE MORE THAN ONE COMPARTMENT AT A TIME.**
4. Screw trigger sprayer down tightly, and gently agitate to mix solution.
5. Affix label provided.

(Refill Instructions:)

When trigger spray bottle is empty, refill with water. Leave (black) (grey) neck ring on, lift trigger sprayer and pierce next cartridge section following steps 3 & 4. Replace cartridge when all four sections have been used. Use only in bottles labeled: **EASY PAKS 4- SHOT** Disinfectant Cleaner Use Dilution.

ACCEPTED
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Under the Federal Insecticide,
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11/21/00
Page 3 of 6
EPA Reg. No. 70627-GA

(Note to Agency: Text appearing in parenthesis or brackets is intended to show optional text.)

To Disinfect Toilet Bowls: Pre-clean heavily soiled areas. Flush toilet and add 1 oz. of this product directly to bowl water. Swab bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand 10 minutes and flush.

For Use in Food Processing Plants: Before using this product, food products and packaging materials must be removed from the room or carefully protected. To disinfect inanimate, hard non-porous surfaces, add 1 oz. per gallon of water. [For heavily soiled areas, a pre-cleaning step is required. or Remove gross filth or heavy soil prior to application of the product.] Apply solution with mop, cloth, sponge or mechanical sprayer so as to wet all surfaces thoroughly. Allow surfaces to remain wet for 10 minutes. Wipe off with a clean cloth, sponge, or paper towel. After use, all surfaces in the area must be thoroughly rinsed with potable water. This product must not be used to clean the following surfaces: utensils, glassware, and dishes. Prepare fresh solution for each use.

Mildewstat - To control mold and mildew on pre-cleaned, hard non-porous surfaces, add 1 oz. per gallon of water. Apply solution with a cloth, mop, or sponge making sure to wet all surfaces completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

Fungicidal Activity - At 1 oz. per gallon of water, this product is fungicidal against (pathogenic Fungi,) *Trichophyton mentagrophytes* (that causes Athletes foot fungus) when used as directed for disinfection with a contact time of 10 minutes on bathroom floors, shower stalls, glazed tiles and other hard, non-porous inanimate surfaces.

To Clean & Deodorize - At 1 oz. per gallon of water this product may be used to clean and deodorize surfaces. (Apply solution) (Spray) surface until thoroughly wet, then wipe. For heavily soiled areas or stubborn spots, let product stay on surface longer before wiping.

*** EASY PAKS 4-SHOT KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) 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 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

Contact Time: Allow surface to remain wet for 10 minutes.

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

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in EPA Letter Dated:

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(Note to Agency: Text appearing in parenthesis or brackets is intended to show optional text.)

(For use with containers one gallon or less)

STORAGE AND DISPOSAL

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

Storage - Store in original container and place in locked storage area. Store in a dry place no lower in temperature than 50°F or higher than 120°F.

Container Disposal - Do not reuse container (cartridge). Wrap container (cartridge) and put in trash.

(For use with containers larger than one gallon)

STORAGE AND DISPOSAL

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

Pesticide Storage - Store in original container and place in locked storage area. Store in a dry place no lower in temperature than 50°F or higher than 120°F.

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 the 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 - Do not reuse empty container. 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, by burning. If burned, stay out of smoke.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Concentrate causes severe eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling concentrate. Harmful if swallowed or inhaled. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS (for containers of 5 gallons or 50 lbs. or more)

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 agency 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.

FIRST AID

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACCEPTED
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11/21/00
Page 5 of 6
EPA Reg. No. 70627-GA

(Note to Agency: Text appearing in parenthesis or brackets is intended to show optional text.)

(Note to EPA: This text will only be used on Cartridge of the J-SPRAY™ DISPENSING SYSTEM. The size of the cartridge label is 1.25" x 3.875".)

EASY PAKS® 4-SHOT™ Disinfectant Cleaner
Concentrate

ACTIVE INGREDIENTS:

n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈) dimethyl benzyl ammonium chlorides.....4.50%
n-Alkyl (68% C₁₂, 32% C₁₄) dimethyl ethylbenzyl ammonium chlorides.....4.50%

INERT INGREDIENTS:.....91.00%

TOTAL:.....100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER

See outer carton for complete instructions, precautionary information, and storage and disposal statements.

Disposal: Wrap cartridge and discard in trash.

EPA Reg. No. 70627-GA

S.C. Johnson Commercial Markets, Inc., Sturtevant, WI 53177

Made in USA

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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