573-90

UNITE- STATES ENVIRONMENTAL PROTECTION AGENCY

January 24, 2007

Janice L. Dhonau Regulatory Affairs The Procter & Gamble Company 5299 Spring Grove Avenue Cincinnati, OH 45217

Subject: PuR Purifier of Water EPA Registration No. 3573-90 Application Date: December 20, 2006 Receipt Date: December 26, 2006

Dear Ms. Dhonau:

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

Proposed Notification

- addition of non-FIFRA labeling text
- addition of marketing claims

General Comments

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

1. The notification application is unacceptable for the reason below:

The proposed phrase "Removes Sediment" is misleading. The product does not remove sediment from treated water but, as stated in your application and label, coagulates it for removal by filtration.

2. This application must be re-submitted as an amendment.

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

Sincerely,

Wanda Y. Henson Product Reviewer (32) Regulatory Management Branch II

		 CONCURRENC	æs A	minicrobials	Division (751	<i>x y</i> -
MBOL 7510P	7510P					
IRNAME F Brog ITE 1/24/07	Henson					
ITE 1/24/07	1/24/07					

PA Form 1320-1A (1/90)

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The Procter & Gamble Company F&HCIC 5299 Spring Grove Avenue Cincinnati, OH 45217-1025 www.pg.com

December 20, 2006

Document Processing Desk (NOTIF) Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency Room 266A, Crystal Mall 2 1801 S. Bell Street Arlington, VA 22202-4501

Attn.: Ms. Emily Mitchell

Subject:

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EPA Registration Number 3573-90 Notification of Label Change: Non-Mandatory Labeling Changes

Dear Ms. Mitchell,

This provides the Agency notification of non-mandatory labeling changes for PŪR Purifier of Water (EPA Reg. No. 3573-90). Procter & Gamble submits these notifications under the provisions of PR Notice 98-10. It is believed that this submission falls under the auspices of PRN 98-10 rules for notifications, however, due to the number of claims requested, an additional document providing clarification of the key claims is attached.

Enclosed are the following supporting documents:

- Claims Clarification Document
- Application Form (EPA Form 8570-1)
- One copy of revised master label showing revisions
- Two copies of revised master label

If you have any questions regarding this notification, please call me at 513-627-7349 or email at <u>dhonau.il@pg.com</u>.

Sincerely,

Janice L Dhonau

Jahice L. Dhonau Regulatory Affairs Global Household Care

\$-EPA	United States Environmental Protection Agency Washington, DC 20460				Reg ✓ Arr	I. OMB No. 2070-006 Registration Amendment Other		DPP Identifier Number
		Applicati	on for Pestic	ide - Secti	on I			······································
1. Company/Product Numbe 3573	. Company/Product Number 3573			2. EPA Product Manager 3. Proposed Classific Emily Mitchell ✓ None			— ¬	
4. Company/Product (Name) PuR Purifier of Water			PM#	PM#				
5. Name and Address of Applicant <i>(Include ZIP Code)</i> Janice L. Dhonau The Procter & Gamble Company 5299 Spring Grove Avenue, Cincinnati, OH 45			6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No					
Check if this	s is a new address	<i>'</i>		uct Name	<u>.</u>			
<u></u>		·	Section -	<u> </u>				
Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below.			[✓ Final printed labels in repsonse to Agency latter dated				
Notification of a change of no This notification is consistent or the confidential statement further understand that if this be subject to enforcement ac	with the provisions of F of formula of this produ notification is not consi tion and penalties uner	ict. I understan istent with the t	d that it is a violation terms of PRN 98-10	of 18 U.S.C. S and 40 CFR 15	ec. 1001 to	willfully mai	ke any fal	se statement to EPA, I
1. Material This Product Wil	Be Packaged In:							
Child-Resistant Packaging Yes No Certification must	Unit Packaging Ves Vos If "Yes"	No. per	Water Soluble Packaging Yes ✓ No r If "Yes" No. per		2. T	2. Type of Container Metal Plastic Glass Paper Other (Specify)		4 .
be submitted Onit Packaging wgt. Container 3. Location of Net Contents Information 4. Size(s) Ret			Package wgt tail Container 4 g	container	· -	of Label Di		
6. Manner in Which Label is	ontainer Affixed to Product	Lithog Paper Stenci	glued	✓ Other	Label is	printed on	the sach	net
			Section - I	V				
1. Contact Point <i>(Complete</i>	items directly below f	or identificatio	n of individual to b	e contected, if	necessary	, to process	s this app	plication.)
Name Janice L. Dhonau		Title Regulatory Af	e Regulatory Affairs			Tაնթին <mark>ութ No. (Include Area Code)</mark> 51-3-627-7349		
l certify that the stater I acknowledge that an both under appliceble I	y knowlinglly false or i		all attachments the					Date Application Roceived (Stamped)
2. Signature Januice L Shonay			3. Title Regulatory Affairs					
I. Typed Name Janice L. Dhonau	····		5. Date 12/2	20/200	06			
	Previous editions are					Copy (orig		Yellow - Applicant Cop

