2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

January 7, 2013

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Mrs. Kimberlee Young, Consultant Agent Katadyn Products, LLC C/o RegWest Company, LLC 8203 West 20th Street, Suite A Greeley, CO 80634-4696

Subject:Notification Of Minor Label Changes per PR Notice 98-10Product Name:ViruStat ™ Microbial Water Purification CartridgeEPA Registration Number:39444-12Application Date:December 20, 2012Application Receipt:December 21, 2012

Dear Mrs. Young:

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

Proposed Notification:

Katadyn Products, LLC is submitting the following Minor Label Changes for **EPA Reg. No. 39444-12**:

1. Adding optional explanatory graphics for "Bottle Product Name" and "Directions For Use For The Bottle;"

2. Correct typographical errors;

3. Update the Company Address.

General Comments:

Based on a review of the submitted material the following comment applies. Your Notification application is **Acceptable**. A copy of the **accepted** notification is attached in your file (**EPA Reg. No. 39444-12**) for future reference.

Please be willing to submit to the EPA an updated Master Label that would include all of the information included in your "Owner's Manual" plus all of the information on each one of your sub-Labels.

If you have question or comments with regard to this Agency Letter, the please contact Killian Swift via email at <u>Swift.Killian@epa.gov</u> or by telephone at **703-308-6346**. When you are submitting information or data in response to this Agency Letter, please send a copy of this Agency Letter with your response in order to facilitate processing.

Sincerely yours, Monisha Harris,

Monisha Harris, EPA Product Manager 32 Regulatory Management Branch II Antimicrobials Division (7510P)

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Please read instructions on	reverse before comple	ting form.			Fo	orm App	roved. OMB No. 2070-0060.	
United States Environmental Protection Ag 1200 Pennsylvania Avenue, N.W Washington, DC 20460-0001			ie, N.W.		Registration Amendme Other	1	OPP Identifier Number	
	A	oplication f	or Pesticide -	Sect	ion I			
1. Company/Product Numb	er 39444-12	· · · · · · · · · · · · · · · · · · ·	2. EPA Proc		nager	3. Pre	oposed Classification	
4. Company/ Product (Name) ViruStat™ Microbial Water Purification Cartrid			PM #	PM # 32			None Restricted	
5. Name and Address of Applicant (<i>Include ZIP Code</i>) Katadyn Products, Inc. c/o RegWest Company, LLC 8203 West 20 th St., Suite A Greeley, CO 80634-4696			 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 					
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portable water purified address; and 4) other Notification of label change per changes have been made to the any false statement to EPA. I	fication system of r minor changes r PR Notice 98-10. This r a labeling or the Confiden further understand that i	called "MyBo as noted in t notification is consis- tial Statement of Fo f this notification is	ttle; 2) correct the attached Ref stent with the provisions rmula of this product. 10 not consistent with the	typogi erend of PR N understar terms of	caphical erro ce Label. lotice 98-10 and EP. nd that it is a violatio PR Notice 98-10 ar	rs; 3) A regula on of 18	und use directions for update the company tions at 40 C5P 152.46. No other U.S.C. Sec. 1001 to willfully make R 152.46, this product may be in	
violation of FIFRA and I may be			inder sections 12 and 14 Section - III	of FIFRA				
Material This Product V Child Resistant Packaging Yes*			Water Soluble Pack	(es) 🗇 M				
*Certification must be submitted	If "Yes" Unit Packaging Wt.	No. Per Container	If "Yes" Packaging Wt.		Per 🔳 🖬 F	 ☐ Glass ■ Paper 		
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Kimberlee Young (formerly: Kim Davis)			Consultant/Agent			97	0.353.0611 regwest.com	
I certify that the state		Certificatio	n	hment	s thereto are		6. Date Application Received	
accurate and complete punishable by fine or in	e. I acknowledge	that any know oth under appli	ingly false or misl cable law.				(Stamped)	
2. Signature		3. Tit	3. Title					
4. Typed Name Kimberlee Young		5. Da	5. Date					
(formerly		12/20/2012						

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

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Label Revision Notification



December 20, 2012

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

Dear Ms. Harris:

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

One behalf of *Katadyn Products, Inc.*, RegWest Company, LLC is submitting the attached materials as a notification of label revision per PR Notice 98-10. RegWest will act as sole agent in this endeavor.

