# PAPA MADE- ethyl alcohol 80% liquid BBIM INC

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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# **Drug Facts**

# **Active ingredient**

Ethyl alcohol 80% v/v

#### **Purpose**

Antimicrobial

#### Uses

Hand sanitizer to help reduce bacteria on the skin.

## Warnings

#### Flammable, keep away from fire or flame

#### For external use only

# When using this product

- do not use in or near the eyes
- in case of contact, rinse eyes thoroughly with water

### Stop use and ask a doctor

if irritation or rash appears and lasts

#### Keep out of reach of children.

If swallowed, get medical help right away or contact a Poison Control Center right away.

#### **Directions**

- spray enough product on your palm to cover hands and rub hands together briskly until dry.
- children under 6 years of age should be supervised when using Papa Made.

#### Other information

- Store below 110<sup>0</sup>C (43<sup>0</sup>F).
- May discolor certain fabrics or surfaces

# **Inactive ingredient**

Water, Isopropyl Alcohol, Glycerol, Aloe vera, Peppermint oil, Tea tree oil

#### **Product Label**



#### PAPA MADE

ethyl alcohol 80% liquid

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:73709-001

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)

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# Inactive Ingredients Ingredient Name Strength GLYCERIN (UNII: PDC6A3C0OX) ALOE VERA LEAF (UNII: ZY81Z83H0X) PEPPERMINT OIL (UNII: AV092KU4JH) TEA TREE OIL (UNII: VIF565UC2G) WATER (UNII: 059QF0KOOR) ISOPROPYL ALCOHOL (UNII: ND2M416302)

Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
1 NDC:73709-001- 60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		03/18/2020					

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC MONOGRAPH NOT FINAL	part333A	03/18/2020						

# **Labeler - BBIM INC (056844846)**

Establishment								
Name	Address	ID/FEI	Business Operations					
BBIM INC		056844846	manufacture(73709-001)					

Revised: 3/2020 BBIM INC