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Competitive Pricing Analysis*

	Unit Cost	Unit Treatment	Cost per Liter	
PUR Purifier of Water	\$	9.99	60 Liters	0.17
Potable Aqua Iodine	\$	5.00	24 Liters	\$ 0.20
Pristine WPS	\$	29.95	120 Liters	\$ 0.25
Chlorfloc	\$	9.19	30 Liters	\$ 0.31
Potable Aqua Plus	\$	8.29	24 Liters	\$ 0.35
Kat MicrPur Tabs D	\$	13.95	30 Liters	\$ 0.47
Coghlands Water Treat	\$	12.30	24 Liters	\$ 0.51
Potable Aqua Clo/Diox	\$	14.65	19 Liters	\$ 0.77

* Pricing information obtained from Corporate websites.

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PūR Purifier of Water Master Label

Sublabel A: First Responder/Non-Government Organization Use (USA and International use)

Sublabel B: Consumer Use (USA)

Sublabel A: First Responder/Non-Governmental Organization Use (USA and International use)

Front Label/Outer Container OR Supplemental Labeling

PūR Purifier of Water

Active Ingredient:	
Calcium Hypochlorite	0.542%
Other Ingredients:	99.458%
Total:	
2.168 ppm Available Chlorine	

KEEP OUT OF REACH OF CHILDREN

WARNING: See back/side panel/supplemental labeling for all precautions.

Net Contents Statement X sachets\packs\packages\pouches [Treats Y liters/Z gallons of Water.]

If the shipping container also serves as the outer container then the following information may be included on the front/back panel.

PūR Logo Purifier of Water Procter & Gamble Pakistan (Pvt.) Ltd. B-233/234, H.I.T.E Hub, Balochistan Pakistan

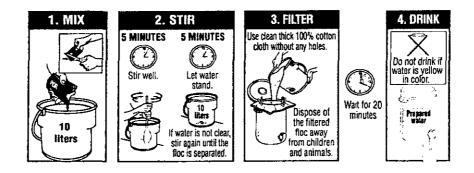
Batch No. XXXXXXX

PūR Purifier of Water (4g) QtyQuantity: 240 sachets of 4g (0.14 oz) Item Code: ZZZZZZZ Made in Pakistan

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Back/Side Container OR Supplemental Label

DIRECTIONS/INSTRUCTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.



1. MIX:

- Open a sachet/package/packet/pouch/pack using a pair of scissors.
- Add the contents of the sachet/package/packet/pouch/pack to a clean mixing vessel/container/bucket containing/with/holding 10 liters [2.5 gallons] of water.

2. STIR:

- Agitate/stir/mix the powder vigorously in the water for 5 minutes. Be sure a vortex/funnel/whirlpool is created when mixing. Then, let the water stand for 5 minutes until it clarifies/becomes clear.
- After adding the powder to the water, the water will become colored./The water will become colored when the powder is added. The color indicates that the product is working. When the process is finished, the water will be crystal clear.

