F11132 US ENVIRONMENTAL PROTECTION AGENCY 67373-1 APR 1 4 1995 OFFICE OF PESTICIDES PROGRAMS TERM OF ISSUANCE REGISTRATION DIVISION (75-767) Conditional NAME OF PESTICIDE PRODUCT NOTICE OF PESTICIDE: REGISTRATION REREGISTRATION (Under the Federal Insecticide, Fungicide, ViralGuard Cartridge and Rodenticide Act, as amended) NAME AND ADDRESS OF REGISTRANT (Include ZIP code) 2505 Trade Center Avenue NGTE: Changes in labeling formula 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 U.S. 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. A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith. Registration is in no way to be construed as an indorsement or approval of this product by this 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 This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you: Submit/cite all data required for registration/ reregistration of your product under FIFRA section 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. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration No. 67373-1."

b. On the ViarlGuard Cartridge label, revise "Only use with SweetWater Guardian" to "Only use with SweetWater Guardina Microfiltration System.".

c. On the ViralGuard Cartridge label, insert "and precautionary statements" after "For complete use instructions

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ATTACHMENT IS APPLICABLE		
IGNATURE OF APPROVING OFFICIAL		DATE

WASHINGTON, DC 20460

SweetWater, Inc.

Longmont, CO 80503

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d. Revise the Ingredient Statement wherever it appears throughout the product labeling (i.e. pg. 5 of ViralGuard Cartridge Owner's manual, ViralGuard Cartridge) in bold print in the following manner:

Active Ingredient
Iodine*.....23.6%
Inert Ingredients......76.4%

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- * bound to strong anion base exchange resin or:
- * bound to polystyrene divinyl benzene quaternary ammonium exchange resin

(Note: The percentages should be aligned to the same right-hand margin and the active ingredient named should written on an indented separate line below the heading "Active Ingredient".)

- e. Separate the Net Contents statement from the Ingredient statement in both the ViralGuard Cartridge Manual (pg.6) and in the ViralGuard Cartridge Package Insert label (pg. 2).
- f. Include the following statement as a separate bullet on the front of ViralGuard Package Insert label (above "Meets EPA standards ...") and, on page 2 of the ViralGuard Cartridge Owner's Manual (above "Fig. 1"):

"For short term or limited or emergency use only and not recommended for long term or routine community water application".

- g. Change "Poliovirus type II" to "Poliovirus type I" at the bottom of page 3 of the ViralGuard Cartridge Owner's Manual.
- h. On page 5 of the ViralGuard Cartridge Manual, revise "Health Warnings" to "Precautionary Statements" and insert the signal word in bold print "CAUTION" beneath the KOROC statement ("Keep Out Of Reach Of Children").
- i. In the ViralGuard Package Insert Label add precautionary language above the precautionary statements "Cartridge contains penta-iodine resin. Because ..." in the following manner:

PRECAUTIONARY STATEMENTS KEEP OUT OF REACH OF CHILDREN CAUTION

j. On pages 2 and 3 of the ViralGuard Cartridge Manual revise "deactivates" to "inactivates".

- k. Revise the description for "Fig 2" on page 2 of the ViralGuard Cartridge Owner's manual to "ViralGuard Cartridge attached to Guardian Micro-filtration System ...".
- 1. On page 4 of the ViralGuard Cartridge Manual, revise the last part of the sentence under the heading "Worst Case Conditions" to: "... at 60 strokes per minute provides immediate potable water.".
- 3. Since the Guardian Plus Box and its text are not considered pesticide product labeling the following revisions should be made to this literature:
- a. Delete "EPA Registration No. 67373-1" from the left panel.
 - b. Revise "deactivates" to "inactivates" on the back panel.
- c. Delete the term "your" in the sentence "Attach it to the Guardian ... " on the back panel.
 - d. Delete the words "virtually all".
- 4. Make the following changes to Guardian Plus Micro-Filtration System Owner's Manual. (As in #3 above this document is not considered pesticide product labeling.)
- a. Revise "deactivates" to "inactivates" wherever this term appears in the manual.
- b. Delete the sentence "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.".
- c. On page 3 of this manual, in the second sentence of the paragraph under the heading "Using the Guardian without the ViralGuard", revise "... such as E. Coli and Cholera" to "... such as Klebsiella terrigena.".
 - d. Delete the term "Giardia" on page 3 of the manual.
- e. Revise the last part of the sentence under "'Worst Case' Conditions" on page 5 of this manual from "... at 60 strokes per minute is immediately safe to drink" to "... at 60 strokes per minute provides immediate potable water.".
- 5. Within ninety (90) days of the date of this notice, submit data demonstrating the ppm residual iodine in the treated water.
- 6. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

A stamped copy of the label is enclosed for your records.

