ALCOHOL HAND WIPES- ethyl alcohol cloth
OLCE GROUP KOZMETIK KIMYA GIDA MEDIKAL VE SAGLIK URUNLERI SANAYI VE TICARET LTD STI

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.

Active Ingredient

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Wipes used on hands and skin to reduce bacteria

Warnings

For external use only, do not ingest. Flammable. Keep away from heat, flame, or direct sunlight. Do not eat, drink, or smoke during use. If irritation or redness occurs and persists for longer than 72 hours, consult a medical professional.

Do not use

- in children less than 2 months of age
- on open skin wounds
- near 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 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.

Stop Use

Stop use and ask a doctor if irritation or rash occurs and persists for longer than 72 hours. 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. Supervise use by children under the age of 6.

Directions

- Peel back open label slowly
- Pull out one wipe at a time
- Reseal packaging tightly
- Wet hands thoroughly with product and allow to dry

- Supervise children under 6 years of age when using this product to avoid ingestion

Storage

- Avoid freezing and excessive heat above 40C (104F)
- Store away from direct sunlight
- Store tightly closed in its original packaging
- Keep away from food, drinks, and animal feed
- Store in places unaccessible to children

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Inactive Ingredients

lemon oil-distilled, peg-7 glyceryl cocoate, edetic acid, anhydrous citric acid, water, polysorbate 20, cocamidopropyl betaine, dexpanthenol, glycerin

Package Label - Principal Display Panel

120 Count Canister NDC: 90083-211-12

200 Count Canister NDC: 90083-211-20

500 Count Canister NDC: 90083-211-50

Drug Facts

Active Ingredient **Purpose**
Ethyl Alcohol .....%70 Antiseptic

Use to decrease bacteria on the skin.

Warnings
For external use only.

Do not use:
- in the eyes.
- if you are allergic to any of the ingredients.

When using this product if eye contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

Drug Facts (continued)

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

Directions
- Thoroughly wipe hands and body as desired.
- Allow to dry without wiping.
- Discard wipe in trash receptacle after use.
- Do not flush.

Other information store below 110° F

Inactive Ingredients
Aqua, Parfum, C12-15 Pareth-12, Glycerin, Polysorbate 20, Propylene Glycol, Tetrasocium EDTA, Piroctone Olamine, Tocopherly Acetate, Panthenol, Citric Acid, Aloe Barbadensis Leaf Extract, Tocopheryl Asetate (Vitamin E)

ALCOHOL HAND WIPES

ethyl alcohol cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:90083-211
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3.059 mL in 4.37 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
EDETIC ACID (UNII: 9G34HU7RV0)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
LEMON OIL, DISTILLED (UNII: ET5GD00TRP)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:90083-211-50	2185 mL in 1 CANISTER; Type 0: Not a Combination Product	09/07/2020	
2	NDC:90083-211-20	874 mL in 1 CANISTER; Type 0: Not a Combination Product	09/07/2020	
3	NDC:90083-211-12	524.4 mL in 1 CANISTER; Type 0: Not a Combination Product	09/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/07/2020	

Labeler - OLCE GROUP KOZMETIK KIMYA GIDA MEDIKAL VE SAGLIK URUNLERI SANAYI VE TICARET LTD STI (595865355)

Registrant - Huzeyfe Islamoglu (595865355)

Establishment

Name	Address	ID/FEI	Business Operations
OLCE GROUP KOZMETIK KIMYA GIDA MEDIKAL VE SAGLIK URUNLERI SANAYI VE TICARET LTD STI		595865355	manufacture(90083-211)

Revised: 9/2020

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