

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 Peroxide, 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



Solugen Blending, LLC
14549 Minetta St.
Houston, TX 77035,
PHONE: (713) 380-2134

3% Hydrogen Peroxide Solution, USP
Antiseptic 3% Topical Solution
Hand Sanitizer
Non-sterile Solution

Bulk

Made in USA

Before handling this material, read accompanying Safety Data Sheet for more detailed safety, health, and environmental data.

Lot#: _____
NDC#: _____

Drug Facts	
Active ingredient[s]	Purpose
Hydrogen Peroxide 3%/v/v	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	
<ul style="list-style-type: none">• 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 at 1-800-222-1222.	
Directions	
<ul style="list-style-type: none">• 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	
<ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients purified water USP	

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
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HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	3 mL in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
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

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