RRUB RINSE FREE HAND WASH-ALCOHOL VERSION- alcohol liquid
RRUB RINSE FREE HAND WASH-NON ALCOHOL VERSION- benzalkonium chloride liquid
RRUB BODY SANITIZING- benzalkonium chloride liquid
CHAMPS INDUSTRIAL PTE LTD

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.

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) (75%, 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. MET® Microbe Encapsulation Technology ingredients.
d. Sterile distilled water or boiled cold water.

The MET® Microbe Encapsulation Technology ingredients help to physically remove the dead bacteria killed by actives ingredients. Thus the effectiveness is enhanced than sanitizing only.

Active Ingredient(s)

alcohol version: Alcohol 75% v/v. Purpose: Antiseptic

non-alcohol version: Benzalkonium chloride, cetyl Pyridinium chloride. 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, purified water USP, MET® Microbe Encapsulation Technology ingredients.

Package Label - Principal Display Panel

rrub Rinse-free Hand Wash Alcohol version NDC: 78974-0001


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rrub Rinse-free Hand Wash Non-alcohol version NDC: 78974-0002

Sanitizing Body Spray

RRUB RINSE FREE HAND WASH-ALCOHOL VERSION

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78974-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALPHA CELLULOSE (UNII: I355QGZ19A)	0.5 mL in 100 mL
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	0.5 mL in 100 mL
CITRIC ACID, 1-STEARYL ESTER (UNII: E945AJ51FA)	0.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:78974-0001-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	07/15/2020	
2	NDC:78974-0001-2	400 mL in 1 BAG; Type 0: Not a Combination Product	07/15/2020	
3	NDC:78974-0001-3	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/13/2020	


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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/15/2020	

RRUB RINSE FREE HAND WASH-NON ALCOHOL VERSION

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78974-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.5 g in 100 mL
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7JI0JV3)	CETYLPYRIDINIUM CHLORIDE	0.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
ALPHA CELLULOSE (UNII: I355QGZ19A)	0.1 mL in 100 mL
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	0.1 mL in 100 mL
CITRIC ACID, 1-STEARYL ESTER (UNII: E945AJ51FA)	0.2 mL in 100 mL
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	0.1 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78974-0002-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	07/15/2020	
2	NDC:78974-0002-2	400 mL in 1 BAG; Type 0: Not a Combination Product	07/15/2020	
3	NDC:78974-0002-3	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/15/2020	

RRUB BODY SANITIZING

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78974-0003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.5 g in 100 mL
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7JI0JV3)	CETYLPYRIDINIUM CHLORIDE	0.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
ALPHA CELLULOSE (UNII: I355QGZ19A)	0.1 mL in 100 mL
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	0.1 mL in 100 mL
CITRIC ACID, 1-STEARYL ESTER (UNII: E945AJ51FA)	0.2 mL in 100 mL
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	0.1 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78974-0003-2	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/20/2020	
2	NDC:78974-0003-1	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/20/2020	

Labeler - CHAMPS INDUSTRIAL PTE LTD (595851023)

Registrant - CHAMPS INDUSTRIAL PTE LTD (595851023)

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