

HAND SANITIZER- hand sanitizer gel
Brands International

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.

Spa Soap Hand Sanitizer 3 Pack

Drug Facts

Active Ingredient

Ethyl alcohol 62%.

Purpose

Antiseptic

For handwashing to decrease bacteria on the skin.

Warnings

Flammable, keep away from fire or flame. For external use only.

When using this product Avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor If redness or irritation develop and persist for more than 72 hours.

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

Directions

Spread on both hands, rub in, let dry.

Inactive Ingredients Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water, Isopropyl Myristate, Aminomethyl Propanol.

Please review individual labels for specific details on colors and additives on 3 different variety of sanitizers.

Packaging

**HAND
SANITIZER**
MOISTURIZING

Spa Soap®

ASSORTED 3 PACK

Kills harmful bacteria/germs

CONTAINS: / CONTIENT : 3 X 59 mL (2 oz liq.)
TOAL: / TOTALE : 177 mL (6 oz liq.)



Drug Facts

Active IngredientsEthyl Alcohol 62% w/w.....Antibacterial

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.

Stop use and ask a doctor if irritation or redness develops.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

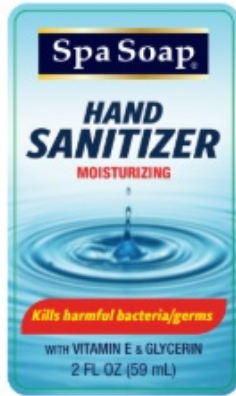
Directions ■ apply palmful to hands ■ rub hands together vigorously until dry ■ supervise children in the use of this product.

Other information ■ store below 110°F (43°C) ■ may discolor certain fabrics or surfaces.

Inactive ingredients Water, Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice (Aloe Vera), Tocopheryl Acetate (Vitamin E), May Contain: FD&C Yellow #5, FD&C Blue #1, D&C Red #33.

Made in Canada
Sante Manufacturing Inc.
Mississauga, ON L4T 1L2

LABEL SIZE: 2.0472" X 1.1811"
SEMI-GLOSS PAPER
FRONT LABEL



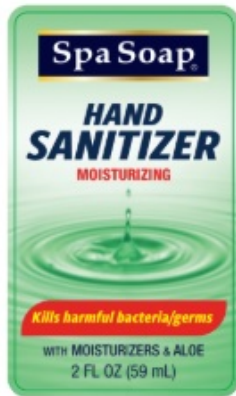
LABEL SIZE: 2.0472" X 1.1811"
WHITE BOPP
BACK LABEL FRONT



LABEL SIZE: 2.0472" X 1.1811"
WHITE BOPP
BACK LABEL INSIDE



LABEL SIZE: 2.0472" X 1.1811"
SEMI-GLOSS PAPER
FRONT LABEL



LABEL SIZE: 2.0472" X 1.1811"
WHITE BOPP
BACK LABEL FRONT



LABEL SIZE: 2.0472" X 1.1811"
WHITE BOPP
BACK LABEL INSIDE



LABEL SIZE: 2.0472" X 1.1811"
SEMI-GLOSS PAPER
FRONT LABEL



LABEL SIZE: 2.0472" X 1.1811"
WHITE BOPP
BACK LABEL FRONT



LABEL SIZE: 2.0472" X 1.1811"
WHITE BOPP
BACK LABEL INSIDE



HAND SANITIZER

hand sanitizer gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50 157-569

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE (UNII: V5VD430YW9)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 157-569-01	1 in 1 KIT	03/04/2020	
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50 157-569-02	1 in 1 KIT	03/04/2020	
2		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:50 157-569-03	1 in 1 KIT	03/04/2020	
3		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

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

Labeler - Brands International (243748238)

Revised: 4/2020

Brands International