

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

November 30, 2005

Kim Davis
RegWest Company, LLC
30856 Rocky Road
Greeley, CO 80631-9375

Subject: Katadyn Products Inc.
VirusStat Microbial Water Purification Cartridge
EPA Registration No. 39444-12
Submission Date: September 20, 2005
Receipt Date: September 21, 2005

Dear Ms. Davis:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is accepted with conditions.

Conditions

1. Remove the misleading kill/removal claim of "More than" that precedes 99.9999% waterborne bacteria, 99.99% waterborne viruses and 99.9% waterborne protozoa as stated in the Owner's Manual.
2. Change the statement "Under the rigid U.S. EPA microbiological water purifier test protocols. . ." to read "Following the U.S. EPA microbiological water purifier test protocols. . ." in the Owner's Manual.
3. Remove the misleading kill/removal claim of "Over" that precedes 99.9999% waterborne bacteria, 99.99% waterborne viruses and 99.9% waterborne protozoa as stated on the Hang Card Label.

General Comments

A stamped copy of the labeling accepted with comments is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES							
SYMBOL	7510C						
SURNAME	Hanson						
DATE	11-30-05						

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Should you have any questions or comments concerning this letter, please call Wanda Henson at (703) 308-6345.

Sincerely,



for

Emily H. Mitchell
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

Sub-Label A: Cartridge Label

VirusStat™
Microbial Water Purification Cartridge

For use with the Exstream portable water purification system as a microbiological water purifier.
Not intended for use with brackish or salt water.

Active Ingredient:

Iodine* 46%
Other Ingredients 54%
Total 100%

*Bound to polystyrene divinyl benzene quaternary ammonium anion exchange resin

Keep Out of Reach of Children
CAUTION

See Owner's Manual for First Aid and Additional Precautionary Statements

Net Contents: 1 cartridge (2.8 oz.)

[Distributed by] [Manufactured for]
Katadyn Products, Inc.
9850 51st Ave. N.
Minneapolis, MN 55442
1-800-755-6701
[www.katadyn.com]

{Logo}
Making Water Drinking Water

ACCEPTED
with COMMENTS
EPA Letter Dated:

NOV 30 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 39444-12

EPA Reg. No. 39444-12 EPA Est. 39444-CHE-1
Serial No. _____

DIRECTIONS FOR USE

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

Only for short-term or limited emergency use and not recommended for long-term or routine community water supply application. For Use Directions see Exstream Personal Water Purification System Owner's Manual.

Storage & Disposal

Storage: Store in a cool, dry place or in a refrigerator (not in the freezer section). **Disposal: Used cartridges:** Do not reuse spent cartridges; place in trash or offer for recycling if available.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: This cartridge contains iodide resin. Persons with iodine allergies or thyroid problems and pregnant women should consult their doctor before using this device because small amounts of iodine may remain in the treated water.

Print No. _____

Sub-Label B: Replacement Cartridge Box Label



Exstream® Personal Water Purifier
For use in Katadyn Exstream and Exstream XR Personal Water Bottle Purifiers.

Ultralight Series

Keep Out of Reach of Children
CAUTION

See Owner's Manual for First Aid and Additional Precautionary Statements

Net Contents:

1 cartridge (2.8 oz.) Each cartridge consists of an Iodinated Resin Cell, One-Micron Cyst Filter and a Carbon Prefilter.
{illustration}

[Distributed by] [Manufactured for]
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Minneapolis, MN 55442
1-800-755-6701
www.katadyn.com

{Logo}
Making Water Drinking Water

EPA Reg. No. 39444-12 EPA Est. 39444-CHE-1

DIRECTIONS FOR USE

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

Use with the Exstream portable water purification system as a microbiological water purifier. Not intended for use with brackish or salt water. Only for short-term or limited emergency use and not recommended for long-term or routine community water supply application. For Use Directions see Exstream Personal Water Purification System Owner's Manual.

Storage & Disposal

Storage: Store in a cool, dry place or in a refrigerator (not in the freezer section). **Disposal: Used cartridges:** Do not reuse spent cartridges; place in trash or offer for recycling if available.

PRECAUTIONARY STATEMENTS

Hazards to Human & Domestic Animals

CAUTION: This cartridge contains iodide resin. Persons with iodine allergies or thyroid problems and pregnant women should consult their doctor before using this device because small amounts of iodine may remain in the treated water.

