

39444 -12

9/20/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 20, 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Kim Davis
Katadyn Products, Inc.
Consultant/Agent, RegWest Company LLC
8203 West 20th St., Suite A, Greeley, CO 80634-4696

FILE COPY

Subject: Virustat™ Microbial Water Purification Cartridge
EPA Reg.#: 39444-12
Notification Date: September 8, 2010
Receipt Date: September 13, 2010

Dear Ms. Davis:

This acknowledges the receipt of your notification, submitted under the provision of PR Notice 98-10 and FIFRA section 3(c)9.

Proposed Notification:

Revise Storage and Disposal Statement in compliance with PR Notice 2007-4 and additional graphics on "Virustat™ Microbial Water Purification Cartridge" (EPA Reg# 1072-13) label/labeling.

General Comment:

Based on the review of the material submitted, the following comments apply:

Change subheading "**Container Disposal**" to "**Container Handling and Disposal**" on page 2, 4, and 8. On page 13 of the label, change subheading "**Pesticide Disposal**" to "**Container Handling and Disposal**".

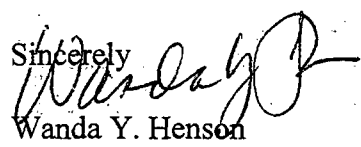
All other proposed minor changes on the product label are acceptable.

This notification and a copy of this letter have been inserted in your file for future reference."

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If you have any questions on this letter, please contact David Liem at 703-305-1284 or by email at liem.david@epa.gov

Sincerely



Wanda Y. Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobial Division (7510P)

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060.

United States Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20460-0001	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number Notification
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Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 39444-12	2. EPA Product Manager Wanda Henson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/ Product (Name) VirusStat™ Microbial Water Purification Cartridge	PM # 32	
5. Name and Address of Applicant (Include ZIP Code) Katadyn Products, Inc. c/o RegWest Company, LLC 8203 West 20th St., Suite A Greeley, CO 80634-4696 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i) my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section – II

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
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Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

**Submit Label Revision Notification per PR Notices 98-10 and 2007-4.
Refer to Reference Label for an illustration of all label revisions.**

This notification is consistent with the provisions of PR Notices 98-10 and 2007-4 and EPA regulations at 40 CFR § 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notices 98-10 and 2007-4 and 40 CFR § 152.46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify):	
*Certification must be submitted		If "Yes" Unit Packaging Wt.	No. Per Container	If "Yes" Packaging Wt.	No. Per Container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.8 oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Other Printed; Self-adhesive					

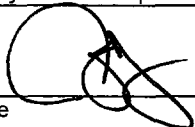
Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)?		
Name Kim Davis	Title Consultant/Agent	Telephone No. (Include Area Code) 970.353.0611 kim@regwest.com

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature 	3. Title Consultant/Agent
4. Typed Name Kim Davis	5. Date September 8, 2010

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Label Revision Notification



September 8, 2010

Ms. Wanda Henson, Product Manager 32
Document Processing Desk - NOTIF
Office of Pesticide Programs - 7504P
U.S. Environmental Protection Agency
One Potomac Yard (South Building), Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

Dear Ms. Henson:

Subject: Katadyn Products, Inc.
VirusStat™ Microbial Water Purification Cartridge
EPA Reg. No. 39444-12

On behalf of Katadyn Products, Inc., RegWest Company, LLC is submitting the attached documents in response to PR Notices 98-10 and 2007-4. RegWest Company will act as sole agent in this endeavor.

Attached are the following documents:

- 1. Application for Pesticide: Notification
2. One Reference Label (illustrating the label revisions)
3. Two New Labels (incorporating the revisions)

In addition to the PR Notices changes, we are replacing multiple references to graphics with actual graphics. Please note on PPLS the incorrect product name is used; per the EPA stamped accepted label dated November 30, 2005 the name of record was changed from "PentaCell™ Microbial Water Purification Cartridge" to "VirusStat™ Microbial Water Purification Cartridge". You may refer to the Reference Label for an illustration of all revisions.

Please contact me at 970.353.0611 or kim@regwest.com if you have any questions or comments concerning this submission.

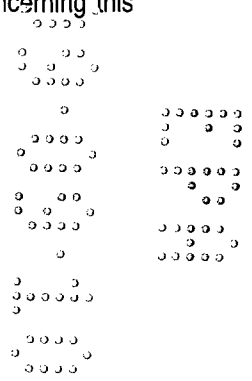
Regards,
RegWest Company, LLC

[Handwritten signature]

Kim Davis,
Consultant/Agent

Attachments

cc: Katadyn - Voxland, C.



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VirusStat™
Microbial Water Purification Cartridge

Master Label

Includes:

- | | |
|--------------|---------------------------------|
| Sub-Label A: | Cartridge Label |
| Sub-Label B: | Replacement Cartridge Box Label |
| Sub-Label C: | Hang Card Label |
| Sub-Label D: | Owner's Manual |

NOTIFICATION
Date Reviewed: 9/20/2010
Reviewed By: *[Signature]*

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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 additional Precautionary Statements.

EPA Reg. No. 39444-12

EPA Est. 39444-CHE-1

Serial No. _____

Net Contents: 1 cartridge (2.8 oz.)

