RECESSA HAND SANITIZER- alcohol gel
Specialty Formulations

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.

Recessa Hand Sanitizer Gel
70% Alcohol

Active Ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Uses

to reduce disease causing bacteria on the skin when soap and water not available

Warnings

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

When using this product

■ Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Do not use:

■ on open skin wounds

■ in children less than 2 months of age

Stop use and ask a doctor if:

Skin irritation or rash develop

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

Directions:

Place enough product on hands to cover all surfaces. Rub hands together until dry. ■ for children under 6, use only under adult supervision

Other Information:

■ Store between 15°- 30°C (59°- 86° F)
■ Avoid freezing and excessive heat above 40°C (104°F

Inactive Ingredients:

Aloe Vera Gel,
Carbomer, Glycerin, Vitamin E, Purified Water, Triethanolamine and Witch Hazel

Package Label - Principal Display Panel

Recessa

Hand Sanitizer

Gel

70% Alcohol

with Moisturizers

16oz (473 ml)

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RECESSA HAND SANITIZER
alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70420-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
WITCH HAZEL (UNII: 101I4J0U34)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70420-001-19	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/28/2020	
2	NDC:70420-001-17	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/28/2020	
3	NDC:70420-001-18	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/28/2020	

Labeler - Specialty Formulations (003989912)

Registrant - Specialty Formulations (003989912)

Establishment

Name	Address	ID/FEI	Business Operations
Specialty Formulations		003989912	manufacture(70420-001)

Revised: 1/2021 Specialty Formulations