Active Ingredient:	
Iodine*	46%
Other Ingredients	<u>54%</u>
Total	100%
*Bound to polystyrene divinyl benzene quaternary ammonium anion exchange resin	

Print No. _____

Sub-Label C: Hang Card Label

VirusStat™
Microbial Water Purification Cartridge

Exstream [XR] Personal Water Purifier

This personal water purification system has been proven to render water microbiologically safe for drinking.
Ultralight Series
Water Purifier

Easy to use. Purifies water without pumps, hoses or separate containers.
Advanced VirusStat technology kills ~~99.9999%~~ 99.9999% of waterborne bacteria
and ~~99.99%~~ 99.99% of waterborne viruses
Removes ~~99.9%~~ 99.9% of waterborne protozoa, such as Giardia
Delivers 160 [120] refills (26 gallons or 100 liters) per replacement cartridge

{Swiss Made Logo}

Keep Out of Reach of Children

CAUTION

See Owner's Manual for First Aid and Additional Precautionary Statements

ACCEPTED
with COMMENTS
EPA Letter Dated:

NOV 30 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 39444-12

{Back Panel}

Exstream [XR] Personal Water Purifier

Ultralight Series products are the lightest water systems available. They are designed for solo use or when ultralightweight is a primary concern. An excellent choice for travel, day hikes, paddling or biking.

Katadyn of Switzerland has been producing high quality portable water systems since 1928. Our history has been one of innovation and durability. Katadyn products are used by military, health organizations and outdoor adventurers worldwide. No other water system provides higher quality or longer lasting performance.

DIRECTIONS FOR USE

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

The Exstream portable water purification system as a microbiological water purifier is not intended for use with brackish or salt water. Only for short-term or limited emergency use and not recommended for long-term or routine community water supply application. For Use Directions see Exstream Personal Water Purification System Owner's Manual.

1. **Bite Valve** – hands-free opening with leak-proof closure
2. **VirusStat Cartridge** – VirusStat microbial water purification cartridge kills waterborne bacteria and viruses
3. **Cyst Filter** – removes pathogenic cysts such as Giardia and other contaminants larger than 1 micron in size
4. **Carbon Prefilter** – removes sediment, eliminates odors and improves taste

{Cut-away diagram of bottle and cartridge showing components described}

Carry Loop – easily attaches to packs, boats, etc.

Technical Information:

Technology: VirusStat Technology plus filtration and carbon prefiltration

Bottle Capacity: 26 fl. oz. (21 fl. oz or 620 ml after cartridge displacement) [34 fl. oz. (28 fl. oz. or 830 ml after cartridge displacement)]

Cartridge Capacity: Up to 26 gallons (100 l) depending on water quality

Weight: Approximately 7.4 oz. (220 g)

Size: 11' x 3" (28 cm x 8 cm)

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Each ViruStat Microbial Water Purification Cartridge consists of the Iodinated Resin Cell, a One-Micron Cyst Filter and the Carbon Prefilter

Storage & Disposal

Storage: Store in a cool, dry place or in a refrigerator (not in the freezer section). **Disposal: Used cartridges:** Do not reuse spent cartridges; place in trash or offer for recycling if available.

PRECAUTIONARY STATEMENTS

Hazards to Human & Domestic Animals

CAUTION: This cartridge contains iodide resin. Persons with iodine allergies or thyroid problems and pregnant women should consult their doctor before using this device because small amounts of iodine may remain in the treated water.

Active Ingredient:

Iodine*	46%
Other Ingredients	54%
Total	100%

*Bound to polystyrene divinyl benzene quaternary ammonium anion exchange resin

Contents:

- 1 Exstream [XR] Sports Bottle
- 1 ViruStat Microbial Water Purification Cartridge
- 1 Carry Loop
- 1 Owner's Manual

[Distributed by] [Manufactured for]
Katadyn Products, Inc.
 9850 51st Ave. N.
 Minneapolis, MN 55442
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amended, for the pesticide,
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EPA Reg. No. 39444-12 EPA Est. 39444-CHE-1

Exstream and ViruStat are trademarks of Katadyn Products, Inc.

Article #8014201 [8014200]

Print No. _____

Sub-Label D: Owner's Manual



{Logo}
Making Water Drinking Water

Owner's Manual

Katadyn Exstream Portable Water Purification System
Katadyn Extream XR Portable Water Purification System
Datadyn ViruStat Replacement Cartridge (Model #8011555)

This personal water purification system has been proven to render water microbiologically safe for drinking. Intended only for short-term, limited or emergency use (not intended for long-term use).

Keep Out of Reach of Children

CAUTION

See end of manual for additional precautionary statements.