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.

Sincerely,

Ruth G. Douglas Product Manager (32) Antimicrobial Program Branch Registration Division (7505C)

Enclosures

C. ViralGuard Cartridge Owner's Manual

outh COMMENTS to EPA Letter Dated:

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Instructions for the ViralGuard Cartridge Revised 4/8/95

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ViralGuard™ Cartridge Owner's Manual

{Line drawing of Guardian with ViralGuard Cartridge being pushed up toward it.}

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ViralGuardTM CARTRIDGE PROTECTS AGAINST WATERBORNE VIRUSES (such as Poliovirus type 1 and Rotavirus Strain SA-11) *
When used with the SweetWater GuardianTM Micro-Filtration System, according to these instructions, the ViralGuardTM Cartridge kills or deactivates*99.99% of waterborne viruses. This level of protection meets U.S. Environmental Protection Agency (EPA) standards. The ViralGuard Cartridge is registered by the EPA for use with the SweetWater Guardian Micro-Filtration System as a microbiological water purifier.

SweetWater, Inc. Logo

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Directions for Use

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

The ViralGuardTM Cartridge is effective only when used with the SweetWater GuardianTM Micro-Filtration System. It should not be used with any other brand product.

Fig. 1: ViralGuard Cartridge in Storage position with callouts

To Use

Remove backflush adapter (Fig. 1)

• Connect ViralGuard Cartridge to base of the SweetWater Guardian Micro-Filtration System(Fig. 2)

• Remove intake plug

Connect intake hose to ViralGuard Cartridge intake barb

• Place pre-filter in water

Pump. Exiting water is immediately safe to drink*

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Fig. 2: ViralGuard Cartridge attached to Guardian and being pumped

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NOTE: Pump no faster that 60 strokes per minute (1 stroke = 1 up and down)
Don't pump more than 8 liters at a single sitting. Wait two hours between
sittings.

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When Should You Use the ViralGuard Cartridge?

- In emergencies when sewage lines can contaminate municipal water systems (such as floods, hurricanes, earthquakes, etc.).
- During traveling to non-industrialized countries. See the Travel Tips section.
- Whenever you want an extra level of protection for outdoor adventures.

Caring for the ViralGuard Cartridge

If backflushed regularly, the ViralGuard Cartridge can effectively treat up to 90 gallons of water. After 90 gallons, the cartridge is not guaranteed to meet EPA standards. Keep track of the amount of water processed by removing one tab from the strap for each gallon pumped. Replace the cartridge after 90 gallons.

When to Backflush the ViralGuard Cartridge

- After pumping turbid, muddy water, or
- · When resistance increases on the upstroke, or
- When the down stroke produces no water.

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To Backflush

• Remove ViralGuard Cartridge from the Guardian Micro-Filtration System.

- Insert vertically aligned back! ush adapter into top of ViralGuard Cartridge
- · Attach intake hose to Guardian intake barb
- Connect Guardian outlet hose to backflush adapter
- Pump 20 strokes; Slow pump rate to 20-30 strokes per minute

NOTE: In addition to backflushing the ViralGuard Cartridge, brush clean the Guardian's filter to ease pumping resistance.

Fig. 3: ViralGuard diagram with adapter closed and ready to flush

Fig. 4: Shows ViralGuard Cartridge being backflushed

U.S.E.P.A. Microbiological Water Purifier Registration

When used with the SweetWater GuardianTM Micro-Filtration System, the ViralGuardTM Cartridge meets U.S. EPA requirements as a microbiological water purifier. The ViralGuardTM Cartridge kills or deactivates 99.99% of waterborne viruses (such as Poliovirus type T) and Rofavirus Strain SA 11). The ViralGuardTM Cartridge/ SweetWater GuardianTM Micro-Filtration System filters 99.9999% of waterborne bacteria (such as Klebsiella terrigena)

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and 99.99% of waterborne protozoa (such as Cryptosporidium). Unless a product can meet these requirements, it can not be called a microbiological water purifier, and users should not assume that they are protected against all three types of waterborne pathogens. Call SweetWater, Inc. (1-800-55-SWEET) for copies of independent test results.

WILL COMPRENSE to EPA Letter Detect

ViralGuard Cartridge Wet Storage

When not in use, the ViralGuard Cartridge must be properly storigized, and Rodenticide Act on amended, for the pesticide registered under EPA Reg. No. maintain its effectiveness before 90 gallons.

