

BIOMATE MULTI-PURPOSE ALCOHOL WIPES- alcohol cellular sheet
KYB KUYUMCULUK INSAAT TURIZM GIDA ITHALAT IHRACAT SANAYI VE 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.

This is a multi-purpose alcohol wipes 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 multi-purpose alcohol wipes 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)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Multi-purpose alcohol wipes 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

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

PREMIUM QUALITY


biomate

Drug Facts	
Active Ingredient Ethanol (EC No : 200-576-69 (CAS No: 54-17-5) : 80% (v/v))	Purpose Antiseptic
Inactive Ingredients Glycerine (EC No : 200 - 289 - 5) (CAS No: 56 -81 - 5) : 1.45% (v/v) Hydrogen Peroxide (EC No: 231 - 765 - 0) (CAS No: 7722 - 84 - 1) : 0.125% (v/v)	
Use Hand sanitizer to help reduce germs on skin that can potentially cause disease.	
Warnings Flammable. Keep away from fire or flame. For external use only. Do not use in the eyes. Discontinue use and ask a doctor if - Irritation and redness develop. - Condition persists for more than 72 hours. Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.	
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Other Information Store in a cool, dry place below 104°F (40°C)	

Multi - Purpose Alcohol Wipes

Kills 99.9% of viruses and germs

Wipes for surface disinfection of non-invasive medical devices.



- Designed for the catering, entertainment, restaurant, airline, public transport, medical, care homes, laboratories, hospitality industries and general use.
- Kills 99.99% germs without the need for soap and water.
- Quick evaporating formula without rinsing.
- Anti-bacterial hand sanitiser wipe sachets ideal for sanitising hands on the go
- Ideal for use in any location no water needed.
- wet impregnated nonwoven wipe containing a hand sanitising mixture.
- Ideal for disinfecting hands before eating and after using the toilet. Our sachets are ideal for placing on food trays to use before meals.
- Conveniently sized, individual sachets are ideal for carrying with you at all times - at home, in the office, in bags, in your vehicle and also when travelling.

PRODUCER BY:
KYB Kuyumculuk İthalat İhracat Sanayi Ticaret Ltd. Sti.
Milli kütüphane caddesi İ.Tepeköyü iş merkezi 17/801
İZMİR / TURKEY

72 pcs.

- Hand and Skin
- Hairdresser equipment
- Clothes and jewels
- Home and Cars
- Electronic Instruments

www.biomateshop.com

175 ml NDC 80560-002-02

PREMIUM QUALITY

biomate

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İZMİR / TURKEY

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80 pcs.

192 ml NDC 80560-002-01

PREMIUM QUALITY

biomate

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100 pcs.

240 ml NDC 80560-002-03

PREMIUM QUALITY

biomate

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150 pcs.


STRONG • EFFECTIVE


ANTIVIRUS


Kills 99.9% of
viruses and germs


Wipes for surface
disinfection of non-invasive
medical devices.




Hand and
Skin

Hairdresser
equipment

Clothes
and jewelry

Home and
Cars

Electronic
Instruments

Designed for the catering, entertainment, restaurant, airline, public transport, medical, care homes, laboratories, hospitality industries and general use.

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İZMİR / TURKEY



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360 ml NDC: 80560-002-04

PREMIUM QUALITY

biomate

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160 pcs.


STRONG • EFFECTIVE


ANTIVIRUS


Kills 99.9% of
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Wipes for surface
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Hand and
Skin

Hairdresser
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Home and
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Electronic
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384 ml NDC: 80560-002-05

PREMIUM QUALITY

biomate

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200 pcs.

480 ml NDC: 80560-002-06

PREMIUM QUALITY

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400 pcs.

480 ml NDC: 80560-002-07

BIOMATE MULTI-PURPOSE ALCOHOL WIPES

alcohol cellular sheet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80560-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	80 mL in 100 mL
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80560-002-01	192 mL in 1 CANISTER; Type 0: Not a Combination Product	08/06/2020	
2	NDC:80560-002-02	175 mL in 1 PACKAGE; Type 0: Not a Combination Product	08/06/2020	
3	NDC:80560-002-03	240 mL in 1 CANISTER; Type 0: Not a Combination Product	08/06/2020	
4	NDC:80560-002-04	360 mL in 1 CANISTER; Type 0: Not a Combination Product	08/06/2020	
5	NDC:80560-002-05	384 mL in 1 CANISTER; Type 0: Not a Combination Product	08/06/2020	
6	NDC:80560-002-06	480 mL in 1 CANISTER; Type 0: Not a Combination Product	08/06/2020	
7	NDC:80560-002-07	960 mL in 1 CANISTER; Type 0: Not a Combination Product	08/06/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	08/06/2020	

Labeler - KYB KUYUMCULUK INSAAT TURIZM GIDA ITHALAT IHRACAT SANAYI VE TICARET LIMITED SIRKETI (365680187)

Establishment			
Name	Address	ID/FEI	Business Operations
KYB KUYUMCULUK INSAAT TURIZM GIDA ITHALAT IHRACAT SANAYI VE TICARET LIMITED SIRKETI		365680187	manufacture(80560-002)

Revised: 10/2020

KYB KUYUMCULUK INSAAT TURIZM GIDA ITHALAT IHRACAT SANAYI VE TICARET LIMITED SIRKETI