DIRECTIONS FOR USE

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

Katadyn Exstream personal water purification systems eliminate the need to carry or locate safe drinking water, whether you are hiking, traveling or in an emergency situation. Only Katadyn Exstream personal water bottle purifiers place the advanced technology of a microbial purification cartridge into a standard water bottle. The result is a personal hydration system that provides antimicrobial protection against cysts, bacteria and viruses.

When to Use

Katadyn Exstream personal water bottle purifiers are designed for use with untreated fresh water sources, such as lakes, rivers and streams. They also provide protection against waterborne pathogens that may still be present in the tap water of many foreign countries. Exstream systems are also effective in emergencies, such as floods, hurricanes and earthquakes, any time service from a municipal water treatment plant fails

Katadyn Exstream personal water bottle purifiers provide a convenient alternative to pump-style water purifiers. Because they are designed for personal use, Exstream systems are not suitable for situations when large volumes of water must be treated.

How They Work

Katadyn Exstream personal water purification systems utilize a multi-stage, modular system. At the heart of the system is the ViruStat microbial purification cartridge. The ViruStat uses PentaPure penta-iodide resin to kill over 99.9999% of waterborne bacteria, including Klebsiella terrigena, and 99.99% of viruses, such as Poliovirus type 1 and Rotavirus Strain SA-11. The ViruStat employs a patented ion-release technology that dramatically reduces residual iodine, and a special layer of coconut-carbon that further minimizes any residue. The ViruStat cartridge is preceded by a replaceable 1-micron filter that removes more than 99.9% of pathogenic cysts, such as Giardia. A prefilter is installed below the cyst filter to remove sediment and organic contaminants.

Please carefully read the following instructions for maximum performance of your Katadyn Exstream personal water purification system. Failure to follow the instructions found in this manual may result in unsafe drinking water.

Thank you for choosing the Katadyn Exstream personal water purification system.

~~Under the rigid~~ ^{Following the} U.S. EPA microbiological water purifier test protocols, the Exstream system's long-lasting, replaceable ViruStat microbial purification cartridge killed or removed:

- ~~99.9999%~~ 99.9999% of waterborne bacteria such as Klebsiella terrigena
- ~~99.99%~~ 99.99% of waterborne viruses including Poliovirus type 1 and Type 1 Rotavirus Strain SA-11
- ~~99.9%~~ 99.9% of waterborne protozoa such as Giardia
- Bad tastes and odors

Key Components

{Illustration of components showing ViruStat cartridge, Cyst Filter, Carbon Prefilter, Bite Valve, Bottle and Bottle Cap}
Figure 1

Important Notes

1. To be purified, water must pass through the ViruStat cartridge. The flow rate is slower than an ordinary sports water bottle to ensure complete purification.
2. New and stored units must be preconditioned. See 'Preconditioning the System' section.
3. Squeeze and sip using continuous pressure. Do not pump. You will notice a 2-4 second pause after squeezing, like using a long straw, before water flows.
4. Always hold bottle upright when drinking. Water will not pass through the cartridge if bottle is upside down or at an angle.

Product Set-Up (Before First Use)

1. **Rinse inside of bottle.**
2. **IMPORTANT! Flush Prefilter**
Attach Carbon Prefilter to Bottle Cap. Fill bottle with tap water. Install Bottle Cap on bottle and tighten. Firmly squeeze bottle with both hands until ½ bottle of water has been run through the system. **Remove bottle cap.**

IMPORTANT!
Remove Safety Seal!
{Illustration of safety seal removal}
Figure 2

3. **Assemble the cartridge**

Remove the red label from the top of the ViruStat (Figure 2). Attach the Cyst Filter to the bottom of the ViruStat and the Prefilter to the bottom of the Cyst Filter. Gently twist each component while pushing it on. Make sure ALL O-rings and components are fully seated and assembled. The cartridge must be assembled in this way to ensure purification in all water conditions. Firmly twist and push the cartridge into the bottle cap (Figure 3)

{Illustration of assembly}
Figure 3

Precondition the System

(When New or After Extended Storage)

1. Prime – Fill the bottle with water to the fill line (indicated on outside of bottle). Insert cartridge/bottle cap into bottle. Turn bottle cap clockwise until tight. Squeeze bottle firmly with both hands to start water flow. Repeat until two bottles of water have been run through the system. While priming, keep bottle as full as possible. Flow rate will improve once the system is fully primed.
2. Again, fill the bottle with water to the fill line. Insert cartridge/bottle cap into bottle. Turn bottle cap clockwise until tight. Allow to sit for two hours prior to use.

