

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 31 2000

Alphen LLC
P. O. Box 19
Maple Grove Road
Georgetown, IL 61846

Mailed To: Kyle Sabinovic, Agent For Alphen, Inc.
Shaldra, Inc.
4327 Reels Mill Road
Frederick, MD 21704-7759

RE: EPA Reg. No. 69268-2
H₂Orange₂ Concentrate 117
Your Amendment Dated 8/3/99

The Amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to submit four new acute toxicology studies in support of a change of the Signal Word from "DANGER" to "CAUTION", is acceptable, providing that you make the following label changes listed in this letter.

A copy of the label stamped "Accepted With Comments" is enclosed for your records.

SIGNAL WORD CHANGE APPROVAL BASIS

This product, and the companion product (EPA Reg. No. 69268-1), were originally registered based on the "Cite All" method of support. Thus, product specific acute toxicology studies were never submitted or reviewed for either product. The "Signal Word", "Precautionary Statements", and "Statement of Practical Treatment" for both products were originally assigned based on the "Peroxy Compounds" RED, and similar "Me Too" registered products.

The four acute toxicology studies you submitted with your Amendment are acceptable (see attached reviews) and apply to both EPA Reg. No. 69268-1 (8% hydrogen peroxide), and EPA Reg. No. 69268-2 (4% hydrogen peroxide). The test substance used was the formula for EPA Reg. No. 69268-1 (8% hydrogen peroxide). The acute toxicology categories for this product, and for the EPA Reg. No. 69268-1 are as follows:

- Oral - 3, MRID 44892603, acceptable
- Dermal - 3, MRID 44892604, acceptable
- Inhalation - 3, Assigned pending contrary data, no MRID ever submitted/cited
- Eye - 3, MRID 44892601, acceptable
- Skin - 4, MRID 44892602, acceptable
- Sensitization - Not a sensitizer pending contrary data, no MRID ever submitted/cited

CONCURRENCES

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LABEL CHANGES

You must submit five copies of a revised final label which incorporates the following changes. Because the newly established acute toxicology categories above apply to both EPA Reg. No.'s 69268-1 and 69268-2, you should also submit an Amendment for EPA Reg. No. 69268-1 requesting a change of the "Signal Word" and other label changes listed below. Please include a copy of this letter with your submission.

Required Label Changes

1. Based on the acute toxicology categories and the EPA "Label Review Manual", you must change the "Precautionary Statements" to read exactly as follows.

"Caution. Causes moderate eye irritation. Harmful if swallowed, absorbed through the skin, or inhaled. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling."

2. Delete the sentence, "Product, after dilution according to directions, is non-irritating."

3. Based on the acute toxicology categories and the EPA "Label Review Manual", you must change the "Statement of Practical treatment" to read in the following order, exactly as follows using boldface and caps.

"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 promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol."

"IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

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

4. Delete the sentence, "In case of contact with product concentrate."

5. On page 3 of the label, the word "officier" is misspelled.

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If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

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FRONT PANEL - ALPHEN 117

MASTER LABEL

04-30-99

(logo)

H₂ORANGE₂ 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

CAUTION

PRECAUTIONARY STATEMENTS

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

ACCEPTED
with COMMENTS
in EPA Letter Dated:
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Under the Federal Insecticide
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
69268-2

EPA Reg. No. 069268-2
EPA Est. No. 069268-IL-001

ALPHEN, INC.
MAPLE GROVE ROAD
GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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PRECAUTIONARY STATEMENTS**HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

Caution. Undiluted product concentrate causes moderate eye damage. Avoid contact with eyes, on skin or clothing. Avoid contamination of food. Wash thoroughly with soap and water after handling.

Product, after dilution according to directions, is non-irritating.

STATEMENT OF PRACTICAL TREATMENT

In case of CONTACT with product concentrate

If in eyes: Flush immediately with plenty of cold water. Remove contact lenses. Get medical attention if irritation persists.

If on skin: Immediately wash with plenty of soap and water. Get medical attention if irritation occurs and persists.

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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in EPA Letter Direct

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69268-2

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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 A₂/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.

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.

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.

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.

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.

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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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

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

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

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

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

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