3. FILTER:

- If you see the water is still colored, you can mix/stir/agitate again and let it rest for another few minutes.
- Once the water looks clear, and the floc/sediment/particulates is/are at the bottom of the vessel/container/bucket, filter the water through a clean cloth filter into a clean storage vessel/container/bucket and cover it with a lid.
- The filter must be a clean, thick 100% cotton cloth, without holes, that prevents the floc/sediment/particulates from passing through. Carefully pour the clear water through the cloth into a bucket/vessel/container. The floc/sediment/particulates will be left behind in bottom of the bucket and in the cloth filter.
- Discard the floc/sediment/particulates from the water treatment process in the latrine [toilet] [utility sink], or on the ground away from children and animals. [Rinse and wash the cloth thoroughly before resuling.]

4. **BEFORE DRINKING:**

• Wait 20 minutes before drinking the water.

- Do not drink water if it is colored or cloudy after treatment. If the floc/sediment/particulates accidentally gets into the treated water, use another cloth to filter the floc/sediment/particulates out of the treated water. The water is still good to drink.
- Drink treated water within 24 hours after its preparation. Water that is not consumed should/may be used for cooking, washing, watering animals or otherwise discarded.
- ALWAYS dispense the water from the storage container into another container, such as a cup or glass for drinking.

PRECAUTIONARY STATEMENTS: Hazards to humans and domestic animals.

WARNING: [For dDry product] Causes substantial but temporary eye injury. Harmful if absorbed through skin or if swallowed. Avoid contact with skin or clothing. Do not get in eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Contains iron sulphate (352 mg ferric iron).

FIRST AID:

If in eyes:

-Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.

- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing...
- -Call poison control center or doctor for treatment advice.

If on skin:

- -Take off contaiminated clothing.
- -Rinse skin immediately with plenty of water for 15 20 minutes.
- -Call poison control center or doctor for treatment advice.

If swallowed:

-Call a poison control center or doctor immediately for treatment advice.

- -Have person sip a glass of water if able to swallow.
- -Do not induce vomiting unless told to by a poison control center or doctor.
- -Do not give anything to an unconscious person.

Have the product container or label with you when consulting a poison control center or doctor, or going for treatment. In North America you may also contact 1-800-xxx-xxxx for emergency medical treatment information.

STORAGE/DISPOSAL: Store away from heat, humidity and sunlight. Dispose of empty container in trash/appropriately. Dispose of floc/sediment/particulates in latrine [toilet] or on the ground away from humans and animals.

EPA Reg. No. 3573-90 EPA Est. No. XXXX-XX-XXX

If the shipping container also serves as the outer container then the following information may be included on the front/top/side panels.

Palet Pattern icons X cases/layer X layers/load 1 pallet high

This side up icon Icon to indicate number of layers Umbrella icon to indicate keep dry Exp. Date: MMM YY (MMM=Month, JAN, FEB, MAR, etc YY= Year, 2008=08, 2009=09, etc.)

Container Mfg. name and address

XXXXXXX (container gcas number) Note, the words in parenthesis are added for clarity, they would not be printed on the container.

Labeling for Individual Sachets (Small package: information may be printed on either side of sachet)

PūR Purifier of Water

Calcium Hypochlorite.....0.542% 2.168 ppm Available Chlorine

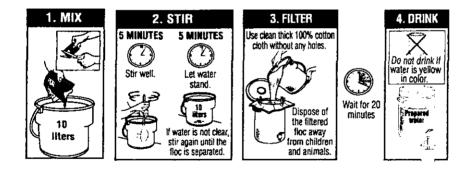
KEEP OUT OF REACH OF CHILDREN

WARNING: [For dDry product] Causes substantial but temporary eye injury. Harmful if absorbed through skin or if swallowed. Avoid contact with skin or clothing. Do not get in eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Contains iron sulphate (352 mg ferric iron). See outer label/container for all precautions.

EPA Reg. No. 3573-90 EPA Est. No. XXXX-XX-XXX

Net Contents: 4 g (0.14 oz) X sachets\packs\packages\pouches[Treats Y liters/Z gallons of Water.]

