

3573-90

11-1-2006

1/14



U.S. ENVIRONMENTAL PROTECTION
AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510-P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

EPA Reg.

Number:

3573-90

Date of

Issuance:

Nov. 1, 2006

Term of Issuance:

Conditional

Name of Pesticide Product:

PuR Purifier of Water

Name and Address of Registrant (include ZIP Code):

Procter and Gamble Company
5299 Spring Grove Ave.
Cincinnati, OH. 45217

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Change EPA File Symbol 3573-ON to EPA Registration Number 3573-90.
3. Delete "s" from Active Ingredients. Change Inert Ingredients to Other Ingredients. Change 100.000% to 100%. Change same information on page 5, Sublabel B.
4. Under all Ingredient statements add "2.168 ppm available chlorine"

Page 1 of 3

Signature of Approving Official:

Mark A. Hartman
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date:

November 1, 2006

5. Change all Signal Words from Caution to Warning.
6. Change the Precautionary language to read: 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.
7. Add brackets to Master Label, all headings and all subheadings at bottom of each page.
8. Add number 1 in front of Mix on page 2.
9. On pages 2, 4, 5, and 7, second graphic, change Leave the water to read Let water stand. Third graphic same pages, add clean in front of thick.
10. On page 2, under STIR add "for 5 minutes" to let water stand.
11. On page 2 under Filter and rest of label, add "clean" in front of "thick".
12. On page 2 under Filter remove brackets at third caveat.
13. Change instruction 4 to read "Before Drinking".
14. On page 3 revise signal word and precautionary language as previously described.

Revise First Aid statement as follows:

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 a poison control center or doctor for treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a 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 calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

15. On page 4, under Calcium Hypochlorite add "2.168 ppm available chlorine".
16. Revise signal word and precautionary language on page 4.
17. On page 5, add for 5 minutes after let stand.
18. On page 6, under Filter, remove brackets.
19. On page 6, change instruction 4 heading to Before Drinking.
20. On page 6, revise signal word, precautionary language and First Aid statement as previously described.
21. On page 8 remove claims against parasites in first and second paragraphs. Eliminate paragraphs 3, 4, 5, 6, 7, and 8.
22. On page 9, eliminate heading Clinically Proven, boxes and contents under heading.
23. On page 9, under General Claims delete claims at caveats 8, 9, 10, 11, 12, 13, 14, and 16 in the left box. On the right box delete claims at caveats at 1, 2, 3, 5, and 6.
24. On page 10, delete claims at caveat 1, 2, 3, and 5 in left box. Delete claims at bottom of box on right.
25. Delete all claims on page 11 as the "where to use" advice is too broad.
26. The deficiencies cited in the Efficacy review dated July 26, 2006 must be addressed to Agency's satisfaction in writing by April 1, 2007.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

Your release for shipment of the product constitutes acceptance of these conditions.

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

Copies of our reviews are enclosed.

Page 3 of 3 EPA Registration 3573-90 Initials MAH

4/1/06

PUR Purifier of Water
EPA Registration Number 3573-XX

4/11/06
Page: 1

PUR 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

PUR Purifier of Water

Active Ingredients:	
Calcium Hypochlorite.....	0.542%
Inert Inert Ingredients:	99.458%
Total:	100.000%

other
Warning

2.168 ppm available chlorine delete

revise per letter

KEEP OUT OF REACH OF CHILDREN
CAUTION: [For dry product] Causes moderate eye irritation. Harmful if swallowed. Do not inhale. [See back/side panel/supplemental labeling]

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.

PUR Logo
Purifier of Water (4.0g)
Procter & Gamble Pakistan (Pvt.) Ltd.
B-233/234, H.I.T.E
Hub, Balochistan Pakistan

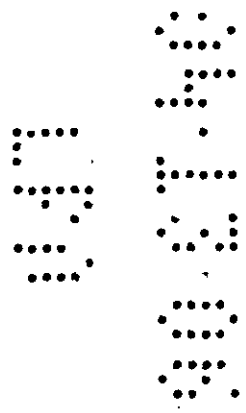
Batch No. XXXXXXXX

PUR Purifier of Water (4g)
Qty: 240 sachets of 4g
Item Code: ZZZZZZZZ
Made in Pakistan

ACCEPTED
with COMMENTS
to EPA letter Dated

NOV - 1 2006

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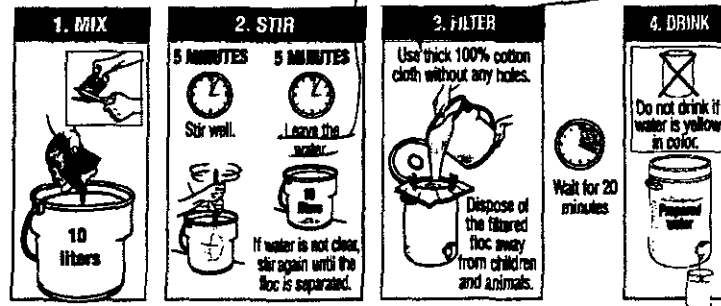


{ Note: Bold, italicized text is for reader clarity only. Bracketed [] text denotes optional text. Backslash \ denotes alternate text. }

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Back/Side Container OR Supplemental Label

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



ACCEPTED
with COMMENTS
re: EPA Letter Dated:
NOV - 1 2006

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 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 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] — remove brackets
- 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. DRINK, as follows: 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.

