HAND SANITIZER- alcohol gel
HAND SANITIZER- alcohol spray
Camden Passage 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.

Ocean Free - Hand Sanitizer

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Glycerol (1.45% v/v).
c. Hydrogen peroxide (0.125% v/v).
d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% 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.

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.

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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

70jug.jpg is the 5L 70% alcohol-based sanitizer NDC: 77385-033-76

70pump.jpg is the 500mL 70% alcohol-based sanitizer NDC: 77385-034-13

80jug.jpg is the 5L 80% alcohol-based sanitizer NDC: 77385-057-38

80pump.jpg is the 500 mL 80% alcohol-based sanitizer NDC: 77385-057-52

5L Antiseptic Disinfectant_v01.jpg is the 5L 70% alcohol-based sanitizer NDC 77385-028-05

500mL Antiseptic Disinfectant_v01.jpg is the 500mL 70% alcohol-based sanitizer spray NDC 77385-028-29

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77385-034
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**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1.33 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.4 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	20 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.35 mL in 100 mL
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	0.6 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:77385-034-13	800 in 1 CASE	12/07/2018	
1		20 in 1 CARTON		
1		500 mL in 1 BOTTLE, PUMP; 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	part356	12/07/2018	

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77385-033
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**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1.33 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.4 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	20 mL in 100 mL
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	0.6 mL in 100 mL

TROLAMINE (UNII: 9O3K93S3TK)	0.35 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77385-033-76	160 in 1 CASE	12/07/2018	
1		4 in 1 CARTON		
1		5000 mL in 1 JUG; 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	part356	12/07/2018	

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77385-057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8 L in 1 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.014 L in 1 L
WATER (UNII: 059QF0KO0R)	0.2 L in 1 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.00125 L in 1 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77385-057-38	160 in 1 CASE	12/07/2018	
1		4 in 1 CARTON		
1		5 L in 1 JUG; Type 0: Not a Combination Product		
2	NDC:77385-057-52	800 in 1 CASE	12/07/2018	
2		20 in 1 CARTON		
2		0.5 L in 1 BOTTLE, PUMP; 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	part356	12/07/2018	

HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77385-028
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	30 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77385-028-29	800 in 1 PACKAGE	12/07/2018	
1		20 in 1 CARTON		
1		500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:77385-028-05	160 in 1 PACKAGE	12/07/2018	
2		4 in 1 CARTON		
2		5000 mL in 1 JUG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	12/07/2018	

Labeler - Camden Passage Inc. (250929382)

Registrant - Rook Quality Systems (929885247)

Establishment

Name	Address	ID/FEI	Business Operations
Camden Passage Inc.		250929382	manufacture(77385-057, 77385-033, 77385-034, 77385-028)