[GRAPHICS FOR SACHET]



Made by/Manufactured by/Distributed by P&G logo Procter & Gamble Pakistan (Pvt.)Ltd. B-233/234, H.I.T.E. Hub, Balochistan, Pakistan XXXXXXXXX PŪR is a trademark of The Procter & Gamble Company

Printed during manufacture: XXXXXXX MFG. MMMYY EXP. MMMYY (Batch No., Date of Manufacture and Date of Expiration stamped on each sachet during production)

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Sublabel B: Consumer Use (USA)

Front Label/ Outer Container/Supplemental Label

PūR Purifier of Water

Active Ingredient:	
Calcium Hypochlorite	0542%
Other Ingredients:	
Total:	
2.168 ppm Available Chlorine	

KEEP OUT OF REACH OF CHILDREN

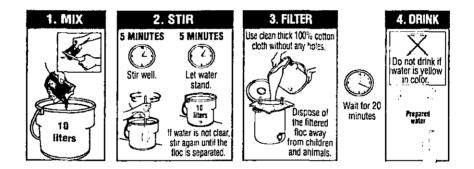
WARNING: See back/side panel/supplemental labeling for all precautions.

Net Contents Statement

X sachets\packs\packets\packages\pouches[Treats Y liters/Z gallons of Water.]

Back/Side/Supplemental Label

DIRECTIONS/INSTRUCTIONS FOR [HOUSEHOLD] USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.



1. MIX:

- · Open a sachet/package/packet/pouch/pack using a pair of scissors.
- Add the contents of the sachet/package/packet/pouch/pack to a clean mixing vessel/container/bucket containing/with/holding 10 liters [2.5 gallons] of water.

2. STIR:

- Agitate/stir/mix the powder vigorously in the water for 5 minutes. Be sure a vortex/funnel/whirlpool is created when mixing. Then, let the water stand for 5 minutes until it clarifies/becomes clear.
- After adding the powder to the water, the water will become colored./The water will become colored when the powder is added. The color indicates that the product is working. When the process is finished, the water will be crystal clear.

3. FILTER:

- If you see the water is still colored, you can mix/stir/agitate again and let it rest for another few minutes.
- Once the water looks clear, and the floc/sediment/particulates is/are at the bottom of the bucket, filter the water through a clean cloth filter into a clean storage container and cover it with a lid.
- The filter must be a clean, thick 100% cotton cloth, without holes, that prevents the floc/sediment/particulates from passing through. Carefully pour the clear water through the cloth into a bucket/vessel/container. The floc/sediment/particulates will be left behind in the bottom of the bucket and in the cloth filter.
- Discard the floc/sediment/particulates from the water treatment process in the latrine [toilet] [utility sink], or on the ground away from children and animals. [Rinse and wash the cloth thoroughly before reusing.]

4. BEFORE DRINKING:

- Wait 20 minutes before drinking the water.
- Do not drink water if it is colored or cloudy after treatment. If the floc/sediment/particulates accidentally gets into the treated water, use another cloth to filter the floc/sediment/particulates out of the treated water. The water is still good to drink.
- Drink treated water within 24 hours after its preparation. Water that is not consumed should/may be used for cooking, washing, watering animals or otherwise discarded.
- ALWAYS dispense the water from the storage container into another container, such as a cup or glass for drinking.

PRECAUTIONARY STATEMENTS: Hazards to humans and domestic animals.

WARNING: [For dDry product] Causes substantial but temporary eye injury. Harmful if absorbed through skin or if swallowed. Avoid contact with skin or clothing. Do not get in eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Contains iron sulphate (352 mg ferric iron). See outer label/container for all precautions.

FIRST AID:

If in eyes:

-Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.

- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- -Call poison control center or doctor for treatment advice.

If on skin;

- -Take off contaiminated clothing.
- -Rinse skin immediately with plenty of water for 15 20 minutes.
- -Call poison control center or doctor for treatment advice.

If swallowed:

- -Call a poison control center or doctor immediately for treatment advice.
- -Have person sip a glass of water if able to swallow.
- -Do not induce vomiting unless told to by a poison control center or doctor.
- -Do not give anything to an unconscious person.

