HAND SANITIZER- alcohol liquid Neptune Health & Wellness Innovation

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 Ingredient(s)

Alcohol 65% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients

Bergamot Essential Oil, Fragrance (Essential Oil Blend), Organic Aloe barbadensis Leaf Juice, Organic Glycerin (Flax Seed), Purified Water.

Package Label - Principal Display Panel

2 fl. oz. (60 mL) NDC: 79965-007-00

2 oz Dieline - 105mm x 53mm



2 oz PeelBack (inside left) -46mm x 45mm







4 oz Dieline - 148mm x 60mm



4 oz PeelBack (inside left) - 74mm x 60mm

Drug Facts (continued)

Warnings

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

Do not use iii in children less than 2 months of age IIII on open skin wounds

When using this product keep out of ey ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation of occurs. These may be signs of a serious

Keep out of reach of children. If swallowed, get medical help or contact Control Center right away. 1-800-222-1

4 oz PeelBack (inside right) - 74mm x 60mm



Drug Facts (continued)

Directions

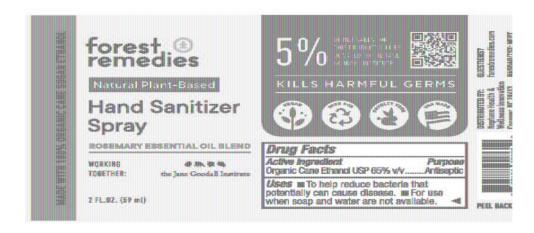
IIII Place enough product on han all surfaces. Rub hands togethe Supervise children under 6 year using this product to avoid swal

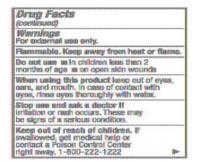
Other information

■ Store between 15-30°C (59-8 freezing and excessive heat about 15 control of the control of th

Inactive ingredients Bergamot Essential Oil, Fragran Blend), Organic Aloe barbadens Organic Glycerin (Flax Seed), Pu

2 fl. oz. (60 mL) NDC: 79965-107-00







Dring Facts
(continued)
Directions
In Place enough product on hands to cove
all surfaces. Aub hands together until dry.
In Supervise children under 6 years of age
when using this product to avoid swellow
Differ information
In Store between 15-30°C (5986°P) In Avoid freezing and excessive
hast above 40°C (104°F)
Inactive Ingredients
Bergamot Essential OII, Fragrance
(Essential OII Blend), Organic Aloe
barbadensis Leaf Juice, Organic
Glycerin (Flax Seed), Purified Water.

4 fl. oz. (120 mL) NDC: 79965-107-01

4 oz Dieline - 148mm x 60mm



4 oz PeelBack (inside left) - 74mm x 60mm

Drug Facts (continued)

Warnings

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

Do not use iii in children less than 2 months of age iii on open skin wounds

When using this product keep out of ey ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation o occurs. These may be signs of a serious

Keep out of reach of children. If swallowed, get medical help or contact Control Center right away. 1-800-222-1

4 oz PeelBack (inside right) - 74mm x 60mm



Drug Facts (continued)

(CONTROLLING CO)

Directions

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Other information

■ Store between 15-30°C (59-8 freezing and excessive heat about

Inactive ingredients

Bergamot Essential Oil, Fragran Blend), Organic Aloe barbadens Organic Glycerin (Flax Seed), Pu

HAND SANITIZER

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79965-107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL	
BERGAMOT OIL (UNII: 39W1PKE3JI)	0.3 mL in 100 mL	
WATER (UNII: 059QF0KO0R)	31.68 mL in 100 mL	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.02 mL in 100 mL	

F	Packaging				
#	Item Code	Package Description Marketing Start Date		Marketing End Date	
1	NDC:79965- 107-00	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2021		
2	NDC:79965- 107-01	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2021		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2021	

HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79965-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL
ALCOHOL (UNII: 3K9958V9UM) (ALCOHOL - UNII:3K9958V9UM)	ALCOHOL	65 ML IN 100 ML

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL	
BERGAMOT OIL (UNII: 39W1PKE3JI)	0.3 mL in 100 mL	
WATER (UNII: 059QF0KO0R)	31.68 mL in 100 mL	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.02 mL in 100 mL	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79965- 007-00	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2021		
2	NDC:79965- 007-01	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2021		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2021	

Labeler - Neptune Health & Wellness Innovation (117560399)

Establishment			
Name	Address	ID/FEI	Business Operations
Dimensional Merchandising Inc.		076693183	manufacture(79965-007, 79965-107), label(79965-007, 79965-107), pack(79965-007, 79965-107)

Revised: 6/2021 Neptune Health & Wellness Innovation