NEUTREVO INSTANT HAND SANITIZER- alcohol gel SCK ZETA DIS TICARET

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

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 (0.1% v/v).
- c. Trolamine (0.07% v/v).
- d. Sterile distilled water or boiled cold water.
- e. ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (0.4% v/v).

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 70% 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, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, Trolamine, purified water USP

Package Label - Principal Display Panel









Use: Hand-sanitizer to help reduce bacteria on the skin. "Kills 99,99% of Staphylococcus aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Interpococus Hime ATC 10541, Esherichia Golf ATCC 10536, Gandida albicans ATCC 10234, Candida albicans and other ignition sources. No smoking. P233: Keep container tightly dosed: P242: Use only non-spatring tools. P403 + P235: Store in a well ventilated place. Keep cool. P305+351+338: IF IN EYES-IF-IN EYES. Rinse cautiously with water for several minutes. Remove contact clenses if present and easy to do—continue trising. Children under 6-yeaks of age should be supervised when using this product. Direction for use? Apply a small amount of the gel on the palm of your hand and rubyour hands. For external use only. Keep out reach of children. Ingedenters: Ethyl Action (CAS Nico 44-75) - S670(W/n.) Aqua, Ays/182*(CA) 30 Milor Maytate Crosspolymer, inethanolamine. Glycerine. Eth: Hygienic antibacterial hand desinging gel, which's effective against bacteria, that does not require water and towels-1F. Gel rigienizzantie antibatteric per la pulizia delle main. Il prodotto è efficace contro i hatteri e luso non richiede acqua e asciugamano. DE Hygienisches antibatterielle Handiderielle Handiderielle Staterial per la contro i hatteri e luso non richiede acqua e asciugamano. DE Hygienisches antibatterielle y totales. P80: Gel entitopat mise delle minera de niños artibacterian pas e la produce de mano; efficient importiva bacteria, que no requiree aqua y totales. P80: Gel entitopat major e la entitación de bacteria, que no requiree aqua y totales. P80: Gel entitopat major antibacterian per la primarka parte en en globej Gel Staterian, de la produce de la produce de la companya antibacterian per la primarka parte en en globej Gel bacterian delle matica en la produce de la contro produce de la produce de la companya PRD:04.2020 EXP:04.2023 LOT:1071 Los Sis Soal 1x 2 D - 4 Transiye setacompany com





NEUTREVO INSTANT HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86818-002	
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
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	0.4 mL in 100 mL
GLYCERIN (UNII: PDC6 A3C0 OX)	0.1 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.07 mL in 100 mL
WATER (UNII: 059QF0KO0R)	29.43 mL in 100 mL

II	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:86818-002- 05	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020		
	NDC:86818-002- 06	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020		
	NDC:86818-002- 07	45 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020		
	NDC:86818-002- 08	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/27/2020		

Labeler - SCK ZETA DIS TICARET (356290986)

Revised: 6/2020 SCK ZETA DIS TICARET