Have the product container or label with you when consulting a poison control center or doctor, or going for treatment. In North America you may also contact 1-800-xxx-xxxx for emergency medical treatment information.

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STORAGE/DISPOSAL: Store away from heat, humidity and sunlight. Dispose of empty container in trash. Dispose of floc/sediment/particulates in latrine [toilet] or on the ground away from humans and animals.

Questions? Comments? In North America Call 1-800-XXX-XXXX Visit Us At: www.xxxx.com EPA Reg. No. 3573-90 EPA Est. No. XXXX-XX-XXX Made in Pakistan

YYYYYYY (a container identification number for P&G tracking)

XXXXXXX (Batch number for tracking)

Expiration [Exp.] Date: MMMYY

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Labeling for Individual Sachets (Small package: information may be printed on either side of sachet)

PūR Purifier of Water

Calcium Hypochlorite.....0.542% 2.168 ppm Available Chlorine

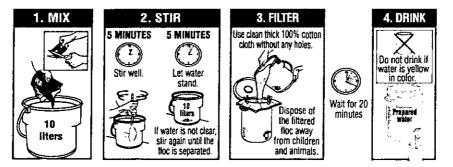
KEEP OUT OF REACH OF CHILDREN

WARNING: [For dry product] Causes substantial but temporary eye injury. Harmful if absorbed through skin or if swallowed. Avoid contact with skin or clothing. Do not get in eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Contains iron sulphate (352 mg ferric iron).

EPA Reg. No. 3573-90 EPA Est. No. XXXX-XX-XXX

Net Contents: 4 g (0.14 oz)

[GRAPHICS FOR SACHET]



Made by/Manufactured by/Distributed by P&G logo Procter & Gamble Pakistan (Pvt.)Ltd. B-233/234, H.I.T.E. Hub, Balochistan, Pakistan XXXXXXXXX PŪR is a trademark of The Procter & Gamble Company

XXXXXXX MFG. MMMYY EXP. MMMYY (Batch No., Date of Manufacture and Date of Expiration stamped on each sachet during production)

