### BIOLUSTRE HYGIENIC HAND CLEANSING GEL- ethyl alcohol gel KOYUNCU BILISIM TEKNOLOJILERI 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.

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Alcohol 70% v/w

Antiseptic

Used for antibacterial hand skin, prevent bacteria.

For external use only. Flammable. Keep away from fire.

- Keep away from fire.
- Do not wipe your eyes.
- Do not throw into the toilet (not soluble in water).
- Please wait until the alcohol has completely evaporated after wiping.
- Before use, check whether the packaging is intact. Do not use if it is damaged.

Stop use and ask a doctor for those with alcohol allergy or sensitive skin.

Keep out of reach of children.

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

Water, Glycerin, Carbomer, Triethanolamine

Use it as needed, after following the usage instructions. For external use only.





# **Hygienic Hand Cleansing GEL**

Safe Usage Information: Washed and free from dirt. Apply in dry hands. Take 3ml biolustre hand gel in your palm and along 30 seconds scrub into your hand. If applied to gloves please be sure to change the gloves when you're done and does not require rinsing. The Properties of Storage Containers and Storage: Store in dry, ventilated and keep away from daylight. Do not store with dangerous substances. Keep it in a closed and upright position. Other Precautions: Free from flammable and violent reaction substances tobacco. Check that the product is not closed, torn, crushed, and openPlease. Attention: Beesand aquatic animals can be poisonous to criminal organisms. Contents: Ethyl Alcohol, Aqua Water, Glycerin, Triethanolamine



P.D.: 28/05/2020 EXP.: 27/05/2022



50 mle



Producer Company and License Holder; KOYUNCU BİLİŞİM TEKNOLOJİLERİ SAN. ve TİC. LTD. ŞTİ. Nissa Q2 3/15 Bahçeşehir-İstanbul/TURKEY

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Strength

### BIOLUSTRE HYGIENIC HAND CLEANSING GEL

ethyl alcohol gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80371-104

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

GLYCERIN (UNII: PDC6A3C0OX)
TROLAMINE (UNII: 9O3K93S3TK)

WATER (UNII: 059QF0KO0R)

#### CARBOMER 940 (UNII: 4Q93RCW27E)

l	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:80371-104- 01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/29/2020			
	2 NDC:80371-104- 02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/29/2020			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	09/29/2020				

# Labeler - KOYUNCU BILISIM TEKNOLOJILERI SANAYI VE TICARET LIMITED SIRKETI (505247089)

## Registrant - KOYUNCUBILISIM TEKNOLOJILERISANAYIVETICARET LIMITED SIRKETI (505247089)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
KOYUNCU BILISIM TEKNOLOJILERI SANAYI VE TICARET LIMITED SIRKETI		505247089	manufacture(80371-104)

Revised: 9/2020 KOYUNCU BILISIM TEKNOLOJILERI SANAYI VE TICARET LIMITED SIRKETI