

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



Oceanfree+

- KILLS 99.99%**
- ✓ **VIRUSES**
 - ✓ **GERMS**
 - ✓ **BACTERIA**

70% ALCOHOL
HAND SANITISER GEL

Refreshes and leaves hands feeling soft

5 Litres e 1.32 US Gal

How to use: No water required. Apply to hands, rub in, ensuring contact with fingernails and in-between fingers. Can also be applied to the body. Do not use on damaged, sensitive or irritated skin. **Warning:** Classification according to Regulation (EC) No 1272/2008 (CLP/GHS). Avoid eye contact. Do not use on damaged, sensitive or irritated skin. Adult supervision required for child use. Highly flammable liquid and vapour. Keep away from heat/sparks/open flames/hot surfaces. No smoking. **Ingredients:** Ethanol / Alcohol Denat (70% v/v), Aqua (Water), Propylene Glycol, Glycerin, Carbomer, Triethanolamine, Hydrogen Peroxide.



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www.oceanfree.com



Wrimes Cosmetics Ltd, Unit 1 Access Business Park, Gunnels Wood Road, Stevenage, SG1 2GR, United Kingdom

Batch: 690059 Expires: 04-2022

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



Recommended use: Effective in destroying harmful bacteria to provide antiseptic cleaning. Directions for use: Supervise children when they use this product. For occasional and personal domestic use, rub thoroughly into hands for at least 30 seconds. Allow to dry. Caution and warnings: Flammable. Keep away from open flame and sources of heat. Adult supervision required for child use. Keep out of reach of children. For external use only. If swallowed, call a poison control centre or get medical help right away. Stop use and consult a doctor if irritation develops. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Medical ingredients: 2-Propanol (Isopropyl alcohol), Isopropyl alcohol, 70%. Non-medical ingredients: Water. Contraindications: Do not use on children under 2 years of age (unless directed by a doctor). Other information: Store in a cool dry place.

Usage recommandé: Efficace pour détruire les bactéries (nocives) pour fournir un nettoyage antiseptique. Mode d'emploi: Surveillez les enfants lorsqu'ils utilisent ce produit. Pour un usage domestique occasionnel et personnel. Frottez abondamment dans vos mains pendant au moins 30 secondes. Laissez sécher. Méfiez-vous du feu et des vêtements: Inflammable. Tenez le produit à l'écart des flammes nues et des sources de chaleur. La surveillance d'un adulte est requise pour l'utilisation des enfants. Garder hors de la portée des enfants. Pour usage externe seulement. En cas d'ingestion, appeler un centre antipoison ou consulter immédiatement un médecin. Évitez l'utilisation et évitez le contact avec les yeux. Si un contact a lieu, rincez abondamment à l'eau. Ingrédients médicaux: Propyl-2-ol (Alcool isopropylique, Alcool isopropylique) - 70%. Ingrédients non-médicaux: Eau. Contre-indications: Ne pas utiliser sur les enfants moins de 2 ans (sauf si il y a l'autorisation d'un médecin). Autres renseignements: Conserver dans un endroit sec et frais.

5 Litres e 1.32 US Gal



www.oceanfree.ca

Camden Passage Inc. Collingwood, Ontario L9Y 4W3
 Batch/Lot: 09009 Expiry/Expiration: 05-2022
 NPN: 00000000 NDC: 00000-000-00

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



Recommended use: Effective in destroying harmful bacteria to provide antiseptic cleaning. Directions for use: Supervise children when they use this product. For occasional and personal domestic use, rub thoroughly into hands for at least 30 seconds. Allow to dry. Caution and warnings: Flammable. Keep away from open flame and sources of heat. Adult supervision required for child use. Keep out of reach of children. For external use only. If swallowed, call a poison control centre or get medical help right away. Stop use and consult a doctor if irritation develops. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Medical ingredients: 2-Propanol (Isopropyl alcohol), Isopropyl alcohol, 70%. Non-medical ingredients: Water. Contraindications: Do not use on children under 2 years of age (unless directed by a doctor). Other information: Store in a cool dry place.

Usage recommandé: Efficace pour détruire les bactéries (nocives) pour fournir un nettoyage antiseptique. Mode d'emploi: Surveillez les enfants lorsqu'ils utilisent ce produit. Pour un usage domestique occasionnel et personnel. Frottez abondamment dans vos mains pendant au moins 30 secondes. Laissez sécher. Méfiez-vous du feu et des vêtements: Inflammable. Tenez le produit à l'écart des flammes nues et des sources de chaleur. La surveillance d'un adulte est requise pour l'utilisation des enfants. Garder hors de la portée des enfants. Pour usage externe seulement. En cas d'ingestion, appeler un centre antipoison ou consulter immédiatement un médecin. Évitez l'utilisation et évitez le contact avec les yeux. Si un contact a lieu, rincez abondamment à l'eau. Ingrédients médicaux: Propyl-2-ol (Alcool isopropylique, Alcool isopropylique) - 70%. Ingrédients non-médicaux: Eau. Contre-indications: Ne pas utiliser sur les enfants moins de 2 ans (sauf si il y a l'autorisation d'un médecin). Autres renseignements: Conserver dans un endroit sec et frais.

www.oceanfree.ca
 Camden Passage Inc. Collingwood, Ontario L9Y 4W3
 Batch/Lot: 09009 Expiry/Expiration: 05-2022
 NPN: 00000000 NDC: 00000-000-00



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: 059QF0K00R)	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)

Revised: 5/2020

Camden Passage Inc.