DEWMED ANTIBACTERIAL ADVANCED HAND SANITIZER- benzalkonium chloride gel
DewMed, 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.

DewMed Antibacterial Advanced Hand Gel Sanitizer

DRUG FACTS

Active ingredient[s]

Benzalkonium Chloride 0.1%

Purpose

Antiseptic

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. 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

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).

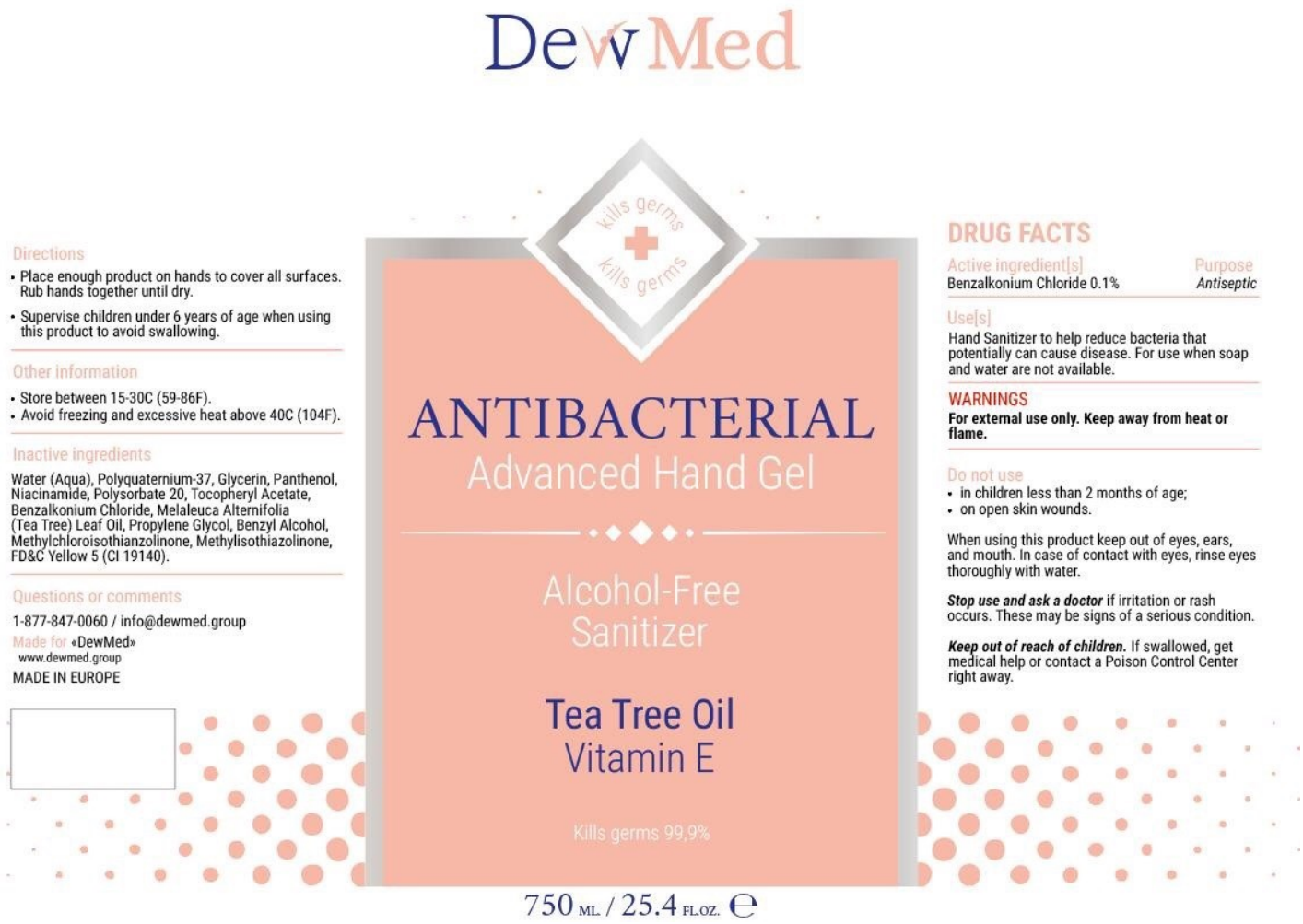
Inactive ingredients

Water (Aqua), Polyquaternium-37, Glycerin, Panthenol, Niacinamide, Polysorbate 20, Tocopheryl Acetate, Benzalkonium Chloride, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Propylene Glycol, Benzyl Alcohol, Methlchloroisothiazolinone, Methylisothiazolinone, FD&C Yellow 5 (CI 19140).

Questions or comments

1-877-847-0060 / info@dewmed.group

Package Labeling:



DEWMED ANTIBACTERIAL ADVANCED HAND SANITIZER

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80065-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
POLYQUATERNIUM-37 (10000 MPA.S) (UNII: 41QWS48DFN)	
GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WV9CM0O67Z)	
NIACINAMIDE (UNII: 25X51I8RD4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TEA TREE OIL (UNII: VIF565UC2G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80065-000-01	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/20/2020	

Labeler - DewMed, LLC (117608946)

Revised: 9/2020 DewMed, LLC