

**DISINFECTING WIPES- hand sanitizer cloth**  
**Tmd 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.*

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**Active Ingredient(s)**

Benzalkonium Chloride 0.184% w/w, Purpose: Antimicrobial  
Didecylidimonium Chloride 0.2% w/w, Purpose: Antimicrobial

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

For hand washing to help reduce bacteria on the skin.

**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.

Stop use and ask a doctor if irritation develops and persists for more than 72 hours.

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

**Directions**

- For use apply thoroughly to hands as desired. Allow to dry without wiping. Discard wipe in trash after use. Do not flush.
- For dispensing flip open dispensing cap and remove entire lid from canister by lifting upward.
- Locate wipe at center of roll, twist corner to a point and thread through small opening in lid.
- DO NOT PUSH FINGER THROUGH OPENING.
- Replace lid and pull sheet up at an angle. Remaining wipes feed automatically.
- When finished, snap lid cap shut to retain moisture.

**Other information**

- Store below 110F(43C)
- May discolor certain fabrics.

**Inactive ingredients**

Ethylhexylglycerin, Glycerin, Fragrance(Parfum), Phenoxyethanol, Propylene Glycol, Purified water

**Package Label - Principal Display Panel**

160 Wipes NDC: 80297-031-01

## DISINFECTING WIPES

hand sanitizer cloth

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80297-031
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.184 g in 100 g
<b>DIDECYLDIMONIUM CHLORIDE</b> (UNII: JXN4009Y9B) (DIDECYLDIMONIUM - UNII:Z7F472XQPA)	DIDECYLDIMONIUM CHLORIDE	0.2 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	0.1 g in 100 g
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	0.1 g in 100 g
<b>WATER</b> (UNII: 059QF0K00R)	98.786 g in 100 g
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	0.5 g in 100 g
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	0.1 g in 100 g
<b>FRAGRANCE LAVENDER &amp; CHIA F-153480</b> (UNII: SXS9C02TZK)	0.03 g in 100 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80297-031-01	1050 g in 1 PAIL; Type 0: Not a Combination Product	08/26/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/26/2020	

**Labeler** - Tmd Holdings, Llc (962827502)

**Registrant** - Tmd Holdings, Llc (962827502)

### Establishment

Name	Address	ID/FEI	Business Operations
Fuan Huh Bio Tech co.,Ltd		415711361	manufacture(80297-031)

### Establishment

Name	Address	ID/FEI	Business Operations
Zhangzhou KangBei Hyginenic Products Co.,Ltd		415797593	manufacture(80297-031)

### Establishment

Name	Address	ID/FEI	Business Operations
ZHEJIANG BINGER NONWOVEN CO., LTD.		529311763	manufacture(80297-031)

Revised: 8/2020

Tmd Holdings, Llc