

TOUCH OF SHEA HAND SANITIZER- ethyl alcohol gel
Homemade Shea 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.

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

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Ethyl Alcohol 70%

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Do not use in eyes. In case of contact with eyes, rinse with water.

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When using this product

Do not use in eyes. In case of contact with eyes, rinse with water.

irritation and redness develop and persist.

ask doctor if irritation and redness develop and persist

If swallowed, get medical help promptly.

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Inactive Ingredients

WATER

ISOPROPYL ALCOHOL

GLYCERIN

POLYACRYLIC ACID

PROPYLENE GLYCOL

.ALPHA.-TOCOPHEROL ACETATE

ALOE VERA LEAF

Other Information - Store under 105°F

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Uses

For handwashing to decrease bacteria on the skin

Wet hands thoroughly with product and allow to dry without wiping.

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Purpose

Antiseptic

2oz NDC: 78401-444-02





TOU

2 FL OZ (60 mL)



TOUCH OF SHEA HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 401-444(NDC:66902-343)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78401-444-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/10/2020	

Labeler - Homemade Shea LLC (097200813)**Establishment**

Name	Address	ID/FEI	Business Operations
Homemade Shea		097200813	repack(78401-444)

Revised: 6/2020

Homemade Shea LLC