CLEANSE PURE- alcohol solution
Frozen Wheels, Llc

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.

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cleansepure

Drug Facts

Active ingredient

Alcohol 70% v/v.

Purpose

Antiseptic

Use[s]

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.

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

Inactive Ingredients

demineralized water, glycerin, carbomer, aloe vera extract, triethanolamine, disodium EDTA.

NON-STERILE SOLUTION

Made in Mexico.

Imported by:

Frozen Wheels, LLC

16565 NW 15th Ave.

Miami, FL 33169

Distributed by:

Distribu LLC

Packaging

CLEANSE PURE

alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77031-505
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**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:77031-505-33	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
2	NDC:77031-505-01	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph not final	part333A	05/18/2020	

Labeler - Frozen Wheels, Llc (069055731)

Revised: 6/2020 Frozen Wheels, Llc