FRESHQUITAS ANTISEPTIC HAND WIPES- alcohol cloth Carmel Industria e Comercio de Produtos de Higiene e Limpeza Ltda

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 package of hand sanitizer wipes containing the following ingredients:

- a. Alcohol (ethanol) (70% volume/volume (v/v)).
- b. Aqua
- c. Propylene Glycol,
- d. Phenoxyethanol, PEG-40
- e. Hydrogenated Castor Oil
- f. PEG-12 Dimethicone
- g. Prunus Amygdalus Dulcis (Sweet Almond) Oil
- h. Edetate Disodium

The firm does not add other active or inactive ingredients.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic Hand Wipes

Use

- For hand washing to decrease bacteria on the skin disease
- Recommended for repeated use

Warnings

For external use only.

Flammable. Keep away from fire or flame.

Allergy Alert: Contains Almond Oil.

When using this product:

- avoid contact with eyes, ears, and mouth. If contact occurs with eyes, flush thoroughly with water
- avoid contact with broken skin
- avoid inhalation
- if inhaled for prolonged period, seek immediate medical attention

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.

Do not use

- in children less than 2 months of age
- if you are allergic to any ingredients
- on open skin wounds

Directions

- Remove wet wipe and apply thoroughly to hands as desired
- Allow to dry without wiping
- Supervise children in the use of this product
- Use only as directed.

Other information

- Store between 59-86°F
- Keep sealed after between uses
- Avoid freezing and heat above 104°F
- May discolor certain fabrics or surfaces

Inactive ingredients

Aqua, Propylene Glycol, Phenoxyethanol, PEG-40 Hydrogenated Castor Oil, PEG-12 Dimethicone, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Edetate Disodium

Package Label - Principal Display Panel

10 Wipes NDC: 79089-501-01

Do not use in children less than 2 months of age mif you are allergic to any ingredents to decrease bacteria on the skin disease Recommende Uses - For hand washin Hydrogenated Castor Oil, PEG-12 Dimethicone, Prunus Amygdalus Duids (Sweet Almond) Oil, with water ■ av nactive ingredien Aqua, Propylene Glycol, Phenoxyethanol, PEG-40 or prolonged period, see mmediate medical attent I imitation or rash occurs These may be signs of a serious condition. ping Supervise childre the use of this product Flammable, keep away from fire or flame Children. If swallowed, g medical help, or contact The use of this product
 Use only as directed. Directions -Remov Warnings For external use only Poison Control Center wet wipe and apply thoroughly to hands 1 ctive ingredient.

Antiseptic Hand Wipes



hygienic Kills 99.99% of germs or dyes

Alcohol 70%

Does not dry out

- Fast & effective
- No animal testing
- No artificial fragrances or dyes
- Paraben Free

Contains

O WIPES 7.9 IN X 5.5 IN (20cm X 14cm)







- Does not dry out the skin
- Dermatologically



Dispose of used wipes in trash receptacle after use. Do not flush. 4. Apply the wipe as directed, applying thoroughly to hands as desired, and allow to dry without wiping.

2. Pull the first wet whe by its tip and thread through the lid.
3. Replace the lid and pull the first wipe completely free cap.
Through until the next wipe appears, then re-seal with the cap.
A Anoly the wipe as directal enotiant products as

Remove the seal and the cap to access the wet wipes. INSTRUCTIONS FOR USE

FRESHQUITAS HYGIENIC HAND WIPES were specially developed to ellminate hand germs in a practical and efficient way. They can be used anytime and anywhere.

The antiseptic formula contains Alcohol 70% that cleans your skin.

40 Wipes NDC: 79089-501-02



150 Wipes NDC: 79089-501-03



FRESHQUITAS ANTISEPTIC HAND WIPES

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79089-501	
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	
EDETATE DISODIUM (UNII: 7FLD91C86K)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
WATER (UNII: 059QF0KO0R)		
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)		
ALMOND OIL (UNII: 66YXD4DKO9)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79089- 501-01	10 in 1 PACKAGE	03/01/2021	
1		32 mL in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:79089- 501-02	40 in 1 PACKAGE	03/01/2021	
2		110 mL in 1 PACKAGE; Type 0: Not a Combination Product		
3	NDC:79089- 501-03	150 in 1 PACKAGE	03/01/2021	
3		411 mL in 1 CANISTER; 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	part333E	03/01/2021	

Labeler - Carmel Industria e Comercio de Produtos de Higiene e Limpeza Ltda (903638113)

Establishment			
Name	Address	ID/FEI	Business Operations
Carmel Industria e Comercio de Produtos de Higiene e Limpeza Ltda		903638113	manufacture(79089-501)

Revised: 2/2021 Carmel Industria e Comercio de Produtos de Higiene e Limpeza Ltda