

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**

Alcohol Antiseptic
80% Solution

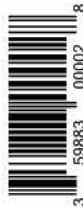
Hand Sanitizer

NDC 59883-303-05

KILLS GERMS ON CONTACT



5 fl. oz. (148 mL)



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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. There may be signs of a serious condition.	
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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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients: glycerin, hydrogen peroxide, water USP, scent	

Manufactured for
Synchrony
777 Long Ridge Road
Stamford, CT 06902

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LOT
EXP

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: 059QF0K00R)	
MINT (UNII: FV98Z 8GITP)	

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