Attached are the following items:

- 1. Application for Pesticide: Other (Notification)
- 2. Agent authorization letter
- 3. One Reference Label (illustrating the revisions)

4. Two *New Labels* (incorporating the revisions)

The purposes of this submission are to: 1) add optional graphics, bottle product name and use directions for portable water purification system called "MyBottle; 2) correct typographical errors; 3) update the company address; and 4) other minor changes as noted in the attached *Reference Label*.

Please contact me or Mary Beth Endres at 970.353.0611 or marybeth@regwest.com if you have any questions or require additional information.

Regards, RegWest Company, LLC

Kimberlee Young (formerly: Kim Davis), Consultant/Agent

Attachments

cc: KNA – Voxland, C. CPI – Hacker, S.

> 8203 West 20th St.; Suite A Greeley, CO 80634-4696 p 970-353-0611 f 970-353-0613

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ViruStat®

Microbial Water Purification Cartridge

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

NOTIFICATION
Date Reveiwed:_____
Reviewed By:_____

January 7,2013 Killian B.Swift

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39444-12 New Label: Page 2 of 15 11/30/05 SAL + 09/08/2010 and 12/20/2012 Notifications 10

Sub-Label A: Cartridge Label

ViruStat®

Microbial Water Purification Cartridge

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

Active Ingredient:

lodine*	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

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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 [MyBottle] Personal Water Purification System Owner's Mariual.

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 Handling** and **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. 4830 Azelia Avenue North Minneapolis, MN 55429 1-800-755-6701

39444-12 New Label: Page 3 of 15 11/30/05 SAL + 09/08/2010 and 12/20/2012 Notifications



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© _____ All rights reserved.

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Sub-Label B: Replacement Cartridge Box Label

ViruStat®

Microbial Water Purification Cartridge

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

Ultralight Series

Active Ingredient:	
lodine*	
Other Ingredients	
otal	
Bound to polystyrene divinyl benzene quaternary ammonium ani 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 [MyBottle] 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 [MyBottle], 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 Handling and Disposal: Used cartridges:** Non-refillable container; do not reuse or refill spent cartridges; place in trash or offer for recycling, if available.

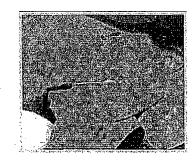
{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

39444-12 New Label: Page 5 of 15 11/30/05 SAL + 09/08/2010 and 12/20/2012 Notifications

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≋KATADY MAKING WATER DRINKING WATER

Print No.

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Sub-Label C: Hang Card Label

ViruStat®

Microbial Water Purification Cartridge

Exstream [XR] [MyBottle] 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 ViruStat 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:

lodine*	46%
Other Ingredients	54%
Total	
*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-

Contents:

1 Exstream[®] [XR] [MyBottle[®]] Sports Bottle 1 ViruStat[®] Microbial Water Purification Cartridge 1 Carry Loop 1 Owner's Manual [1 Straw for use with treated water]

Exstream® [MyBottle®] and ViruStat® are registered trademarks of Katadyn Products, Inc.

{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.

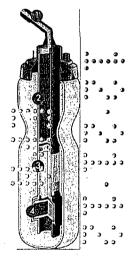
The Exstream [MyBottle] portable water purification system as a microbiological water purifier is not intended for use with brackish or salt water. Only for short-term or limited emergency use and not recommended for long-term or routine community water supply application. For Use Directions see Exstream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

Exstream [XR] [MyBottle] 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.

