HAND SANITIZER- alcohol gel
Den-Mat Holdings, 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.

Drug Facts

Active Ingredient(s)

Alcohol 80% v/v

Purpose

Antiseptic

Use

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

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

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.

Directions

■ Place enough product on hands to cover all surfaces. Rub hands together until dry.
■ Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients

Package Label - Principal Display Panel

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59883-303
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**
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
MINT (UNII: FV98Z8GITP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59883-303-05	5 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/08/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/08/2021	

Labeler - Den-Mat Holdings, LLC (809857704)

Establishment

Name	Address	ID/FEI	Business Operations
Den-Mat Holdings, LLC		809857704	manufacture(59883-303) , label(59883-303) , pack(59883-303)

Revised: 10/2021 Den-Mat Holdings, LLC