OPTIONAL CLAIMS FOR SUBLABELS A and B

	I - FLOCULATION
This product is for home\household use and removes\is effective in removing\reduces [the level of] <i>list of and/or options:</i>	Purifier\cleaner\cleanser of water
 bacteria viruses 	Water purifier\cleaner\cleanser
 cysts from [most] dirty\contaminated\polluted\ muddy 	Water purification\cleaning\cleansing product\powder
\unclean\impure\ water [sources].	For the disinfection of water prior to drinking.
Removes\effective in removing\reduces [the level of] <i>list of and/or options:</i>	Contains chlorine disinfectant
 viruses cysts 	Uses chlorine [as a] disinfectant
from [most] dirty\contaminated\polluted\ muddy \unclean\impure\ water [sources].	Provides 24 hour protection of drinking water.
[Provides] [flocculation] [and]	Water can be drunk is drinkable for 24 hours after treatment.
disinfection\disinfects [most] dirty\contaminated\polluted\ muddy	Removes Sediment A new water treatment product that uses the same ingredients used in municipal water
\unclean\impure\ water [sources]. Disinfects	systems. Engineered to be a mini water treatment plant in
Kills viruses, bacteria Removes dirt, cysts, pollutants	a packet. Same ingredients used in municipal water
Removes soil, dirt, bacteria, viruses, cysts and impurities from polluted water. Removes the following as a water purifier:	systems. Engineered to be a mini water treatment plant in a kit.
Sediment, Dirt, Soil, Bacteria, Viruses, cysts, pollutants	Contains a combination of flocculating and coagulating agents which promote rapid
	formation of a sediment in the treated water
	Pollutants in the form of gross organic matter and microscopic particles adhere to the sediment by the action of the flocculating and coagulating agents
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GENERAL CLAIMS				
Clarifier of Water				
Water Clarifier				
Water Clarifying Product\Powder	Six packets of 4g (0.14 oz)			
Water Treatment Product\Powder				
	This package treats 15 gallons/60 liters of water.			
[Developed\Formulated\Designed] For home\household	For a total of 15 gallons/60 liters of water.			
use\see list of potential use areas.	[Intended for packages containing 6 sachets]			
[Developed\Formulated\Designed/Acceptable] for	Three packets of 4g (0.14 oz)			
military installation/field use.	Each packet treats 2.5 gallons/10 liters of water			
Treat your water with PūR	For a total of 7.5 gallons/30 liters of purified water			
Water treatment product/powder				
For emergency use/usage [with]	[Product is] [shelf] stable for 3 years			
dirty\contaminated\polluted\ muddy \unclean\impure\				
water [sources].	Effective with lake\river\pond\spring\rain\well\wide			
	variety\dam\pond\earth pan waters			
Purified water for drinking and sanitation purposes is an				
important element of being prepared.	For lake\river\pond\spring\rain\well\wide			
	variety\dam\pond\earth pan waters			
The US Department of Homeland Security				
recommends your emergency preparation kit includes	Water is good/acceptable for drinking use after 30			
one gallon of water per person per day for at least three	minutes			
days, for drinking and sanitation.	Water is ready to drink after 30 minutes			
Reliance has been the hydration and sanitation expert	Water is ready to unink after 50 minutes			
for over forty years.	[PūR]Clean/refreshing water			
This kit has been specifically designed to aid in the	[Provides] Healthy\hygenic water			
mixing and preparation of water using PUR Purifier of				
Water, ensuring you have clean and fresh tasting water	Simple\easy to use			
when you need it.				
	No equipment needed			
After clarification of the water by separating sediment				
from the treated water, the chlorine released by the	Requires filtration			
active ingredient is then free to kill list of and/or options:	The cloth can be reused after rinsing with clarified,			
• • • •	treated water			
 viruses Emergency water purification powder\product. 	Maintains pure fresh taste			
For emergency treatment of polluted water	Reliance			
For treatment of polluted water	For more information visit			
Each sachet\pack\packet\package\pouch treats 10	www.purpurifierofwater.com			
liters [2.5 gallons] of Water	Questions? Comments? In North America, Call: 1-			
For use with the Reliance clean drinking water kit.	800-XXX-XXXX			
This kit is specifically designed to be used with and	Visit: www.purpurifierofwater.com			
includes PUR Purifier of Water product.	Waterworks.			
Includes: Mixing container, storage container, stirring	People Matter.			
wand, cotton filter cloth, packet opener, 3 PUR Purifier				
of Water packets				
Loss cost per gallon tracted than other				
Less cost per gallon treated than other commercial/chemical/purification treatments				
Maintains pure fresh taste.				

OCCASIONS TO USE

Provides clean drinking water for your family's outdoor and emergency needs.

Ensure clean and fresh tasting drinking water for your family's outdoor and emergency needs.

Everyone should be prepared whether exploring the outdoors, camping, or making emergency preparedness plans for the safety of you and your family.

Perfect for many outdoor and emergency needs.

Perfect for us in: camping, hiking, backpacking, international travel, fishing, hunting, emergency situations, natural disasters.

CHILDREN'S SAFE DRINKING WATER PROGRAM

Buy PUR, help save lives.

Water is life.

Every day, over 4,000 children in the developing world die from illness associated with unsafe drinking water, which is why PUR and Reliance are working together to expand the Children's Safe Drinking Water program.

There is hope!

To date, global relief groups including Population Services International\PSI, CARE, and AmeriCares have provided more than 500 million liters of clean drinking water using the PUR Purifier of Water packets.

Partner with us.

Children's Safe Drinking Water. P&G Live, Learn and Thrive™ Initiative.

Buy PUR today to help continue our efforts to provide clean drinking water to children in countries like Kenya*

*For every PUR purchase, PUR will contribute a percentage of your purchase to Population Services International/PSI, up to \$XXX,XXX. For additional program details visit <u>www.purpurifierofwater.com</u>.

Used as a part of global relief efforts by CARE, Population Services International\PSI and AmeriCares.