

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 13 1995

American Sterilizer Company
2424 West 23rd Street
Erie, PA 16512

Attention: Lori A. Haller
Corporate Regulatory Affairs

Subject: Amsco Vaprox Hydrogen Peroxide Sterilant
EPA Registration No. 5749-8
Your Amendment Dated June 7, 1995
and your cover letter dated June 8, 1995

The amendment (label update) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Make the following labeling changes below before you release the product for shipment bearing the amended labeling. (Cartridge - Master Label).

a. Our records indicate that company number 5749 is assigned to American Sterilizer Company. This company name must appear on the label.

b. Add the heading: Net Contents.

c. The following form of the ingredient statement complies with the Act.

ACTIVE INGREDIENT

Name of the ingredient..... %

INERT INGREDIENTS..... %

d. Place the signal word: DANGER to appear directly below and centered under the heading: KEEP OUT OF REACH OF CHILDREN.

e. Revise the referral statement to read: See back panel for additional precautionary statements.

CONCURRENCES

| | | | | | | | |
|---------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

275

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

- 2 -

f. Add the Note to Physician Statement to read:

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

g. Revise the precautionary statement section to read:

Danger. Corrosive. Causes eye and skin damage. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Do not breathe vapor or spray mist. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

h. Revise the heading: "Chemical and Physical Hazards" to read:

Physical or Chemical Hazards

i. Revise the subheading: Hazard to Humans..." to read: Hazards to Humans ..."

2. Make the following labeling changes below before you release the product for shipment bearing the amended labeling. (Outer Container Shipping Label).

a. Our records indicate that company number 5749 is assigned to American Sterilizer Company. This company name must appear on the label.

b. Add the heading: Net Contents.

c. The following form of the ingredient statement complies with the Act.

ACTIVE INGREDIENT

Name of the ingredient..... %

INERT INGREDIENTS..... %

d. Place the signal word: DANGER to appear directly below and centered under the heading: KEEP OUT OF REACH OF CHILDREN.

e. Add the following referral statement to read: See back panel for additional precautionary statements.

f. Just a reminder that items 2c, 2d, & 2e all must be placed directly under the product name on the front panel of the label.

CONCURRENCES

| | | | | | | | | |
|---------|--|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | | |
| SURNAME | | | | | | | | |
| DATE | | | | | | | | |

375

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

- 3 -

g. Add the Note to Physician Statement to read:

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

h. Revise the precautionary statement section to read:

Danger. Corrosive. Causes eye and skin damage. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Do not breathe vapor or spray mist. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

i. Revise the heading: "Chemical and Physical Hazards" to read:

Physical or Chemical Hazards

j. Revise the subheading: Hazard to Humans..." to read: Hazards to Humans ..."

k. Add a Storage and Disposal section for this outer box label.

1. Add a referral statement which states that the use directions are on the cartridge label.

3. It has noted for the files that the Foreign language: French, has not been translated. It is your responsibility to ensure the translation is accurate.

4. A release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

5. A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, contact V. Goncarovs at 703-305-6663.

Sincerely,

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

Enclosures

| CONCURRENCES | | | | | | | |
|--------------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

CARTRIDGE LABEL - MASTER LABEL

AMSCO
VAPROX™
 HYDROGEN PEROXIDE
 STERILANT 200 ML
 REORDER NO.
P8010

ACTIVE INGREDIENT: 35% Hydrogen Peroxide
 INERT INGREDIENT: 65% Water
 INGREDIENT ACTIF: 35% Peroxyde hydrogene
 INGREDIENT INERTE: 65% Eau

DANGER
 KEEP OUT OF REACH
 OF CHILDREN.
 OXIDIZER;
 CORROSIVE
 SEE BACK PANEL
 FOR STATEMENT OF
 PRACTICAL
 TREATMENT.
 FOR USE IN AMSCO
 VHP® INDUSTRIAL
 EQUIPMENT ONLY.
 DIN 02047616
 AMSCO CANADA, INC., WOODBRIDGE, ON