• Iodinated resin in the cartridge must be kept wet (you should be able to hear water inside if you shake it).

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- Always store with the intake plug and the backflush adapter in place (Fig. 1)
- You should be able to hear water inside if you shake it
- If cartridge dries out, pump water through the ViralGuard Cartridge and set it aside for 2 hours to reactivate iodinated resin

"Worst Case" Conditions

In all but the worst case conditions, water passing through the ViralGuard™ Cartridge/ SweetWater GuardianTM Micro-Filtration System at 60 strokes per minute is immediately safe to drink. Worst case conditions includes a combination of: notes as in # 22

- A brown and murky water source (your hand is not visible 6 inches below the surface) and
- Very cold water (39°F; 4°C)

Most common in bogs or a marshes in a northern latitude, these conditions may indicate a high organic content and an acidic pH. Under these conditions it is difficult for iodinated resin to inactivate viruses to the EPA standard of 99.99%. To achieve the best results in these worst-case conditions, it must be used together with a SweetWater Silt-StopperTM - available as an accessory in retail stores selling the GuardianTM. With the Silt-Stopper attached:

- Slow pump rate to 40 strokes per minute.
- Pump water through the system twice, then ...
- Let water stand for fifteen minutes prior to drinking.
- Pump no more than two liters per sitting.
- Wait two hours between sittings.

NOTE:

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Worst case conditions demand extra precautions. (See above). The ViralCuard Cartridge should not be used in brackish (salty) water and is not recommended for use with raw sewage.

Durability and Disposal

To protect the Guardian's Labyrinth Depth Filter, do not pump water in excess of 120°F (55°C). Encased in a High-Impact ABS Thermoplastic casing, it is also very durable, although users should use their common sense and not abuse this health protection device. When the ViralGuard Cartridge has pumped 90 gallons, dispose of used cartridge by securely wrapping cartridge in newspaper and discarding in trash.

NOTE:

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Do not insert sharp objects into the cylinder, as they may rupture the iodinated resin screen.

Health Warnings

Due to the presence of iodinated resin:

 Pregnant women and individuals with thyroid conditions should consult

ACCEPTED their doctors prior to use. ETEL COMMONTS to EPA Letter Dated:

Do not sniff vapors if cartridge dries.

Keep Out of Reach of Children.

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Furnish and Rodenticide Act as
amended, for the pesticide

• ViralGuard Cartridge must be used with SweetWater Guardian

Under the Federal Insecticide,
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amended, for the pesticide
Micro- under EPA Reg. No. Filtration System to be effective.

Backflush effluent is harmless, but can stain clothes and skin.

 Harmless discoloration could occur on the Guardian intake hose barb if ViralGuard Cartridge is left attached to the Guardian.

Taste

The Guardian's Granular Activated Carbon will remove 85-90% of the residual iodine from the water treated with the ViralGuard Cartridge, thus reducing the iodine taste and odor. However, some people have a greater sensitivity and thus could still detect the iodine. While the iodine concentration of the ViralGuard Cartridge will decrease over its lifetime, drinking from a narrow mouth water bottle will lessen the odor. Adding small amounts of Vitamin C to the purified water will also chemically counteract the taste and odor of iodine. Also, the first liter or two of purified water provided by the ViralGuard will contain greater concentrations of residual iodine. For improved taste, each time you use the ViralGuard Cartridge * pump and discard the first liters and drink those that follow.

NOTE: In worst case conditions, drink the first two liters and do not add Vitamin C as it reduces the effect of the iodinated resin (see "Worst Case Conditions:).

Travel Tips

In addition to waterborne pathogens, unsafe eating practices or unsanitary conditions can also cause gastrointestinal distress among travelers abroad. To reduce these risks, we suggest the following steps.

- Consult your physician or the Centers for Disease Control to obtain current health recommendations for the area you plan to visit.
- Avoid vegetables, fruit, and other raw foods that might have been washed with contaminated water.
- Make sure all prepared food is thoroughly cooked.
- Wash your hands often with soap and water.

 Use the ViralGuard Cartridge with SweetWater's Guardian Micro-Filtration System for protection against waterborne pathogens. (such as Klebsiella terrigena, Poliovirus type 1, Rotavirus Strain SA-11 and Cryptosporidium)

Contains one Iodinated Resin Cartridge Net Contents: Active Ingredient: Nodine Resin* (23.6%) Inert Ingredient: (76.4%)

*bound to polystyrene divinyl benzene quaternary ammonium anion exchange resin

Warranty

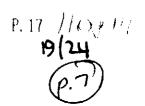
The SweetWater ViralGuard CartridgeTM is warranted for three (3) years from the date of purchase against all defects in material and workmanship. Should this product prove defective during the warranty period, return it to the dealer from whom it was purchased, or return the unit, prepaid and with your proof of purchase, to SweetWater, Inc.. SweetWater, Inc. will repair or replace the unit without charge. This warranty does not cover improper use, failure to properly maintain, or early clogging caused by processing heavily turbid water. This warranty gives you specific legal rights. You may have other rights, which vary from state to state.

