### C-TIZERS 99.9- ethyl alcohol, isopropyl alcohol gel TIZER KOZMETIK LIMITED 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.

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# Active Ingredient Purpose

Ethyl Alcohol 60% v/v..... Antiseptic
Isopropyl Alcohol 10% v/v..... Antiseptic

#### Uses

Antibacterial Hand Sanitizer.

## Warnings

Flammable, Keep away from eyes.

#### **Directions**

Tear a single use pack of C-Tizers 99.9% and gently squeeze the full sachet onto your hands. Slowly rub your hands, covering the whole surface area until they are fully dry. No need to rinse at all afterwards.

## **Inactive ingredients**

2,2,2-Nitrilotri(ethan-1-ol), Glycerin, Aloe vera extract, (2R)-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12-trimethyltridecyl]-3,4-dihydro-2H-1-benzopyran-6-ol, CarboxyvinylPolymer, B.OCEAN 345276, C.I.:42090, Water.

#### **Product label**



## **C-TIZERS 99.9**

ethyl alcohol, isopropyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80637-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>ALCOHOL</b> (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	60 mL in 100 mL		
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	10 mL in 100 mL		

	Inactive Ingredients	
ı	Ingredient Name	Strength

.ALPHATO COPHEROL (UNII: H4N855PNZ1)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
TROLAMINE (UNII: 903K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:80637-001-01	1.5 mL in 1 POUCH; Type 0: Not a Combination Product	10/06/2020			
2	NDC:80637-001- 02	1.5 mL in 1 PACKET; Type 0: Not a Combination Product	10/06/2020			
3	NDC:80637-001- 03	3 mL in 1 POUCH; Type 0: Not a Combination Product	10/06/2020			
4	NDC:80637-001- 04	3 mL in 1 PACKET; Type 0: Not a Combination Product	10/06/2020			
5	NDC:80637-001- 05	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/06/2020			
6	NDC:80637-001- 06	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/06/2020			
7	NDC:80637-001- 07	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/06/2020			
8	NDC:80637-001- 08	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/06/2020			
9	NDC:80637-001- 09	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/06/2020			
10	NDC:80637-001-10	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/06/2020			
11	NDC:80637-001-11	150000 mL in 1 DRUM; Type 0: Not a Combination Product	10/06/2020			
12	NDC:80637-001-12	45 mL in 1 POUCH; Type 0: Not a Combination Product	10/06/2020			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	10/06/2020		

# **Labeler** - Tizer Kozmetik Limited Sirketi (595844669)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
TIZER KOZMETIK LIMITED SIRKETI		595844669	manufacture (80637-001)	