

PM 33 69268-2 9/10/98



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
401

"M" St., S.W.

Washington, D.C. 20460

EPA Reg. Number:

69268-2

Date of Issuance:

SEP 10 1998

Term of Issuance:

CONDITIONAL

Name of Pesticide Product:

H<sub>2</sub>ORANGE<sub>2</sub>  
CONCENTRATE 117

NOTICE OF PESTICIDE:

Registration  
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Alphen, Inc.  
Division of Dynachem  
P.O. Box 19, Maple Grove Road  
Georgetown, IL 61846

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. "69268-2".

Signature of Approving Official:

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobial Division (7510W)

Date:

SEP 10 1998

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3. This conditional registration will expire automatically in exactly 12 months (365 calendar days) from the date stamped on this Notice of Pesticide Registration unless you meet the condition stated below. If you fail to satisfy this condition imposed in the registration, EPA may issue a Notice To Cancel under section 6(e) of FIFRA.

You must submit three copies of: (a) raw data from all the efficacy studies that were submitted for review, and (b) characterization data (identity, strength, purity, and composition of test substances for lot numbers 97199, 97220, 97227, 168, 181, 97168, 97181, 10003, 10004, 10053, and 10054). If EPA verifies and accepts (within the 12 month time restriction) that the efficacy data were developed at the proper concentrations, then a conditional registration can be issued without the 12 month time limitation.

4. Increase the type size of the Signal Word "DANGER" to conform to the latest edition of the EPA Label Review Manual.

5. Move the "Statement of Practical Treatment" boldfaced heading so that it is flush left, and just before "In case of CONTACT with product concentrate".

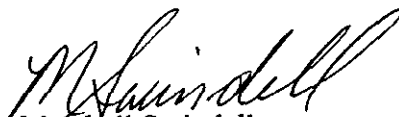
6. Submit two copies of the revised final printed label for the record.

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.

If you have any questions concerning this letter, please contact Tony Kish at (703) 308-9443.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobial Division (7510W)

Enclosure

FRONT PANEL - ALPHEN 117

MASTER LABEL

09-08-98

(logo)

## H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT	
Hydrogen peroxide	3.95%
OTHER INGREDIENTS	96.05%
TOTAL	100.00 %

KEEP OUT OF REACH OF CHILDREN

**DANGER**

PRECAUTIONARY STATEMENTS

SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-  
EPA Est. No. 069268-IL-001

ALPHEN, INC.  
MAPLE GROVE ROAD  
GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

NET WEIGHT:

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

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Under the Federal Insecticide,  
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This product is not to be used as a terminal sterilant/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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMAN AND DOMESTIC ANIMALS

#### Statement of Practical Treatment

**Danger.** Undiluted product concentrate may cause severe eye damage. Do not get in eyes, on skin or clothing. Wear safety glasses or other eye protection and rubber gloves when handling concentrate. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

*After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.*

#### In case of CONTACT with product concentrate

**If in eyes:** Flush immediately flush with cold water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

**If on skin:** Immediately wash with plenty of soap and water. Get medical attention.

**If swallowed:** Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mouth to an unconscious person.

#### STORAGE AND DISPOSAL

**IN CASE OF SPILL:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

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**DIRECTIONS FOR USE**

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

**Alphen 117**, when used as directed as a sanitizer, kills 99.99% or more of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, **Alphen 117** kills the following viruses in 5 minutes or less at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

**To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces:** Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

**To use as a sanitizer and virucide in bathrooms:** Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

**HIV:** To kill HIV in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of **Alphen 117** to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/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 I (HIV-1 Associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

**Contact time:** While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

**Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

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**CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute with Alphen's Dispensing System Only)

**LIGHT DUTY (1 Oz / gal) GREEN** (bottle or label)

Streak free window, mirror and stainless steel cleaning  
General floor cleaner for mopping & auto scrubbers  
Bonnet cleaning solution for carpets  
Light wipe down cleaner

**GENERAL PURPOSE (2 Oz / gal) BLUE** (bottle or label)

General wipe down cleaner  
Mopping solution for Bathroom and Kitchen floors  
General carpet spot remover

**HEAVY DUTY (10 Oz / gal) RED** (bottle or label)

Bathroom, shower room, tile & grout cleaner  
Urine and garbage odor eliminator  
Pre-spray for carpet extraction  
General degreaser  
Heavy soil wipe down cleaner  
Heavy carpet spot remover  
Cleans Mold & mildew

**SUPER DUTY (24-48 Oz / gal) PURPLE** (bottle or label)

Renovation of tile & grout surfaces  
Difficult urine & garbage odor destruction  
Scuff marks and stubborn stains  
Cleans heavy mold & mildew

**1-Step Cleaning and Sanitizing:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

**Deodorizing**

For general deodorizing, use 2 part **Alphen 117** to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts **Alphen 117** to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

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