Note: Bold, italicized text is for reader clarity only. Bracketed [] text denotes optional text. Backslash \ denotes alternate text.

Federal Insecticide,
Fungicide, and
Rodenticide Act as
amended, and
EPA Reg. No.
3573-90

clean

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PUR Purifier of Water
EPA Registration Number 3573-XX

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- 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: Hazardous to humans and domestic animals.

~~**CAUTION:** [For dry product] Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling. Do not inhale. Contains iron sulphate (352 mg ferric iron).~~

revise
per
letter

~~**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 the eye. If on skin, take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. If swallowed, have person sip a glass of potable water if able to swallow. Do not induce vomiting unless directed by poison control center or doctor. Consult a doctor or poison control center for treatment advice.~~

~~Have the label or sachet with you when consulting a poison control center or doctor, or going for treatment.~~

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-xx EPA Est. No. 3573-PAK-001

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
Xcases/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
XXXXXXXX (internal tracking number)

ACCEPTED
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Labeling for Individual Sachets

(Small package: information may be printed on either side of sachet)

PUR Purifier of Water

Calcium Hypochlorite.....0.542%
2.168 ppm available chlorine

KEEP OUT OF REACH OF CHILDREN

revise per letter

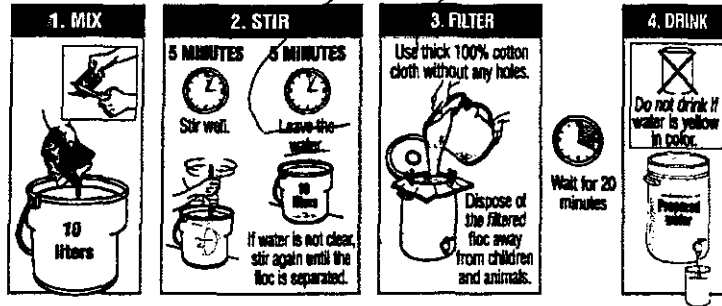
~~CAUTION: [For dry product] Causes moderate eye irritation. In case of contact with skin or eyes, rinse thoroughly with water. Harmful if swallowed. If swallowed, sip water. Contains iron sulphate (352mg ferric iron). Do not inhale. See outer label/container for all precautions.~~

EPA Reg. No. 3573-XX
EPA Est. No. 3573-XX-001.

4 g (0.14 oz)

Let water stand clean

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
XXXXXXXXXX
PUR is a trademark of The Procter & Gamble Company

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

REGISTERED
TRADE MARK
P&G

NOV - 1 2006

Insecticide,
Fungicide, etc.
Pest Control
Company

3573-90

Note: Bold, italicized text is for reader clarity only. Bracketed [] text denotes optional text. Backslash \ denotes alternate text.

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Sublabel B: Consumer Use (USA)

Front Label/ Outer Container/Supplemental Label

PUR Purifier of Water

Active Ingredients:

Calcium Hypochlorite.....0.542%

~~Inert~~ Ingredients:99.458%

Total:100.000%

2,168 ppm available chlorine

KEEP OUT OF REACH OF CHILDREN

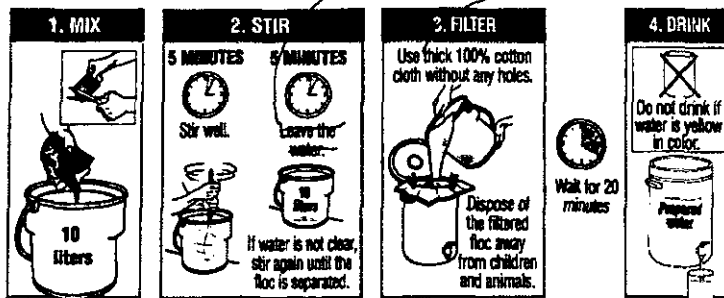
~~CAUTION:~~ [For dry product] Causes moderate eye irritation. Harmful if swallowed. Do not inhale. [See back/side panel/supplemental labeling]

Net Contents Statement

X sachets/packs/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.



