

SURGE INDUSTRIAL HAND SANITIZER GEL- alcohol solution Premalux, 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.

Surge Industrial® Hand Sanitizer Gel - 80% Alcohol Gel - Topical Solution - 128 fl oz (3.78L)

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) (80%, 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. Hydrogen peroxide (0.125% v/v).
- d. 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)

Alcohol 80% 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

Glycerin, Hydrogen Peroxide, Purified Water USP

Package Label - Principal Display Panel

SURGE INDUSTRIAL

HAND SANITIZER GEL

80% Alcohol Gel
Topical Solution

128 FL OZ (3.78L)

Drug Facts

Active ingredient[s]	Purpose
Ethyl Alcohol 80%	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"> on 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	
<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 Water (Aqua), 1,3-Propanediaminium, Hydroxypropyl cellulose	

Manufactured by: Premalux, LLC, 300 Lena Drive, Aurora, OH 44026
300.995.4000

FDA NDC#

Part # SIHZG 0001



SURGE INDUSTRIAL HAND SANITIZER GEL

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81696-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0KO0R)	18.425 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:81696-001-01	3.78541 L in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2021	
2	NDC:81696-001-05	18.9271 L in 1 CONTAINER; Type 0: Not a Combination Product	03/29/2021	
3	NDC:81696-001-55	208.198 L in 1 DRUM; Type 0: Not a Combination Product	03/29/2021	
4	NDC:81696-001-27	1040.99 L in 1 POUCH; Type 0: Not a Combination Product	03/29/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/29/2021	

Labeler - Premalux, LLC (055494147)

Establishment

Name	Address	ID/FEI	Business Operations
Premalux, LLC		055494147	manufacture(81696-001)

Revised: 3/2021

Premalux, LLC