DANGER
 CONSERVER HORS DE
 LA PORTEE DES
 ENFANTS.
 OXYDANT;
 CORROSIF
 VOIR PRECAUTIONS
 D'EMPLOI AU DOS.
 A UTILISER QU'AVEC
 L'EQUIPEMENT DE
 INDUSTRIAL VHP®
 AMSCO.
 DIN 02047616

VAPROX™ UN2014
 HYDROGEN PEROXIDE STERILANT

STATEMENT OF PRACTICAL TREATMENT
 Do not get in eyes! **IN CASE OF EYE CONTACT:**
 Immediately flush with plenty of water for at least 15 minutes,
 lifting upper and lower lids intermittently. Call a physician.
 Do not take internally! **IF SWALLOWED:** Drink plenty of
 water immediately to dilute. Do not induce vomiting. Never give
 anything by mouth to an unconscious person. Call a physician.
 Avoid breathing vapors! **USE ONLY WITH ADEQUATE**
VENTILATION! IF INHALED: Remove to fresh air. If not
 breathing, give artificial respiration. If breathing is difficult, give
 oxygen. Call a physician.
 Avoid contact with skin and clothing!
IN CASE OF SKIN CONTACT: Immediately flush skin with plenty
 of water for 15 minutes while removing contaminated clothing and
 shoes. Get medical attention if irritation persists. Wash contaminated
 clothing and shoes promptly. Discard contaminated shoes in a
 fireproof container.
SEE EQUIPMENT MANUAL AND MATERIAL SAFETY DATA
SHEET FOR ADDITIONAL INFORMATION.
POUR PLUS D'INFORMATIONS, CONSULTEZ LE MANUEL
DE L'EQUIPEMENT ET LA FICHE TECHNIQUE SUR LA
SECURITE DES SUBSTANCES.



PRECAUTIONARY STATEMENTS
 Hazard to humans and domestic animals.
DANGER! OXIDIZER, CORROSIVE
 Liquid hydrogen peroxide causes eye damage, skin irritation,
 and is harmful if swallowed, inhaled or absorbed through the
 skin. Direct eye contact may cause irreversible tissue damage
 and blindness. Wear goggles or face shield and vinyl or
 neoprene gloves when handling open container. Vapors cause
 irritation to the eyes, nose, throat, and lungs.
CHEMICAL AND PHYSICAL HAZARDS
 Liquid hydrogen peroxide is a strong oxidant and poses a FIRE,
 EXPLOSION OR CONTAINER RUPTURE HAZARD. Avoid
 excessive heat, contamination, or contact with combustible
 materials. Clothing, shoes or other combustible materials that
 have come into contact with hydrogen peroxide must be
 immediately and thoroughly washed with water. If allowed to
 dry in the materials, a fire may result. Discard shoes in a
 fireproof container.
IN CASE OF FIRE use water only.
WHEN HANDLING an open container, wear a
 NIOSH/MSHA approved respirator as necessary, chemical splash
 goggles or full face shield, vinyl or neoprene gloves and other
 protective clothing and boots.
CONTAIN SPILLS and dilute with 20 parts of water. After
 dousing the spill, sodium metabisulfite or sodium sulfite (1.9
 lbs. SO₂ equivalent per 500 ml of peroxide) may be used to
 destroy the peroxide.



DIRECTIONS
 this product
 This product
 sterilant (i.e.,
 AMSCO VHP
 personnel U
 procedures of
STORAGE
 or 25°C in a
 chromium co
 materials, or
PESTICIDE
 parts water a
 Hydrogen pe
 waste under
 violation of M
CONTAIN
 container the
 drain. Avoid
 down the dr
 accordance v
 container.

