ALCOHOL WIPES- ethyl alcohol cloth
Valley of the Sun Cosmetics 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.

Alcohol Wipes

Active Ingredients

Ethyl Alcohol 80%

Purpose

Antimicrobial

Uses

Alcohol wipes is used to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warning

For external use only. Flammable. Keep away from heat or flame.

Do not use

- In children less than 2 years of age, do not use as baby wipe.
- On open skin wounds

When using this product

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 doctor

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- To dispense, lift cover, remove seal, pull center sheet from roll, twist to a point and feed through dispenser hole in cover. Keep lid closed to prevent moisture loss.
- Open and unfold wipe
- Thoroughly wipe hands, fingers and wrists. Be sure to use the entire wipe. Allow to dry.
- For dirty hands, use first wipe to clean hands, then discard wipe; sanitize with the second wipe.
- Discard after single use

- Supervise children under 2 years of age when using this product to avoid swallowing

Other information

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

Inactive ingredients

Water (aqua), hydrogen peroxide, glycerin, aloe barbadensis (aloe vera) leaf juice

Package Label

80, NDC: 76523-090-80

Label Specs: 4 color
Coating: Laminate
Material: White BOPP Adhesive
Label Size: 12.4" x 5.4"

ALCOHOL WIPES

ethyl alcohol cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76523-090
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
WATER (UNII: 059QF0KO0R)	18.13 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76523-090-80	80 mL in 1 CANISTER; Type 0: Not a Combination Product	11/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/06/2020	

Labeler - Valley of the Sun Cosmetics LLC (176470664)

Registrant - Valley of the Sun Cosmetics LLC (176470664)

Establishment

Name	Address	ID/FEI	Business Operations
Valley of the Sun Cosmetics LLC		176470664	manufacture(76523-090)

Revised: 11/2020 Valley of the Sun Cosmetics LLC