

NAKED NATURALS HAND SANITIZER WITH VITAMIN E- 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.

Hand Sanitizer with Vitamin E - Welburn Corporation

Drug Facts

Active ingredients

Alcohol 70% v/v

Purpose

Antiseptic

Uses

Hand Sanitizer to help reduce bacteria that can potentially 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 seek a doctor

If irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children.

If ingested, 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 ingestion.

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, Tocopheryl Acetate, Blue 1 (CI 42090).

Questions?

call 888 387 3887

Company Information

Dist: Welburn Corporation

PO BOX 1392

Hermosa Beach, CA 90254

Made in Guatemala

Product Packaging - 500ml

ADVANCED FORMULA!

NAKED

NATURALS

HAND SANITIZER

WITH VITAMIN E

NON STERILE SOLUTION

ALCOHOL 70%

16.9 fl. oz. / 500ml

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alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77622-007
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)	
METHYLISO THIAZOLINO NE (UNII: 229D0E1QFA)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
.ALPHA.-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77622-007-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020	
2	NDC:77622-007-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020	
3	NDC:77622-007-04	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020	
4	NDC:77622-007-03	280 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020	
5	NDC:77622-007-05	458 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020	
6	NDC:77622-007-06	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020	
7	NDC:77622-007-07	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020	
8	NDC:77622-007-08	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020	
9	NDC:77622-007-09	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/25/2020	
10	NDC:77622-007-10	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/25/2020	

Labeler - Welburn Corporation (117515830)

Revised: 6/2020

Welburn Corporation