ALCOHOL HAND WIPES- ethyl alcohol cloth Fuson LLC

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 (Ethanol) 70%

Inactive Ingredients

Aqua, glycerin, peg-7 glyceryl cocoate, polysorbate 20, cocamidopropyl betaine, dexpanthenol, citrus limon peel, citric acid, EDTA

Purpose

Antiseptic- Antibacterial hand towelettes

Use

Wipes used on hands and skin to reduce bacteria

Warnings

For external use only, do not ingest. Do not use near eyes. Keep away from flame and 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

Do not use near eyes. Do not ingest. Do not eat, smoke, or drink during use. Do not use on or in open skin wounds. Do not use on children under 2 months of age.

When Using

If ingested, contact a poison control center immediately. If eye contact occurs, flush eyes with water repeatidly.

Stop Use

Stop use if redness, irritation, or rash occurs.

Store in places out of reach of children. Supervise use by children under the age of 6.

Dierctions

Peel back open label slowly. Pull out one wipe at a time and re-seal the packaging tightly. Wet hands thoroughly with product and allow to dry without wiping.

Storage

Keep away from direct sunlight. Store tightly closed in its original packaging and in a cool, dry place. Keep away from food, drinks, and animal feed. Store away from reach of children.

Package Label

120 Count Canister: 78141-211-12200 Count Canister: 78141-211-20500 Count Canister: 78141-211-50

190 MM



Drug Facts Drug Facts (continued) Keep out the reach of children. If swallowed, Active Ingredient Purpose get medical help or contact to Poison Center immediately. Ethyl Alcohol . %70 Antiseptic Directions Use to decrease bacteria on the Thoroughly wipe hands and body as desired. skin. Allow to dry without wiping. Discard wipe in trash receptacle after use. Warnings Do not flush. For extermal use only. Other information store below 110° F Do not use: in the eyes. Inactive Ingredients if you are allergic to any of the ingredients. Aqua, Parfum, C12-15 Pareth-12, Glycerin, Polysorbate 20, Propylene Glycol, Tetrasocium EDTA, When using this product if eye contact Piroctone Olamine, Tocopherly Acetate, Panthenol, occurs, rinse eyes thoroughly with water. Citric Acid, Aloe Barbadensis Leaf Extract, Tocopheryl Asetate (Vitamin E)

В

ALCOHOL HAND WIPES

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

ethyl alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78141-211
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	
DEXPANTHENOL (UNII: 106C93RI7Z)		
PEG-7 GLYCERYL CO CO ATE (UNII: VNX7251543)		
EDETIC ACID (UNII: 9G34HU7RV0)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
WATER (UNII: 059QF0KO0R)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
CO CAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)		
LEMON OIL, DISTILLED (UNII: ET5GD00TRP)		
GLYCERIN (UNII: PDC6A3C0OX)		

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78141-211- 50	2185 mL in 1 CANISTER; Type 0: Not a Combination Product	09/16/2020	
2	NDC:78141-211- 20	874 mL in 1 CANISTER; Type 0: Not a Combination Product	09/16/2020	
3	NDC:78 141-211-12	524.4 mL in 1 CANISTER; Type 0: Not a Combination Product	09/16/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/16/2020	

Labeler - Fuson LLC (113376279)

 $\textbf{Registrant -} \ \, \text{OLCE GROUP KOZMETIK KIMYA GIDA MEDIKAL VE SAGLIK URUNLERI SANAYI VE TICARET LTD STI (595865355)}$

Revised: 8/2020 Fuson LLC