LOT
 EPA REG. N
 EPA EST. NO
 AMSCO, A


Under the Federal Insecticide
 Fungicide and Rodenticide Act
 see instructions for the material
 registered under FIFRA Part 201
 5749-8

ACCEPTED
 with COMMENTS
 in EPA Letter dated
 SEP 1 0 1995

| | | | |
|-----------------------------------|-----------------------|---------|---------|
| AMSCO HYDROGEN PEROXIDE STERILANT | | Date | 3.1.95 |
| Part No. | 400077-637 | Art No. | XAC 228 |
| Art Farm Job No. | 3.1.95.CMF 400077-637 | | |
| Size | 11.625" X 3.4375" | | |

BEST COPY AVAILABLE

OUTER CONTAINER SHIPPING LABEL



**VAPROX™
HYDROGEN PEROXIDE
STERILANT**

**FOUR 200 ML
CARTRIDGES**

**REORDER NO.
PB010**

FOR USE IN AMSCO VHP® INDUSTRIAL EQUIPMENT ONLY.
SHADE FROM RADIANT HEAT. STOW AWAY FROM
POWDERED METALS AND PERMANGANATES.
À N'UTILISER QU'AVEC L'ÉQUIPEMENT DE INDUSTRIAL VHP®
AMSCO.
TENIR À L'ÉCARTE DE LA CHALEUR RAYONNANTE.
CONSERVER À L'ÉCARTE DES MÉTAUX ENPOUDRE ET
PERMANGANATES.

LOT NUMBER: Not for sale or use after.

[Empty box for lot number]



**VAPROX™
HYDROGEN PEROXIDE
STERILANT**

UN2014

STATEMENT OF PRACTICAL TREATMENT
Do not get in eyes! **IN CASE OF EYE CONTACT:** Immediately flush with plenty of water for at least 15 minutes, lifting upper and lower lids intermittently. Call a physician.
Do not take internally! **IF SWALLOWED:** Drink plenty of water immediately to dilute. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a physician.
Avoid breathing vapors! **USE ONLY WITH ADEQUATE VENTILATION! IF INHALED:** Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

Avoid contact with skin and clothing!
IN CASE OF SKIN CONTACT: Immediately flush skin with plenty of water for 15 minutes while removing contaminated clothing and shoes. Get medical attention if irritation persists. Wash contaminated clothing and shoes promptly. Discard contaminated shoes in a fireproof container.

PRECAUTIONARY STATEMENTS
Hazard to humans and domestic animals.
DANGER! OXIDIZER, CORROSIVE

Liquid hydrogen peroxide causes eye damage, skin irritation, and is harmful if swallowed, inhaled or absorbed through the skin. Direct eye contact may cause irreversible tissue damage and blindness. Wear goggles or face shield and vinyl or neoprene gloves when handling open container. Vapors cause irritation to the eyes, nose, throat, and lungs.

CHEMICAL AND PHYSICAL HAZARDS

Liquid hydrogen peroxide is a strong oxidant and poses a FIRE, EXPLOSION OR CONTAINER RUPTURE HAZARD. Avoid excessive heat, contamination, or contact with combustible materials. Clothing, shoes, or other combustible materials that have come into contact with hydrogen peroxide must be immediately and thoroughly washed with water. If allowed to dry in the materials, a fire may result. Discard shoes in a fireproof container.

IN CASE OF FIRE use water only.

CONTAIN SPILLS and dilute with 20 parts of water. After diluting the spill, sodium metabisulfite or sodium sulfite (1.9 lbs. SO₂ equivalent per 500 ml of peroxide) may be used to destroy the peroxide.

SEE EQUIPMENT MANUAL AND MATERIAL SAFETY DATA SHEET FOR ADDITIONAL INFORMATION



AMSCO CANADA, INC. WOODBRIDGE, ON

ACTIVE INGREDIENT: 35% Hydrogen Peroxide
INERT INGREDIENT: 65% Water

DANGER
KEEP OUT OF REACH OF CHILDREN.
OXIDIZER; CORROSIVE
STORAGE

Store cartridges at or below 77°F or 25°C in a dry location

EPA REG. NO. 5749-8
EPA EST. NO. 5749-NC-1

AMSCO, ATEX, INC. 27502 400077-638 3.1.95
(FOR AMSCO USE ONLY: 400021-312)

**VAPROX™
PÉROXYDE D'HYDROGÈNE
PREMIERS SOINS**

UN2014

Ne pas mettre dans les yeux! **EN CAS DE CONTACT AVEC LES YEUX:** Rincer immédiatement avec beaucoup d'eau pendant au moins 15 minutes, en soulevant les paupières supérieures et inférieures l'une après l'autre, contacter un médecin.