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.

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

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place or in a refrigerator (not in the freezer section). **Container Disposal:**

Used cartridges: Non-refillable container; do not reuse or refill spent cartridges; place in trash or offer for recycling, if available.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

[Distributed by] [Manufactured for]

Katadyn Products, Inc.

6325 Sandburg Road

Minneapolis, MN 55427

1-800-755-6701

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Print No. _____

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Product of Switzerland

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Sub-Label B: Replacement Cartridge Box Label

VirusStat™
Microbial Water Purification Cartridge

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

Ultralight Series

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 additional Precautionary Statements.

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

Net Contents:

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

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.

DIRECTIONS FOR USE

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

For 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

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place or in a refrigerator (not in the freezer section). **Container Disposal:** **Used cartridges:** Non-refillable container; do not reuse or refill spent cartridges; place in trash or offer for recycling, if available.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

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[Distributed by] [Manufactured for]
Katadyn Products, Inc.
6325 Sandburg Road
Minneapolis, MN 55427
1-800-755-6701

 **KATADYN**[®]
MAKING WATER DRINKING WATER

Print No. _____

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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% of waterborne bacteria
and 99.99% of waterborne viruses*

Removes 99.9% of waterborne protozoa, such as Giardia

Delivers 160 [120] refills (26 gallons or 100 liters) per replacement cartridge



Active Ingredient:

Iodine*	46%
Other Ingredients	<u>54%</u>
Total	100%

*Bound to polystyrene divinyl benzene quaternary ammonium anion exchange resin

Keep Out of Reach of Children

CAUTION

See Owner's Manual for additional Precautionary Statements.

EPA Reg. No. 39444-12

EPA Est. 39444-CHE-1

Contents:

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

Exstream and VirusStat are trademarks of Katadyn Products, Inc.

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{Back Panel}

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.

DIRECTIONS FOR USE

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

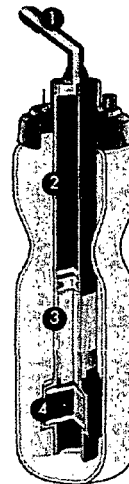
The Exstream portable water purification system as a microbiological water purifier is not intended for use with brackish or salt water. Only for short-term or limited emergency use and not recommended for long-term or routine community water supply application. For Use Directions see Exstream Personal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

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.

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



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 gm)

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

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place or in a refrigerator (not in the freezer section). **Container Disposal:** **Used cartridges:** Non-refillable container; do not reuse or refill spent cartridges; place in trash or offer for recycling, if available.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

[Distributed by] [Manufactured for]

Katadyn Products, Inc.

6325 Sandburg Road

Minneapolis, MN 55427

1-800-755-6701



Article #8014201 [8014200]

Print No. _____

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Sub-Label D: Owner's Manual

VirusStat™
Microbial Water Purification Cartridge



Owner's Manual

Katadyn Exstream Portable Water Purification System
Katadyn Extream XR Portable Water Purification System
Katadyn VirusStat 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).

Active Ingredient:

Iodine*	46%
Other Ingredients	<u>54%</u>
Total	100%

*Bound to polystyrene divinyl benzene quaternary ammonium anion exchange resin

Keep Out of Reach of Children

CAUTION

See end of manual for additional Precautionary Statements.

EPA Reg. No. 39444-12

EPA Est. 39444-CHE-1

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.

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*.

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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, or 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 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 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.

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

Key Components

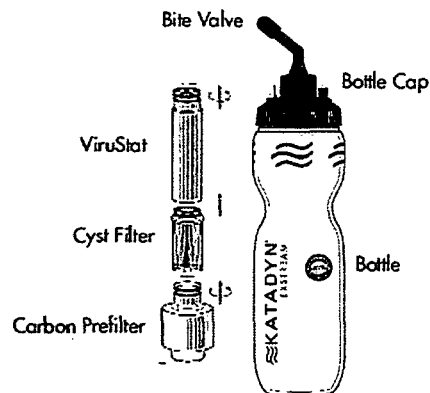


Figure 1

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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!



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).



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.

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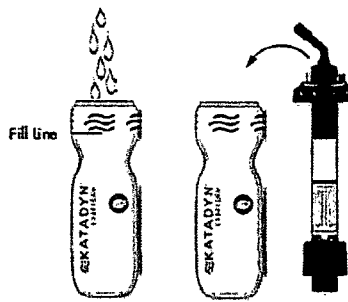


Figure 4

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.

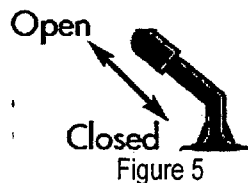


Figure 5

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 ____.

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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 of 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

Do not contaminate water, food or feed by storage or disposal.

Pesticide 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.

Pesticide Disposal: Used cartridges or filters: Non-refillable containers; do not reuse or refill spent cartridges or filters; place in trash or offer for recycling if available.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

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 which 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. To the extent consistent with applicable law, this warranty gives you specific legal rights.

Contact:

Katadyn Products, Inc.
6325 Sandburg Road
Minneapolis, MN 55427 U.S.A.
1-800-755-6701

Print No. _____

[] Denotes alternate/optional language

{ } Denotes language that does not appear on the market labeling