DISINFEX- alcohol gel
RK KOZMETIK VE HIJYEN URUNLERI SANAYI DIS TICARET ANONIM SIRKETI

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.

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) recommendations:

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, 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 (0.5% v/v).
c. Aloe Vera Leaf (0.1% v/v).
d. Carbomer 940 (0.3% v/v).
e. Aminomethylpropanol (0.15% v/v).
f. Sterile distilled 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 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Disinfex Hand Sanitizer

Uses

to help reduce bacteria on the skin. For use when soap and water are not avaliable.

Warnings

For external use only. Flammable liquid and vapor. Keep away from heat/sparks/open flame. No smoking. Avoid sprayin in eyes.

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation or redness devolops and lasts.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a poison Control Center immediately.

Directions

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

Other information

- Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F)
- may discolor certain fabrics or surfaces.

Inactive ingredients

Water (Aqua), Glycerin, Aloe Barbadensis Leaf Juice, Carbomer, Aminomethylpropanol.

Package Label - Principal Display Panel

100 mL NDC: 79320-120-02

DISINFEX
alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79320-120
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)	0.5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.15 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:79320-120-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph not final	part333A	07/15/2020	

Labeler - RK KOZMETIK VE HIJYEN URUNLERI SANAYI DIS TICARET ANONIM SIRKETI (520068126)

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