Let water stand clean

ACCEPTED WITH COMMENTS
DATE RECALCULATED:

NOV - 1 2006
Insecticide,
EPA Reg. No. 3573-90

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 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.

for 5 minutes

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revise per letter

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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 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. *remove brackets*
- 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.]

clean

4. **DRINK, as follows:**

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.

CAUTION: [For dry product] ~~Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling. Do not inhale. 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 the eye. If on skin, take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. If swallowed, have person sip a glass of water if able to swallow. Do not induce vomiting unless directed by poison control center or doctor. Call a poison control center for treatment advice.~~

~~Have the label or sachet with you when calling poison control center or doctor, or going for treatment.~~

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? Call 1-800-XXX-XXXX
Visit Us At: www.xcxxx.com
EPA Reg. No. 3573-xx EPA Est. No. 3573-PAK-001
Made in Pakistan

NOV - 1 2006

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

YDDPPPB (Batch number for tracking)

Expiration Date: MMYYY

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Note: Bold, italicized text is for reader clarity only. Bracketed [] text denotes optional text. Backslash \ denotes alternate text.

revise per letter

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Labeling for Individual Sachets

(Small package: information may be printed on either side of sachet)

PuR Purifier of Water

Calcium Hypochlorite.....0.542%
2.168 ppm available chlorine

KEEP OUT OF REACH OF CHILDREN

~~CAUTION: [For dry product] Causes moderate eye irritation. In case of contact with skin or eyes, rinse thoroughly with water. Harmful if swallowed. If swallowed, sip water. [Contains iron sulphate (352mg ferric iron). Do not inhale. See outer label/container for all precautions.~~

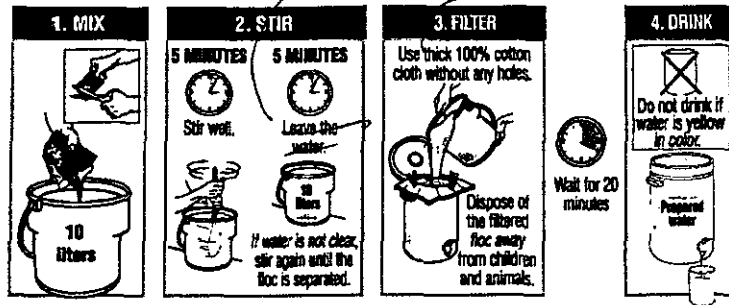
revise per letter

EPA Reg. No. 3573-XX
EPA Est. No. 3573-XX-001.

4 g (0.14 oz)

Let water stand

GRAPHICS FOR SACHET



clean

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

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

ACCEPTED
with COMMENTS
In the original label
NOV - 1 2006

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Note: Bold, italicized text is for reader clarity only. Bracketed [] text denotes optional text. Backslash \ denotes alternate text.

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OPTIONAL CLAIMS FOR SUBLABELS A and B

DISINFECTION

This product is for home\household use and removes\is effective in removing\reduces [the level of] ***list of and/or options:***

- bacteria
- viruses
- cysts

~~• parasites~~

from [most] dirty\contaminated\polluted\ muddy \unclean\impure\ water [sources].

Removes\effective in removing\reduces [the level of] ***list of and/or options:***

- bacteria
- viruses
- cysts

~~• parasites~~

from [most] dirty\contaminated\polluted\ muddy \unclean\impure\ water [sources].

~~Kills\eliminates\destroys\reduces\removes\is effective in removing [99.99999% of] ***list of and/or options:***~~

- common waterborne fecal bacteria
- Escherichia coli (E. coli)
- Salmonella typhi\Salmonella
- Vibrio cholerae
- Klebsiella terrigena

~~Kills\eliminates\destroys\removes [99.999% of] ***list of and/or options:***~~

- Common waterborne viruses
- Poliovirus
- Rotavirus

~~Kills\eliminates\destroys\removes [99.9% of] ***list of and/or options:***~~

- Common cysts
- Common waterborne cysts
- Cryptosporidium parvum
- Giardia lamblia

[Provides] [flocculation] [and] disinfection\disinfects [most] dirty\contaminated\polluted\ muddy \unclean\impure\ water [sources].

Disinfects

[Provides] residual\long lasting disinfection benefit—

~~Robust in removal of turbidity, parasites (>3.3 logs), viruses (>4 logs), bacteria (>7 logs), and chemical contaminants~~

Purifier\cleaner\cleanser of water

Water purifier\cleaner\cleanser

Water purification\cleaning\cleansing product\powder

For the disinfection of water prior to drinking.

Contains chlorine disinfectant

Uses chlorine [as a] disinfectant

Provides 24 hour protection of drinking water.

Water can be drunk for 24 hours after treatment.

