ZEST HAND SANITIZER- ethyl alcohol gel TCP HRB HOLDINGS 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.

ZEST HAND SANITIZER GEL - 70% ALCOHOL

ACTIVE INGREDIENT

ETHYL ALCOHOL (70% w/v)

PURPOSE

ANTIMICROBIAL

USES

HAND SANITIZER TO HELP REDUCE BACTERIA THAT CAN POTENTIALLY CAUSE DISEASE. FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE.

WARNINGS

- FLAMMABLE.
- KEEP AWAY FROM FIRE OR FLAME.
- FOR EXTERNAL USE ONLY.

When using this product do not use it in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

- Store below 110°F (43°C)
- May discolor certain fabrics.

INACTIVE INGREDIENTS

WATER, PEG-8, PROPYLENE GLYCOL, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, TERT-BUTYL ALCOHOL, AMINOMETHYL PROPANOL, TOCOPHERYL ACETATE, DENATONIUM BENZOATE.



Drug Facts

Active ingredient[s] Alcohol 70% v/v..... Purpose .Antiseptic

- To help reduce bacteria on skin 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

Directions ■ Place enough product on hands to cover all surfaces. Rub hands together until dry.

Not for oral use. ■ Supervise children under 6 years of age when using this product

Other Information ■ Avoid freezing and excessive heat above 40°C (104°F) ■ May discolor certain fabrics or surfaces

Inactive ingredients Water/Aqua/Eau, PEG-8, Propylene Glycol, Fragrance/Parfum, Acrylates/C10-30 Alkyl Acrylate Pragranter Parlinin, Addytetes (10-30 Aiktyr Addytete Crosspolymer, Aminomethyl Propanol, Tocopheryl Acetate, Glycerin, Agastache Mexicana Flower/Leaf/Stem Extract, Agave Tequilana Leaf Extract, Citrus Limon (Lemon) Peel Extract, Coffea Arabica (Coffee) Seed Extract, Coffea Robusta Seed Extract, Malpighia Glabra (Acerola) Fruit Extract, Glycolic Acid, Citric Acid, Malic Acid, Yellow 5 (Cl 19140), Yellow 6 (Cl 15985)

ZEST HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81277-102(NDC:77352-102)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	

AGASTACHE FOENICULUM WHOLE (UNII: ZV7TA06J2V)	
AGAVE TEQUILANA LEAF (UNII: 05545M0E3M)	
LEMON PEEL (UNII: 720054U628)	
COFFEE BEAN (UNII: JFH385Y744)	
MALPIGHIA GLABRA FRUIT (UNII: B94O42LA9M)	
GLYCOLIC ACID (UNII: 0 WT12SX38S)	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
MALIC ACID (UNII: 817L1N4CKP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:81277-102-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/15/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	12/15/2020			

Labeler - TCP HRB HOLDINGS LLC (117465959)

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