

COTTON SOFT- hand sanitizing wipes cloth
SEPA MENSUCAT SANAYI VE 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.

HAND SANITIZING WIPES

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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold 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)

Ethyl Alcohol 75%. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

For Hand sanitizing to decrease bacteria and germs on skin

Apply topically to skin to help prevent cross contamination

Dries in seconds

Warnings

For external use only. Harmful if swallowed

Highly Flammable.

Keep away from heat or flame.

Avoid contact with open or exposed skin wounds

Do not use

- Do not use as baby wipes
- Do not flush down the toilets
- Do not use in or contact the eyes

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 skin irritation and sensitivity develops or increases.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

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Directions

- Lift the tab on the top of the lid to open
- Open moisture seal film package before use.
- Pull out first wipe through the dispensing center of the canister. Next sheets pops up automatically.
- Close the lid to retain moisture.
- Wipe down with this product. Let air dry.

Other information

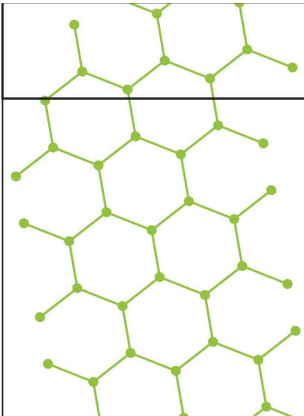
- Store at room temperature between 15-30C (59-86F)
- Lot No., manufacture date and expiration date can be found on package.

Inactive ingredients





Purified water

Hand Sanitizing wipes-Package Label - Principal Display Panel





Hand Sanitizing wipes 50 pcs NDC: 81406-001



NDC 81406-001-50

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 Mamurteyg Mah.10.Yol Sok. No:124 Bağcılar/İstanbul/TÜRKİYE

50
pcs





HAND SANITIZING WIPES

75% ALCOHOL



50
pcs



MAKE FOR SKIN KILLS 99.9% OF GERMS ON HANDS



HAND SANITIZING WIPES

75% ALCOHOL

Ultra Protection Extra Soft







HAND SANITIZING WIPES

75% ALCOHOL




50
pcs




Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol, 75%	Antiseptic
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<ul style="list-style-type: none"> • For Hand sanitizing to decrease bacteria and germs on skin • Apply topically to skin to help prevent cross contamination • Dries in seconds 	
Warning	
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Other Information	
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Inactive Ingredients	
Water	

Hand Sanitizing Wipes- 50 pcs

Hand Sanitizing Wipes- 50 pcs



NDC 81406-001-50

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Sepa Mensucat San Ve Tic.A.Ş.





MADE IN Turkey

50 pcs



Colton[®] Soft

HAND SANITIZING WIPES

75% ALCOHOL

50 pcs



MAKE FOR SKIN KILLS 99.9% OF GERMS ON HANDS

HAND SANITIZING WIPES

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Ultra Protection Extra Soft

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hand sanitizing wipes cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81406-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	25 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81406-001-50	220 g in 1 POUCH; Type 0: Not a Combination Product	01/07/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/07/2021	

Labeler - SEPA MENSUCAT SANAYI VE TICARET ANONIM SIRKETI (366438166)

Registrant - MASTER CUSTOMS BROKER (054631555)

Establishment

Name	Address	ID/FEI	Business Operations
SEPA MENSUCAT SANAYI VE TICARET ANONIM SIRKETI		366438166	manufacture(81406-001)

Revised: 10/2021

SEPA MENSUCAT SANAYI VE TICARET ANONIM SIRKETI