BIOLUSTRE DISPOSABLE 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.

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.





BIOLUSTRE DISPOSABLE HAND CLEANSING GEL

ethyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80371-105	
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		
CARBOMER 940 (UNII: 4Q93RCW27E)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
TROLAMINE (UNII: 9O3K93S3TK)			

Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NI	DC:80371-105-01	3 mL in 1 POUCH; 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 - KOYUNCU BILISIM TEKNOLOJILERI SANAYI VE TICARET LIMITED SIRKETI (505247089)

Establishment			
Name	Address	ID/FEI	Business Operations
KOYUNCU BILISIM TEKNOLOJILERI SANAYI VE TICARET LIMITED SIRKETI		505247089	manufacture(80371-105)

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