

**HYDRATING ANTI-BACTERIAL HAND SANITIZER- alcohol lotion**  
**SHISEIDO AMERICAS CORPORATION**

*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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**Hydrating Anti-Bacterial Hand Sanitizer**

**Drug Facts**

**Active ingredient**

Ethyl alcohol 70% v/v

**Purpose**

Antimicrobial

**Use**

- Hand sanitizer to help reduce bacteria on skin

**Warnings**

**Flammable. Keep away from fire or flame.**

**For external use only**

**When using this product** do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation or rash appears and lasts

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

**Directions**

- Put enough product in your palm to cover hands and rub hands together briskly until dry
- Children under 6 years of age should be supervised when using this product

**Other information**

- Store below 110°F (43°C)
- May discolor certain fabrics and surfaces

**Inactive ingredients**

water, glycerin, carbomer, triethanolamine

**PRINCIPAL DISPLAY PANEL - 100 mL Bottle Label**

SHISEIDO  
AMERICAS

Hydrating Anti-Bacterial

Hand Sanitizer

THE  
BEAUTY OF HELPING  
OTHERS

SERVING OUR  
COMMUNITIES

Label donated by  
Standwill Packaging

3.4 FL. OZ. (100 mL)

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AMERICAS

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Standwill Packaging

3.4 FL. OZ. (100 mL)

"We believe in taking action to help communities  
with the greatest needs to thrive."



- Kills 99.99% of germs
- Hydrates skin with 2% Glycerin

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SHISEIDO AMERICAS CORPORATION DIST. NEW YORK, NY 10017

Not intended for sale

EXP 12/31/2020

**HYDRATING ANTI-BACTERIAL HAND SANITIZER**

alcohol lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-535
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-535-10	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
2	NDC:58411-535-11	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
3	NDC:58411-535-12	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	04/01/2020	

**Labeler** - SHISEIDO AMERICAS CORPORATION (193691821)

## Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICAS INC.		782677132	MANUFACTURE(58411-535) , ANALYSIS(58411-535)

Revised: 4/2020

SHISEIDO AMERICAS CORPORATION