

NAKED NATURALS HAND SANITIZER- alcohol gel
Welburn Corporation

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.

Naked Naturals Hand Sanitizer - Welburn Corporation

Drug Facts

Active ingredients

Alcohol 70% v/v

Purpose

Antiseptic

Uses

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

- 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 thoroughly with water.

Stop use and ask a doctor if

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

Inactive ingredients

Water, Carbomer, Glycerin, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone.

Questions?

call 888 387 3887

Company Information

Dist: Welburn Corporation

PO BOX 1392

Hermosa Beach, CA 90254-1392

Made in Guatemala

Product Packaging - 458 ml

IMPROVED

FORMULA!

NAKED

NATURALS

HAND SANITIZER

NON STERILE SOLUTION

with moisturizing ingredients

ALCOHOL 70%

15.5 fl. oz. / 458ml

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NAKED NATURALS HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77622-001
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
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HO MO POL YMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77622-001-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
2	NDC:77622-001-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
3	NDC:77622-001-04	280 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
4	NDC:77622-001-03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
5	NDC:77622-001-05	458 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
6	NDC:77622-001-06	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
7	NDC:77622-001-07	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
8	NDC:77622-001-08	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	
9	NDC:77622-001-09	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/12/2020	
10	NDC:77622-001-10	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/12/2020	

Labeler - Welburn Corporation (117515830)

Revised: 5/2020

Welburn Corporation