{Illustration of bottles and filtration system}
Figure 4

Normal Operation

(After Preconditioning)

1. Fill the bottle with water to the fill line (Figure 4). Remember, the clearer the water, the longer the Cyst and Prefilter will last.
2. Insert cartridge/bottle cap into bottle. Turn bottle cap clockwise until tight.
3. Open bite valve. Note: the bite valve has two positions. Pull the bite valve out to open. Push it in to close (Figure 5). **Do not remove bite valve.**
4. Hold the bottle upright when drinking. Squeeze and sip using continuous pressure.

{Illustration of bite valve on bottle top}
Figure 5

Cartridge Installation

The ViruStat microbial purification cartridge is for use with the Exstream or Exstream XR personal portable water purification system as a microbiological water purifier. Each replaceable ViruStat purification cartridge will treat up to 26 gallons (100 liters) of water.

Changing the Cyst Filter

When water flow becomes restricted, use the following steps to change the Cyst Filter:

- a. Remove the Cartridge/Bottle Cap from the bottle.
- b. Remove the Cyst Filter from the bottom of the ViruStat cartridge and the Prefilter from the bottom of the Cyst Filter.
- c. Gently twist and push the new Cyst Filter onto the ViruStat cartridge (see Figure 1).
- d. Gently twist and push the Prefilter onto the Cyst Filter.
- e. Put Cartridge/Bottle Cap back on bottle.

Changing the ViruStat Microbial Purification Cartridge

After 26 gallons (100 liters) use the following steps to change the ViruStat cartridge.

- a. Remove the Cartridge/Bottle Cap from the bottle.
- b. Remove the ViruStat microbial purification cartridge with the cyst filter and prefilter from the cap. Discard cartridge components in trash receptacle.
- c. Flush Prefilter (see step 2 of product set-up on page ____).
- d. Assemble the Cartridge (see step 3 of product set-up on page ____).
- e. Follow the Preconditioning procedure on page ____.

Cleaning

Wash and dry the inside of the Exstream bottle thoroughly before using and regularly during heavy periods of use. If using with safe water and without the ViruStat cartridge, the bottle must be completely disinfected to prevent contamination from previous contact with contaminated water. Your Exstream bottle and cap are dishwasher safe (without the cartridge). Do NOT use soap to clean the ViruStat cartridge, the Cyst Filter or the Prefilter.

Before storage, remove excess water from the ViruStat cartridge by disassembling all three components. Shake out excess water. Allow the components to thoroughly dry. Wash and dry bottle. Wash well and follow conditioning instructions before resuming use. Replace a used Cyst Filter when taking the Exstream system out of prolonged storage.

Do NOT use with carbonated or flavored beverages, as they may damage the ViruStat microbial purification cartridge.

IMPORTANT: Refer to the Important Notes and the Product Set-Up before using.

Storage and Disposal

Storage: Store purification components in a cool, dry place or in a refrigerator (not in the freezer section). Store empty bottle (without the ViruStat cartridge, Cyst Filter or Prefilter installed) with the cap on. **Disposal: Used cartridges or filters:** Do not reuse spent cartridges or filters; place in trash or offer for recycling if available.

PRECAUTIONARY STATEMENTS

Hazards to Human & Domestic Animals

CAUTION: This cartridge contains iodide resin. Persons with iodine allergies or thyroid problems and pregnant women should consult their doctor before using this device because small amounts of iodine may remain in the treated water.

Active Ingredient:

Iodine*	46%
Other Ingredients	54%
Total	100%

*Bound to polystyrene divinyl benzene quaternary ammonium anion exchange resin

Limited Warranty

Your Katadyn Exstream Personal Water Purifier is warranted for one (1) year from the date of purchase against defects in materials and workmanship. Should your Katadyn Exstream Personal Water Purifier prove defective within one year from the date of purchase, return it to the Katadyn retailer from whom it was purchased. If you do not receive a satisfactory resolution, contact Katadyn Customer Relations at 1-800-755-6701 for service assistance. Katadyn, at its discretion, will replace or repair the damaged item. Please retain purchase receipt or proof of date purchased. This warranty gives you specific legal rights and you may have other legal rights which vary from state to state.

Contact Katadyn Products, Inc.
9850 51st Ave. N.
Minneapolis, MN 55442 U.S.A.
1-800-755-6701
outdoor@katadyn.com www.katadyn.com

Print No. _____

- [] Denotes alternate/optional language
- { } Denotes language that does not appear on the market labeling