3 PERCENT HYDROGEN PEROXIDE- 3% hydrogen peroxide gel Solugen Blending, 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.

3% Hydrogen Perxoide, USP

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. Hydrogen peroxide (H2O2) (USP or Food Chemical Codex (FCC) grade) (3%, volume/volume (v/v)) in an aqueous solution .
- b. 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)

Hydrogen Peroxide 3% 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.

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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

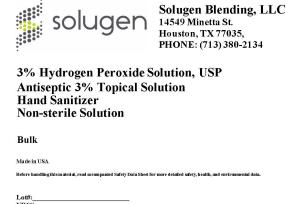
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

purified water USP

Package Label - Principal Display Panel

22712 L NDC: 79975-011-01



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3 PERCENT HYDROGEN PEROXIDE 3% hydrogen peroxide gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:79975-011 Route of Administration TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

HYDRO GEN PERO XIDE	UNII: BBX060AN9V) (HYDROGEN PEROXIDE -
LINII-BRX060 ANOV)	

HYDROGEN PEROXIDE 3 mL in 100 mL

Inactive	Ingredients
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Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R) 97 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79975-011- 01	22712000 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/12/2020	

Marketing Information

With Keting Internation			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/12/2020	

Labeler - Solugen Blending, LLC (117590261)

Establishment

					
Name	Address	ID/FEI	Business Operations		
Solugen Blending-Minetta		117590261	manufacture (79975-011)		

Establishment Name Address ID/FEI Business Operations Solugen Blending-Slaton 117605218 manufacture(79975-011)

Revised: 10/2020 Solugen Blending, LLC