

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 24 1995

S.C. Johnson & Son, Inc.  
1525 Howe Street  
Racine, WI 53403

Attention: Stephen Smith  
Senior Registration Specialist

Subject: Virex II 128  
EPA Registration No. 4822-357  
MOU Compliance Amendment dated June 12, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

The labeling submitted in compliance with PR Notice 94-4 is acceptable. A stamped copy is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely yours,



Marion J. Johnson, Jr.  
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (7505C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

298

VIREX II 128  
One Step Germicidal Cleaner and Deodorant

Pseudomonacidal Staphylocidal Salmonellacidal  
Fungicidal \*Virucidal

ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride .....	4.352%
n-Alkyl [C <sub>14</sub> 50%, C <sub>12</sub> 40%, C <sub>16</sub> 10%] dimethyl benzyl ammonium chloride .....	4.095%
INERT INGREDIENTS .....	91.553%

KEEP OUT OF REACH OF CHILDREN  
**DANGER**

See additional precautionary statements on back

**ACCEPTED**  
JUL 24 1995

Under the Federal Insecticide, Fungicide, and  
Rodenticide Act, as amended, for the  
pesticide registered under  
EPA Reg. No. 4822-357

VIREX II 128 is a germicidal cleaner and deodorant that is effective in hard water up to 400 ppm (calculated as CaCO<sub>3</sub>) plus 5% organic blood serum. VIREX II 128 is labor saving, providing broad spectrum disinfection, mold and mildew control, and odor elimination with mild cleaning.

VIREX II 128 is recommended for use on non-food contact surfaces in hospitals, nursing homes, schools and colleges, veterinary clinics, animal life science laboratories, hotels and federally inspected meat and poultry establishments.

VIREX II 128 is specially formulated to be non-dulling to floor finishes. VIREX II 128 eliminates the time and labor normally required for rinsing.

VIREX II 128 is bactericidal at 1:128 (1 ounce per gallon) against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Staphylococcus aureus* (methicillin resistant - MRSA), *Escherichia coli*, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Proteus mirabilis*, *Proteus vulgaris*, *Salmonella enteritidis*, *Salmonella pullorum*, *Salmonella typhi*, *Serratia marcescens*, *Streptococcus agalactiae*, *Streptococcus faecalis*, and *Streptococcus pyogenes* according to the AOAC Use Dilution Test Method modified in the presence of 400 ppm synthetic hard water (calculated as CaCO<sub>3</sub>) plus 5% organic serum.

VIREX II 128 is fungicidal at 1:128 dilution against *Trichophyton mentagrophytes*, *Candida albicans* and *Aspergillus niger* according to the AOAC Use Dilution Test, modified in the presence of 400 ppm hard water (calculated as CaCO<sub>3</sub>) plus 5% organic serum.

VIREX II 128 is virucidal at 1:128 dilution against \*HIV-1 (AIDS virus), Influenza A<sub>2</sub>/J305, Herpes Simplex Type 1, Herpes Simplex Type 2, Adenovirus Type 2, New Castle disease virus, Avian influenza, and Pseudorabies virus according to the virucidal qualification test, modified in the presence of 400 ppm hard water (calculated as CaCO<sub>3</sub>) plus 5% organic serum.

**DIRECTIONS FOR USE:**

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

**This product is 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 in contact with the bloodstream 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 may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.**

**GENERAL USE DIRECTIONS FOR DISINFECTING:**

For use on hard inanimate non-porous surfaces such as floors, walls, metal surfaces, porcelain, and plastic surfaces. Remove gross filth and heavy soil deposits then thoroughly wet surfaces as required. Use 1 ounce per gallon of water for a minimum contact time of 10 minutes in a single application. Can be applied with a mop, sponge, or cloth as well as coarse spraying or soaking. The recommended use solution is prepared fresh for each use, then discarded. Rinsing is not necessary unless floors are to be waxed or polished. Prepare a fresh solution daily or when use solution becomes visibly dirty.

\* Kills HIV-1 (AIDS virus) 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

ACCEPTED  
JUL 24 1995  
Under the Federal Insecticide Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 14822-357

4 7 8

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS virus) 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.

ACCEPTED  
JUL 22  
Under the Federal Acquisition Regulation and its amendments, this contract is being used in accordance with FAR Reg. No. 48.222-357

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CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

CONTACT TIME: HIV-1 (AIDS virus) is inactivated after one (1) minute contact time.

Use a ten (10) minute contact time for disinfection against all other bacteria, fungi, and viruses listed on labeling.

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.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

May be fatal if inhaled. Do not breathe mist. Corrosive: 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. Harmful or fatal if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT

If inhaled: Remove to fresh air and ventilate treated area. If symptoms persist, call a physician. If on skin: Immediately flush with plenty of water. If in eyes: Immediately rinse with plenty of water for 15 minutes and call a physician. If swallowed: Drink one glass of water and get medical attention. Do not induce vomiting. Note to Physician: Probable mucosal damage may contraindicate gastric lavage.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

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.

