

**THEORIE ANTI-MICROBIAL INSTANT HAND SANITIZER- ethyl alcohol 70% v/v gel
Dynas tis, 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 Anti-Microbial Instant Hand Sanitizer

DRUG FACTS

Alcohol 70% v/v - Antiseptic

Uses:

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings:

For external use only. Flammable. Keep away from heat or flame.

If swallowed, get medical help or contact a Poison Control Center immediately.

KEEP OUT OF REACH OF CHILDREN SECTION

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:

Place one pump quantity of the product in you palm and rub your hands entirely until product is completely absorbed and dry. Children must be supervised when using this product.

Inactive Ingredients:

Water, Glycerin, Carbomer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Sodium Hyaluronate, Argania Spinosa Kernel (Argan) Oil, Tocopheryl Acetate, Phenoxyethanol, Ethylhexylglycerin, 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
 Instant Hand Sanitizer**

FOR ALL SKIN TYPES

Argan oil, vitamin E, and hyaluronic acid nourish and moisturize to keep hands soft and hydrated.

- + Anti-Microbial
- + Lightweight Formula
- + Hydrating & Cleansing

**INSTANTLY ELIMINATES
 GERMS AND BACTERIA**

NET 420 mL (14.2 FL. Oz.)

THEORIE
 ADVANCED CLEAN

**Anti-Microbial
 Instant Hand Sanitizer**

CLEANSE AND PROTECT YOUR HANDS INSTANTLY WITH THIS ANTI-MICROBIAL SANITIZER THAT'S POWERFUL YET NOURISHING.

FOR ALL SKIN TYPES

Anti-Microbial Instant Hand Sanitizer kills microorganisms living on the skin. Powered by alcohol, this potent formula immediately eliminates bacteria and germs while moisturizing argan oil and soothing hyaluronic acid keep your hands soft and hydrated. Highly effective as well as nourishing, our hydrating sanitizer won't dry out or irritate skin – so you can use as often as needed.

- INSTANTLY KILLS MICROORGANISMS LIVING ON THE SKIN**
- ARGAN OIL FOR NOURISHED, SMOOTH SKIN**
- HYALURONIC ACID FOR RICH HYDRATION**
- SUPER LIGHTWEIGHT FORMULA**
- SOOTHING, NON-ALCOHOLIC SMELL**
- ABSORBS FAST**

Drug Facts

Active ingredient Alcohol 70% v/v	Purpose Antiseptic
Uses Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings For external use only. Flammable. Keep away from heat or flame. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
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 may be signs of a serious condition.	
Directions Place one pump quantity of the product in your palm and rub your hands entirely until product is completely absorbed and dry. Children must be supervised when using this product.	
Inactive ingredients Water, Glycerin, Carbomer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Ammonium Propyl, Sodium Hydroxide, Argania Spinosa Kernel Oil, Tocopherol/Acetate, Phenoxyethanol, Ethylhexylglycerin, 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 10th Terrace, Fort Lauderdale, FL, 33311	

Distributed by:
 Hautehouse, LLC
 Fort Lauderdale, Florida 33311
 MADE IN THE USA

yourtheorie.com | @yourtheorie

TH-HS1420



THEORIE
 ADVANCED CLEAN

70% ALCOHOL

**Anti-Microbial
 Instant Hand Sanitizer**

FOR ALL SKIN TYPES

Argan oil, marula oil, vitamin E, and hyaluronic acid nourish and moisturize to keep hands soft and hydrated.

- + Anti-microbial
- + Lightweight Formula
- + Hydrating & Cleansing

**INSTANTLY ELIMINATES
 GERMS AND BACTERIA**

NET 400 mL (13.5 FL. Oz.)

70% ALCOHOL

**Anti-Microbial
 Instant Hand Sanitizer**

CLEANSE AND PROTECT YOUR HANDS INSTANTLY WITH THIS ANTI-MICROBIAL SANITIZER THAT'S POWERFUL YET NOURISHING.

FOR ALL SKIN TYPES

Anti-Microbial Instant Hand Sanitizer kills microorganisms living on the skin. Powered by alcohol, this potent formula immediately eliminates bacteria and germs while moisturizing argan oil and soothing hyaluronic acid keep your hands soft and hydrated. Highly effective as well as nourishing, our hydrating sanitizer 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**
- SUPER LIGHTWEIGHT FORMULA**
- ABSORBS FAST**

Drug Facts

Active ingredient Alcohol 70% v/v	Purpose Antiseptic
Uses Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings For external use only. Flammable. Keep away from heat or flame. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
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 may be signs of a serious condition.	
Directions Place one pump quantity of the product in your palm and rub your hands entirely until product is completely absorbed and dry. Children must be supervised when using this product.	
Inactive ingredients Water, Glycerin, Carbomer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Ammonium Propyl, Sodium Hydroxide, Argania Spinosa Kernel (Argan) Oil, Sclerocarya Birrea Seed (Shilandia) Oil, Tocopherol/Acetate, Phenoxyethanol, Ethylhexylglycerin, 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 10th Terrace, Fort Lauderdale, FL, 33311	

Distributed by:
 Hautehouse, LLC
 Fort Lauderdale, Florida 33311
 MADE IN THE USA



yourtheorie.com | @yourtheorie

THEORIE ANTI-MICROBIAL INSTANT HAND SANITIZER

ethyl alcohol 70% v/v gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73857-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	.7 L in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ARGAN OIL (UNII: 4V59G5UW9X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73857-001-00	0.420 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
2	NDC:73857-001-01	0.400 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/03/2020	

Labeler - Dynastis, LLC (021238554)

Registrant - Dynastis, LLC (021238554)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc		016433141	manufacture(73857-001) , relabel(73857-001) , pack(73857-001)

Revised: 8/2020

Dynastis, LLC