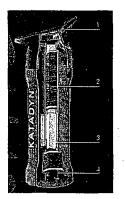
Katadyn of Switzerland has been producing high quality portable water systems since 1928. Our history has been one of innovation and durability. Katadyn products are used by military, health organizations and outdoor adventurers worldwide. No other water system provides higher quality or longer lasting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

- 1. Bite Valve hands-free opening with leak-proof closure
- [1. **Cushioned Mouth Piece** easy drinking and folds flat to prevent leaking. Removable for easy cleaning.]
- ViruStat Cartridge ViruStat[®] 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



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{Optional MyBottle Graphic:}



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

Technical Information:

Technology: ViruStat® 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] [27 fl. oz. (22 fl. oz. or 650 ml after cartridge displacement)] Cartridge Capacity: Up to 26 gallons (100 L) depending on water quality Weight: Approximately 7.4 oz. (220 gm) [9.5 oz. (270 g)] Size: 11' x 3" (28 cm x 8 cm)

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 Handling and 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. 4830 Azelia Avenue North Minneapolis, MN 55429 1-800-755-6701



MAKING WATER DRINKING WATER

Article #8014201 [8014200] [8017756]

Print No.

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Sub-Label D: Owner's Manual

ViruStat®

Microbial Water Purification Cartridge



MAKING WATER DRINKING WATER

Owner's Manual

Katadyn Exstream [MyBottle] Portable Water Purification System Katadyn Extream XR [MyBottle] Portable Water Purification System Katadyn 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).

Active Ingredient:	
lodine*	
Other Ingredients	
Total	
*Bound to polystyrene divinyl benzene quaternary 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

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

How They Work

Katadyn Exstream [MyBottle] 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 [MyBottle] 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 [MyBottle] personal water purification system.

Following the U.S. EPA microbiological water purifier test protocols, the Exstream [MyBottle] system's long-lasting, replaceable ViruStat[®] microbial purification cartridge killed or removed:

Key Components

- 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

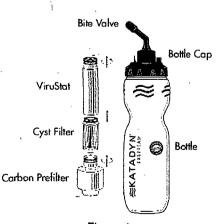
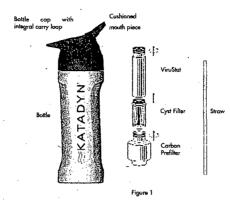


Figure 1

{Optional MyBottle Figure 1:}

Key Components



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**.





Figure 2

{Optional MyBottle Figure 2:}



Assemble the cartridge 3.

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).

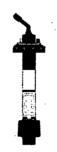


Figure 3



Preconditioning 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.

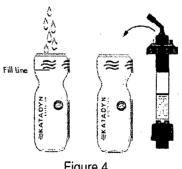
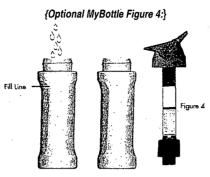


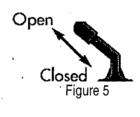
Figure 4



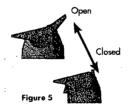


Normal Operation (After Preconditioning)

- 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.**
- [3. Flip open mouth piece. Note: the mouth piece has two positions. Pull the mouth piece up to open. Push it down to close (Figure 5). **Do not remove mouth piece.**]
- 4. Hold the bottle upright when drinking. Squeeze and sip using continuous pressure.



{Optional MyBottle Figure 5:}



Cartridge Installation [MyBottle]

The ViruStat[®] microbial purification cartridge is for use with the Exstream or Exstream XR [MyBottle] 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.
- 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.

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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 [MyBottle] 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 [MyBottle] 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 preconditioning instructions before resuming use. Replace a used Cyst Filter when taking the Exstream [MyBottle] 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. **Container Handling and 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 [MyBottle] Personal Water Purifier is warranted for one (1) year from the date of purchase against defects in materials and workmanship. Should your Katadyn Exstream [MyBottle] 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 of proof of date purchased. To the extent consistent with applicable law, this warranty gives you specific legal rights.

Contact: Katadyn Products, Inc. 4830 Azelia Avenue North Minneapolis, MN 55429 U.S.A.

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1-800-755-6701

Print No.

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