HAND SANITIZER- alcohol liquid 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

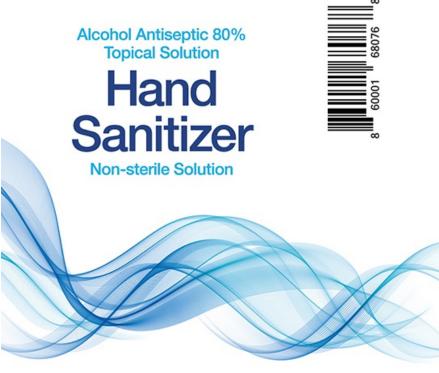
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP



148 mL 237mL

MADE IN THE USA

5 fl. oz. (148 mL)

Drug Facts Active ingredient[s] Alcohol 80% v/v..... Use[s] 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.

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001400285 R:1 05/20SN

Manufactured by
Den-Mat Holdings, LLC
Lompoc, CA 93436

Den-Mat*



LOT **EXP**

Purpose

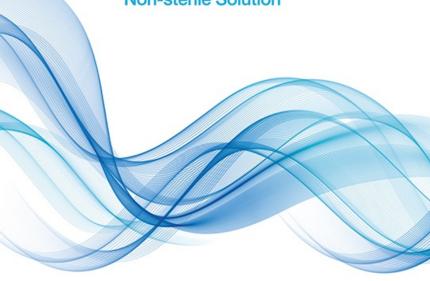
.Antiseptic

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Non-sterile Solution



MADE IN THE USA

8 fl. oz. (237 mL)



Drug Facts

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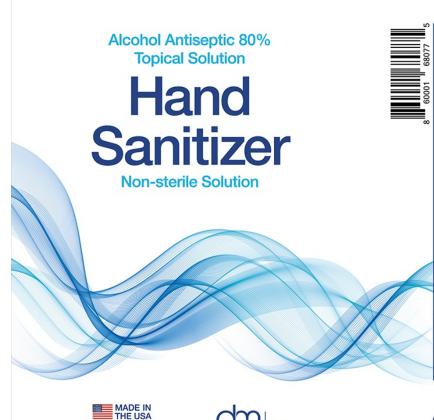
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473mL

16 fl. oz. (473 mL)

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer

Non-sterile Solution



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Active ingredient(s) Alcohol 80% v/v.....

Purpose Antiseptic

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Manufactured by Den-Mat Holdings, LLC Lompoc, CA 93436

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128 fl. oz. (1 gal.) 3.78 L



3.78L

HAND SANITIZER

alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59883-301

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name **Basis of Strength** Strength

ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)	ALCOHOL	80 mL in 100 mL
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Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)		
WATER (UNII: 059QF0KO0R)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-301- 36	106 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/16/2020	04/29/2020
2	NDC:59883-301- 05	148 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/21/2020	
3	NDC:59883-301- 08	237 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/13/2020	
4	NDC:59883-301- 16	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/13/2020	
5	NDC:59883-301- 01	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/12/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/13/2020	

Labeler - Den-Mat Holdings, LLC (809857704)

Establishment			
Name	Address	ID/FEI	Business Operations
Den-Mat Holdings, LLC		809857704	manufacture(59883-301), pack(59883-301), label(59883-301)

Revised: 5/2020 Den-Mat Holdings, LLC