Ne pas ingérer! **EN CAS D'INGESTION:** Boire beaucoup d'eau immédiatement pour diluer le produit. Ne pas faire vomir. Ne jamais rien faire avaler à une personne inconsciente. Contacter un médecin.
Éviter de respirer les vapeurs! **À UTILISER QU'AVEC UNE VENTILATION ADEQUATE! EN CAS D'INHALATION:** Amener la personne à l'air libre. Si la victime ne respire pas, faire la respiration artificielle. Si elle respire difficilement, donner de l'oxygène. Consulter un médecin.

Éviter tout contact avec la peau et les vêtements!
EN CAS DE CONTACT AVEC LA PEAU: Rincer immédiatement la peau avec beaucoup d'eau pendant 15 minutes et retirer les vêtements et chaussures contaminés. Si l'irritation persiste, consulter un médecin. Laver rapidement les vêtements contaminés. Jeter les chaussures usagées dans un récipient résistant à l'incendie.

PRECAUTIONS D'EMPLOI
Danger pour les humains et les animaux domestiques.

DANGER! OXYDANT, CORROSIF

Le peroxyde d'hydrogène liquide cause des lésions des yeux, des irritations de la peau et est dangereux en cas d'ingestion, d'inhalation ou d'absorption par la peau. Tout contact avec les yeux peut causer des dommages irréversibles aux tissus et la cécité. Porter des lunettes de protection ou un masque facial et des gants en vinyle ou en néoprène pour manipuler des contenants ouverts. Les vapeurs causent une irritation des yeux, du nez, de la gorge et des poumons.

DANGERS CHIMIQUES ET PHYSIQUES

Le peroxyde d'hydrogène liquide est un oxydant puissant et représente un DANGER D'INCENDIE, D'EXPLOSION OU DE RUPTURE DES CONTENANTS. Éviter toute chaleur excessive, contamination ou tout contact avec des matériaux combustibles. Les vêtements ou tout autre matériau combustible ayant été en contact avec le peroxyde d'hydrogène doivent être lavés immédiatement à fond avec de l'eau. Si on laisse sécher le produit dans les matériaux, ce la risque de causer un incendie. Jeter les chaussures usagées dans un récipient résistant à l'incendie.

EN CAS D'INCENDIE utiliser de l'eau seulement.

CONTENIR LES RENVERSEMENTS et diluer avec 20 mesures d'eau. Après avoir dilué le renversement, le métabisulfite de sodium ou le sulfite de sodium (1.9 livres SO₂ équivalent par 500 ml de peroxyde) peut être utilisé pour le peroxyde.

POUR PLUS D'INFORMATIONS, CONSULTER LE MANUEL DE L'ÉQUIPEMENT ET LA FICHE TECHNIQUE SUR LA SÉCURITÉ DES SUBSTANCES.

INGRÉDIENT ACTIF: 35% Peroxyde d'hydrogène
INGRÉDIENT INERTE: 65% Eau

DANGER
CONSERVER HORS DE LA PORTÉE DES ENFANTS.
OXYDANT; CORROSIF
ENTREPOSAGE

Conserver les cartouches à ou sous 77°F or 25°C dans un endroit sec.

EPA REG. NO. 5749-8
EPA EST. NO. 5749-NC-1

DIN 02047616

| | | | |
|------------------|-----------------------------|---------|---------|
| AMSCO | HYDROGEN PEROXIDE STERILANT | Date | 3.1.95 |
| Part No. | 400077-638 | Art No. | XAC 229 |
| Art Form Job No. | 3.1.95.CMF 400077-638 | Rev. | |

ACCEPTED
with COMMENTS
In Full Letter Dated
SEP 10 1995
5749-8

BEST COPY AVAILABLE