SweetWater, Inc. Logo 2505 Trade Centre Avenue Suite D Longmont, CO 80503 Tel: 303-678-0447

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FAX: 303-678-0457

Toll Free: 800-55-SWEET

Recycled Paper Logo

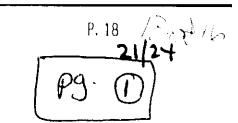
(Mouse Type)
Guardian, Silt-Stopper, and ViralGuard Cartridge are trademarks of SweetWater, Inc.
Date of Manual

D. ViralGuard Cartridge Package Insert Label

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in EPA Letter Dated:

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VIRALGUARD PACKAGH Revised 4/8/95

1. Front Header Card

SPR-08-95 SAT 15:57

Keep out of Reach of Children (Enlarged from 4pt to 6pt) CAUTION

VIRALGUARD™ Cartridge Microbiological Water Purifier

- Kills or inactivates 99.99% of waterborne viruses (such as Poliovirus type 1 and Rotavirus Strain SA-11). .
- Effective only when used with the SweetWater GUARDIAN™ Micro-Filtration Systems.
- For emergencies (such as floods, earthquakes) when municipal water supplies become contaminated.
- For foreign travel to countries with waters of unknown microbiological quality.
- Meets EPA standards as a microbiological water purifier.
- Cartridge life: up to 90 gallons.

MADE IN THE USA

SweetWater, Inc. LOGO

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Under the Federal Insection Fungicide, and Redention Accomended, for the public registered under EPA Reg.

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2. Back of Header Card

VIRALGUARD™ Cartridge Microbiological Water Purifier

When used with the SweetWater's Guardian Micro-Filtration System, ViralGuardTM Cartridge, meets or exceeds U.S. EPA requirements for the removal of:

- 99.9999% of waterborne bacteria (such as Klebsiella terrigena)
- 99.9% of waterborne protozoa (such as Cryptosporidium)
- 99.99% of waterborne viruses (such as Poliovirus type 1 and Rotavirus Strain SA-11).

For complete use instructions refer to the enclosed VIRALGUARD™ OWNER'S MANUAL.

CARTRIDGE CONTAINS PENTA-IODINE RESIN. BECAUSE TRACE AMOUNTS OF IODINE REMAIN IN THE PURIFIED WATER, PERSONS WITH THYROID PROBLEMS AND PREGNANT WOMEN SHOULD CONSULT THEIR PHYSICIAN PRIOR TO USE. NOT FOR USE IN BRACKISH OR SALT WATER.

NET CONTENTS - CONTAINS ONE IODINATED RESIN CARTRIDGE

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ACTIVE INGREDIENT: IODINE (23.6%)

INERT INGREDIENT: (76.4%)

*Bound to strong base anion exchange resin.

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Guardian and ViralGuard are trademarks of SweetWater, Inc.

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Failure to follow the use and cleaning instructions may result in unsafe water.

This package is made from paperboard that contains 30% postconsumer recycled fiber. Please reuse plastic bag. Printed on Recycled Paper sign

Bar Code

Made in the U.S.A.

EPA Establishment #67373-CO-1 *

EPA Registration #67373-1

SweetWater, Inc. Logo

2505 Trade Centre Avenue, Suite D, Longmont, CO 80503,

TEL: 800-55-SWEET (800-557-9338)

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E. ViralGuard Cartridge Label

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to EPA Letter Dated:

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ViralGuard Cartridge Label

VIRALGUARD™ Cartridge

Keep Out of Reach of Children CAUTION

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EPA Establishment #67373-CO-1 * EPA Registration #67373-1 *

SweetWater, Inc. Logo

ACTIVE INGREDIENT: (ÎODINE * (23.6%) — INERT INGREDIENT: (76.4%) *Bound to strong base anion exchange resin.

- Only use with SweetWater Guardian MICRO-FILTRATION SYSTEM
- . Pump no faster than 60/cycles per minute.
- . Backflush when flow decreases
- . Always store wet, ends plugged
- . For "worst case" water, see instructions

For complete use instructions refer to the enclosed VIRALGUARDTM CARTRIDGE OWNER'S MANUAL. *

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