{1}

{2}

{3}

{4}

{5}

{6}

{7}

{8}

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PUR Purifier of Water
EPA Registration Number 3573-XX

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CLINICALLY PROVEN	
Clinically proven [effective] [in reducing diarrhea] [to reduce diarrhea]	<p><i>delete</i></p> <p>NOV - 1 2006</p> <p>Product Insecticide, [unclear] insecticide as [unclear] insecticide, [unclear] insecticide, [unclear] EPA Reg. No.</p>
Reduced/reduces risk of diarrhea [among children/young children/children under 5 years of age]	
Clinically Proven [Water] [Disinfectant]	
Provides [clinically proven] [flocculation and] disinfection	

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GENERAL CLAIMS	
Clarifier of Water	<p>Removes/eliminates/minimizes turbidity/water particulates [sediment from water]</p> <p>[Final/Finished] Water is [measurably] less turbid</p> <p>[Final/Finished] Water meets WHO [and] [EPA] drinking water standards [for] list of and/or options:</p> <ul style="list-style-type: none"> • heavy metals* • arsenic • chromium (III) • lead • organics* • humic acid • pesticides** • DDT <p><i>delete</i></p> <p>Each sachet/package/packet/pouch/pack treats 10 liters [2.5 gallons].</p> <p>[Product is] [shelf] stable for 3 years</p> <p>Removes/effective in removing/reduces the level of list of and/or options:</p> <ul style="list-style-type: none"> • heavy metals* • arsenic • chromium (III) • lead • organics* • humic acid • some pesticides* • DDT • turbidity • dirt • sediment <p><i>delete</i></p> <p>[from]</p> <p>[dirty/contaminated/polluted/suspect/foul/nasty/filthy/tainted/muddy/mucky/unclean/impure/wile/rank] [water] [sources].</p>
Water Clarifier	
Water Clarifying Product\Powder	
Water Treatment Product\Powder	
[Developed/Formulated/Designed] For home\household use\see list of potential use areas.	
[Developed/Formulated/Designed/Acceptable] for military installation/field use.	
Treat your water with PUR	
Water treatment product\powder	
Boiling is a less complete method of water treatment	
Boiling does not remove heavy metals	
Provides visual clue it's working	
You can see it working	
Provides high quality water	
Boiling is expensive	
Effective	
For everyday use\usage [with] dirty\contaminated\polluted\ muddy \unclean\impure\ water [sources].	
For emergency use\usage [with] dirty\contaminated\polluted\ muddy \unclean\impure\ water [sources].	

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{14}
{15}

delete

delete

Note: Bold, italicized text is for reader clarity only. Bracketed [] text denotes optional text. Backslash \ denotes alternate text.

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{1}

~~Removes/reduces/is effective in removing (>94% of) the pesticides* (~~DDT, Aldrin and DDE~~)~~

Effective with lake\river\pond\spring\rain\well\wide variety\dam\pond\earth pan waters

{2}

~~Removes/reduces/is effective in removing (>96% of) heavy metals [like] list of and/or options:~~

For lake\river\pond\spring\rain\well\wide variety\dam\pond\earth pan waters

- ~~• arsenic~~
- ~~• chromium (III)~~
- ~~• lead~~

Water is good/acceptable for drinking use after 30 minutes

{3}

~~Removes/reduces/is effective in removing (>95% of) organics [like] [humic acid]~~

Water is ready to drink after 30 minutes

{4}

After clarification of the water by separating sediment from the treated water, the chlorine released by the active ingredient is then free to kill list of and/or options:

[PuR]Clean/refreshing water

- bacteria
- viruses

[Provides] Healthy/hygienic water

Simple/easy to use

No equipment needed

{5}

Emergency water purification powder.
For emergency treatment of polluted water
For treatment of polluted water

Requires filtration

~~No special equipment needed~~

Removes soil and dirt from water and destroys waterborne microorganisms

Contains a combination of flocculating and coagulating agents which promote rapid formation of a sediment in the treated water

Each sachet\pack\packet\package\pouch treats 10 liters [2.5 gallons] of 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

The cloth can be reused after rinsing with clarified, treated water

- ~~*Removes/reduces arsenic, chromium, and lead~~
- ~~*Removes/eliminates humic acid~~
- ~~*Removes/reduces DDT, Aldrin and DDE~~

delete

5
 Date: _____
 1
 10/1/06
 3573-90

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WHERE TO USE	
<p>This product may be used in/for (<i>list of and/or options</i>)</p> <ul style="list-style-type: none">• homes• schools• colleges• recreational facilities• backpacking• campgrounds• camping• boats• ships• campers• RVs• trailers• mobile homes• churches• military installations• military field operations• emergency situations• emergency relief• disaster relief• home preparedness kits• indoors• outdoors	<p>delete</p>

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