

THEORIE ANTIMICROBIAL HAND WASH- benzalkonium chloride soap Dynastis, 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.

Theorie Antimicrobial Hand Soap

DRUG FACTS

Benzalkonium Chloride 0.13%

Uses

For hand washing to decrease bacteria that can potentially cause disease.

Warnings

For external use only. If swallowed, get medical help or contact a Poison Control Center immediately.

Keep out of reach of children

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Children must be supervised when using this product.

Stop use and ask a doctor if: irritation or rash occurs. These maybe signs of a serious condition.

Directions

For maximum efficiency, pump the product into wet hands, lather vigorously, sinse and dry.

Inactive Ingredients

Water, Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Coco Glucoside, Glycerin, Polysorbate-20, PEG-150 Pentaerythrityl Tetrastearate, PEG-6 Caprylic/Capric Glycerides, Guar Hydroxypropyltrimonium Chloride, Polyquaternium-10, Sodium Hyaluronate, Tocopheryl Acetate, Argania Spinosa Kernel (Argan) Oil, Phenoxyethanol, Ethylhexylglycerin, Citric Acid, Fragrance.

Other Information

Store at room temperature 68°F to 77°F (20° to 25°C)

Do not expose to excessive heat.

You may report a serious adverse reaction to: Hautehouse, LLC, 909 NW Terrace, Fort Lauderdale, FL 33311 USA

For Questions

HAUTEHOUSE INC.
909 NW Terrace
Fort Lauderdale, FL 33311 USA
+1 (954) 376-8966
www.hautehouse.com

THEORIE

ADVANCED CLEAN

Anti-Microbial Hand Soap

FOR ALL SKIN TYPES

Argan oil, marula oil, and vitamin E nourish and moisturize to keep hands clean and soft.

- + Anti-microbial
- + Hydrating & Cleansing
- + Hypoallergenic

INSTANTLY ELIMINATES GERMS AND BACTERIA

NET 400 mL (13.5 Fl. Oz.)

THEORIE

ADVANCED CLEAN

Anti-Microbial Hand Soap

CLEANSE AND PROTECT WITH THIS HYPOALLERGENIC ANTI-MICROBIAL HAND SOAP THAT'S POWERFUL. YET NOURISHING.

FOR ALL SKIN TYPES

Anti-Microbial Hand Soap kills microorganisms living on the skin. Instead of alcohol, this hypoallergenic formula is powered by benzalkonium chloride, a gentle yet powerful alternative that helps to protect against germs after application. Moisturizing argan oil and soothing marula oil keep your hands soft and hydrated. Highly effective as well as nourishing, our hydrating hand soap won't dry out or irritate skin – so you can use as often as needed.

- INSTANTLY KILLS MICROORGANISMS LIVING ON THE SKIN**
- ARGAN OIL & MARULA OIL FOR NOURISHED, SMOOTH SKIN**
- HYALURONIC ACID FOR RICH HYDRATION**
- HYPOALLERGENIC & SAFE**

Drug Facts

Active Ingredients:
Benzalkonium Chloride: 0.13% Fragrance
Antiseptic

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Directions:
For maximum effectiveness, pump the product into wet hands, lather vigorously, rinse and dry.

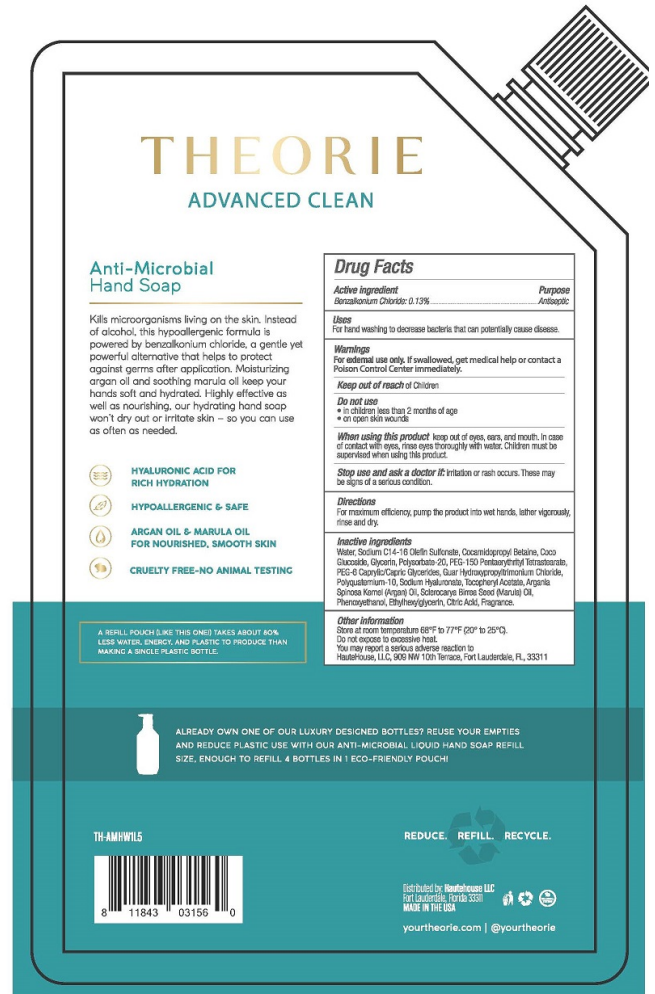
Inactive Ingredients:
Water, Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Coco Glucoside, Glycolin, Polyethylene-20, PEG-150 Perfluoroethyl Tetrafluoracetate, PEG-4 Capryloyl Copolymer, Quaternary Hydroxypropyltrimonium Chloride, Polyquaternium-10, Sodium Hyaluronate, Tocopheryl Acetate, Arginine, Sphingosine Keratin (Argan) Oil, Sclerocarya Elaeagnus Seed (Marula) Oil, Phenylglyoxal, Ethylhexylglycerin, Citric Acid, Fragrance.

Other Information:
Store at room temperature 68°F to 77°F (20° to 25°C). Do not expose to excessive heat. You may report a serious adverse reaction to Hautehouse, LLC, 909 NW Terrace, Fort Lauderdale, FL 33311.

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@yourtheorie



THEORIE ANTIMICROBIAL HAND WASH

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73857-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	.0013 kg in 1 kg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO GLUCOSIDE (UNII: ICS790225B)	
GLYCERIN (UNII: PDC6A3C0OX)	

POLYSORBATE 20 (UNII: 7T1F30V5YH)
PEG-150 PENTAERYTHRITYL TETRASTEARATE (UNII: 8L4OOQ76AM)
PEG-6 CAPRYLIC/CAPRIC GLYCERIDES (UNII: GO50W2HW08)
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)
POLYQUATERNIUM-10 (30000 MPA.S AT 2%) (UNII: C7RDC8Y4JS)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ARGAN OIL (UNII: 4V59G5UW9X)
SCLEROCARYA BIRREA SEED OIL (UNII: WDO4TLS35F)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73857-003-00	0.400 kg in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/14/2020	12/31/2023
2	NDC:73857-003-01	1.5 kg in 1 POUCH; Type 0: Not a Combination Product	08/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/14/2020	

Labeler - Dynastis, LLC (021238554)

Registrant - Dynastis, LLC (021238554)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(73857-003) , label(73857-003) , pack(73857-003)

Revised: 1/2023

Dynastis, LLC