

SPASOAP- hand sanitizer liquid
Sante Manufacturing Inc

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.

Active Ingredients

Ethyl Alcohol 70%

Purpose - Antiseptic

Use hand sanitizer to help reduce bacteria on the skin

Warnings

Flammable

Keep away from fire or flame

For external use only

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

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- apply palmful to hands
 - rub hands together vigorously until dry
 - supervise children in the use of this product

Water, Carbomer, Trethanolamine, Glycerin, Propylene Glycol, Alo Barbdensis Leaf Juice*, Tocopherol Acetate*, Lavandula Angustifolia Flower / Leaf / Stem Extract*, Fragrance*, D&C Red # 33*, FD&C Blue # 1*, FD&C Yellow # 5*,

* Contains 1 or more of these ingredients



SpaSoap
 Hand Sanitizer
 2fl.oz (59ml) Each
 6 fl.oz (177ml) Total

SPASOAP

hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71020-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	700 mL in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
LAVANDULA ANGUSTIFOLIA WHOLE (UNII: 51217XIL5L)	
WATER (UNII: 059QF0K00R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71020-015-02	177 mL in 1 PACKAGE, COMBINATION; Type 1: Convenience Kit of Co-Package	03/11/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/11/2017	

Labeler - Sante Manufacturing Inc (242048747)

Establishment

Name	Address	ID/FEI	Business Operations
Sante Manufacturing Inc		242048747	manufacture(71020-015)

Revised: 3/2017

Sante Manufacturing Inc