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. 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.

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.

Fiber Drums with Liners

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

6 7 8

**Metal Containers**

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(If container is 1 gallon or less, use this container disposal statement.)  
Do not reuse empty container. Wrap container and put in trash.

**General**

Consult Federal, State, or local disposal authorities for approval of alternative procedures such as limited open burning.

EPA Registration No. 4822-357  
EPA Est. No. 4822-WI-1

Net Contents 32 oz - 55 gallons

1992 S. C. Johnson & Son, Inc. Racine, WI 53403-5011, U.S.A.  
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**ACCEPTED**  
JUL 24 1995  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under  
EPA Reg. No. 4822-357

REFERENCE SHEET

VIREX II 128

ONE STEP GERMICIDAL CLEANER AND DEODORANT

VIREX II 128 is a germicidal cleaner and deodorant that is effective in hard water up to 400 ppm (calculated as CaCO<sub>3</sub>) plus 5% organic blood serum. VIREX II 128 is labor saving, providing broad spectrum disinfection, mold and mildew control, and odor elimination with mild cleaning.

Effective at 1:128 dilution (1 ounce per gallon) against the following pathogenic bacteria according to the AOAC Use Dilution Test, 15th edition, 1990, modified in the presence of 400 ppm synthetic hard water (calculated as CaCO<sub>3</sub>) plus 5% organic serum:

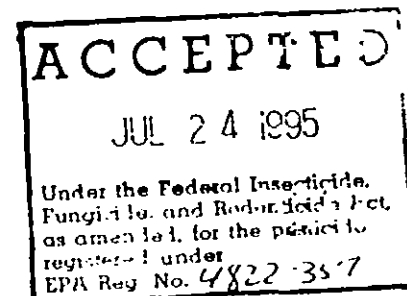
- |                                     |                                    |
|-------------------------------------|------------------------------------|
| Pseudomonas aeruginosa ATCC# 15442  | 1 Salmonella pullorum PI# 3751     |
| Salmonella choleraesuis ATCC# 10708 | Salmonella typhi ATCC# 6539        |
| Staphylococcus aureus ATCC# 6538    | Serratia marcescens ATCC# 14756    |
| 4 Escherichia coli 0157:H7          | 3 Staphylococcus aureus SCJ# 226   |
| Klebsiella pneumoniae ATCC# 4352    | (methicillin resistant - MRSA)     |
| 4 Listeria monocytogenes 20A OHIO   | 2 Staphylococcus aureus SCJ# 225   |
| 1 Proteus mirabilis PI# 366         | 1 Streptococcus agalactiae PI# 517 |
| Proteus vulgaris ATCC# 13315        | 1 Streptococcus faecalis PI# 523   |
| Salmonella enteritidis ATCC# 13076  | Streptococcus pyogenes ATCC# 9342  |
| 4 Salmonella enteritidis E40        |                                    |

Fungicidal at 1:128 dilution against Trichophyton metagrophytes ATCC# 9533, Candida albicans ATCC# 10231, and Aspergillus niger ATCC# 6275 according to the AOAC Use Dilution test, 15th edition, 1990, modified in the presence of 400 ppm hard water (calculated as CaCO<sub>3</sub>) plus 5% organic serum.

Virucidal at 1:128 dilution against \*HIV-1 (AIDS virus), Adenovirus Type 2 ATCC# VR-2, Herpes Simplex Type 1 ATCC# VR-735, Herpes Simplex Type 2 ATCC# VR-734, Influenza A<sub>2</sub>/J305 ATCC# VR-100, New Castle disease virus ATCC# VR623, Avian influenza ATCC# VR797 and Pseudorabies virus ATCC# VR135 according to the Virucidal Qualification test, modified in the presence of 400 ppm hard water (calculated as CaCO<sub>3</sub>) plus 5% organic serum.

Note: Clinical isolates of organisms designated by footnotes.

- 1 Presque Isle Associates
- 2 St. Mary's Hospital, Racine, Wisconsin
- 3 Park West Hospital, Knoxville, Tennessee
- 4 Food Research Institute, Madison, Wisconsin



\* Kills HIV-1 (AIDS virus) 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).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS virus) 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 the disinfectant.

**CONTACT TIME:** HIV-1 (AIDS virus) is inactivated after one (1) minute contact time.

Use a ten (10) minute contact time for disinfection against all other bacteria, fungi, and viruses listed on labeling.

**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.

RECEIVED  
JUL 24 1995  
FEDERAL BUREAU OF INVESTIGATION  
U.S. DEPARTMENT OF JUSTICE  
4822 357