

**HAND KLEEN PREMIUM ANTIBACTERIAL HAND- triclosan soap**  
**Auto-Chlor System, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts**

Triclosan 0.30% w/w

Antiseptic handwash

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

For handwashing to decrease bacteria on the skin.

**For external use only.**

**When using this product**

Do not get into eyes.

If contact occurs, rinse eyes thoroughly with water.

**Directions**

- Wet hands and forearms.
- Apply 5 ml or palmful to hand and forearms.
- Scrub thoroughly for at least 15 seconds.
- Rinse completely and dry.

Water, Sodium C<sub>14-16</sub> Olefin Sulfonate, Sodium Laureth Sulfate, Lauryl Glucoside, Cocamidopropyl Betaine, Tetrasodium EDTA, Anionic/Nonionic Detergent Blend, Glycerin, Sodium Chloride, Lanolin, Sodium Xylenesulfonate, Citric Acid, Fragrance

productlabel



Hand Kleen Premium Antibacterial Hand Soap is a thick, white, pearlized lotion soap that is recommended for institutions, restaurants, offices and clubs. It is a powerful cleanser yet gentle to the most delicate skin. Contains emollients to condition the skin and keep it smooth and soft.

Hand Kleen Un Jabón Antibacterial de primera calidad, espeso, blanco aperlado de primera calidad, es una crema de jabón para las manos, recomendando para restaurantes, oficinas, clubes e instituciones, potente limpiador pero a la vez suave para la piel delicada, manteniéndola lisa y suave.

<b>Drug Facts</b>	
<b>Active ingredient / Ingrediente activ</b>	<b>Purpose / Propósito</b>
Triclosan 0.30% .....	Antiseptic handwash / Antiséptico para las manos
<b>Use</b> • For handwashing to decrease bacteria on the skin. • Limpiador de manos que disminuye las bacterias en la piel	
<b>Warnings</b> For external use only.	
<b>Precauciones</b> Para uso externo solamente.	
<b>When using this product</b>	
• Do not get into eyes. • If contact occurs, rinse eyes thoroughly with water.	
<b>Cuando use este Producto</b>	
• Evite el contacto con los ojos. • Si el contacto ocurre, enjuague con suficiente agua.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. <b>Mantenga este producto fuera del alcance de los niños.</b> Si es ingerido obtenga ayuda médica inmediatamente.	
<b>Directions</b>	
• Wet hands and forearms. • Apply 5 ml or palmful to hand and forearms. • Scrub thoroughly for at least 15 seconds. • Rinse completely and dry.	
<b>Instrucciones</b>	
• Humedezca las manos y antebrazos • Tome 5 ml (o lo que quepa en el puño) y aplíquelo en las manos y antebrazos. • Restriegue por lo menos 15 segundos. • Enjuáguese bien y séquese.	
<b>Inactive ingredients</b> Water, Sodium C14-16 Olefin Sulfonate, Sodium Laureth Sulfate, Lauryl Glucoside, Cocamidopropyl Betaine, Tetrasodium EDTA, Anionic/Nonionic Detergent Blend, Glycerin, Sodium Chloride, Lanoline, Sodium Xylenesulfonate, Citric Acid, Fragrance	

**Auto-Chlor**  
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ACL 10230 045 / 13

## HAND KLEEN PREMIUM ANTIBACTERIAL HAND

triclosan soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG LABEL	<b>Item Code (Source)</b>	NDC:68604-023
<b>Route of Administration</b>	TOPICAL	<b>DEA Schedule</b>	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Triclosan (Triclosan)	Triclosan	0.3 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
Water	
Sodium C14-16 Olefin Sulfonate	
Sodium Laureth Sulfate	
Lauryl Glucoside	
Cocamidopropyl Betaine	
Glycerin	
Lanolin	
Edetate Sodium	
Glycol Distearate	
Sodium Chloride	
Coco Monoethanolamide	
Laureth-12	
Sodium Xylenesulfonate	

Citric Acid Monohydrate

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68604-023-01	3780 mL in 1 BOTTLE, PLASTIC		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/22/2013	

**Labeler** - Auto-Chlor System, LLC (965194330)

**Establishment**

Name	Address	ID/FEI	Business Operations
Auto-Chlor Sytem, LLC		965194330	manufacture(68604-023)

Revised: 10/2012

Auto-Chlor System, LLC