

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.

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 C₁₄₋₁₆ 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.

Drug Facts	
Active ingredient / Ingrediente activ	Purpose / Propósito
Triclosan 0.30%	Antiseptic handwash / Antiséptico para las manos
Use • For handwashing to decrease bacteria on the skin. Usa • Limpiador de manos que disminuye las bacterias en la piel	
Warnings For external use only.	
Precauciones Para uso externo solamente.	
When using this product	
<ul style="list-style-type: none"> • Do not get into eyes. • If contact occurs, rinse eyes thoroughly with water. 	
Cuando use este Producto	
<ul style="list-style-type: none"> • Evite el contacto con los ojos. • Si el contacto ocurre, enjuague con suficiente agua. 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Mantenga este producto fuera del alcance de los niños. Si es ingerido obtenga ayuda médica inmediatamente.	
Directions	
<ul style="list-style-type: none"> • Wet hands and forearms. • Apply 5 ml or palmful to hand and forearms. • Scrub thoroughly for at least 15 seconds. • Rinse completely and dry. 	
Instrucciones	
<ul style="list-style-type: none"> • 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. 	
Inactive ingredients 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	

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ACL 10230 045 / 13

HAND KLEEN PREMIUM ANTIBACTERIAL HAND

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68604-023
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Triclosan (UNII: 4NM5039Y5X) (Triclosan - UNII:4NM5039Y5X)	Triclosan	0.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sodium C14-16 Olefin Sulfonate (UNII: O9W3D3YF5U)	
Sodium Laureth Sulfate (UNII: BPV390UAP0)	
Lauryl Glucoside (UNII: 76LN7P7UCU)	
Cocamidopropyl Betaine (UNII: 5OCF3011KX)	
Glycerin (UNII: PDC6A3C0OX)	
Lanolin (UNII: 7EV65EAW6H)	
Edetate Sodium (UNII: MP1J8420LU)	
Glycol Distearate (UNII: 13W7MDN21W)	
Sodium Chloride (UNII: 451W47IQ8X)	
Coco Monoethanolamide (UNII: C80684146D)	
Laureth-12 (UNII: OAH19558U1)	
Sodium Xylenesulfonate (UNII: G4LZF950UR)	

Citric Acid Monohydrate (UNII: 2968PHW8QP)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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