

MOJITO- hand sanitizer gel gel

MOJITO KOZMETIK URUNLERI VE MATBAA SANAYI TICARET 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.

Mojito GEL

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

- 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 products.

Other information

- Store below 110°F(43C°)
- Avoid freezing and excessive heat above 40C (104F)
- May discolor certain fabrics or surfaces

Inactive ingredients

Carbomer□Glycerin, Triethanolamine, Water (Aqua)

Package Label - Principal Display Panel



Drug Facts	
Active Ingredient Ethyl Alcohol 70% v/v	Purpose Antiseptic
Uses 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 do not use in or near the eyes. In case of contact, 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 • 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 products.	
Other information • Store below 110°F (43°C) • Avoid freezing and excessive heat above 40°C (104°F) • May discolor certain fabrics or surfaces	
Inactive ingredients Carbomer, Glycerin, Triethanolamine, Water (Aqua)	
Manufactured by: Batch no is on the packaging MADE IN TURKEY	
MOJITO KOSMETİK ÜRÜNLERİ ve MATBAA SAN. TİC. LTD. ŞTİ. Office: Axis İstanbul AVM Ofis Topçular Mahallesi Ösmangazi Cad. No: 2/119 34055 Eyüpsultan/İstanbul Factory: Ortaköy Sanayi Bölgesi 160 Ada 25 Parsel Mahal No: 6 Zemin Kat No: 18 Silivri/İstanbul EU Responsible Person: Emel Trade Ltd. Unit 2 Christy Court SS15 6 TL Basildon Essex ENGLAND	

100 mL NDC: 77224-101-02

MOJITO

hand sanitizer gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77224-101
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)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77224-101-01	50 mL in 1 TUBE; Type 0: Not a Combination Product	05/15/2020	
2	NDC:77224-101-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
3	NDC:77224-101-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

4	NDC:77224-101-04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
5	NDC:77224-101-05	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/15/2020	

Labeler - MOJITO KOZMETIK URUNLERI VE MATBAA SANAYI TICARET LIMITED SIRKETI (504584976)

Establishment

Name	Address	ID/FEI	Business Operations
MOJITO KOZMETIK URUNLERI VE MATBAA SANAYI TICARET LIMITED SIRKETI		504584976	manufacture(77224-101)

Revised: 5/2020

MOJITO KOZMETIK URUNLERI VE MATBAA SANAYI TICARET LIMITED SIRKETI