

**DELMA- hand sanitizer gel**  
**Delma Global, 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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**Delma Hand Sanitizer**

**Active Ingredient(s)**

Alcohol 70% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**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.

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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**

Avoid freezing and excessive heat above 40C (104F)

May discolor certain fabrics or surfaces

**Inactive ingredients**

aloe barbadensis extract, aminomethyl propanol, carbomer, caprylyl glycol, glycerin, isopropyl alcohol, isopropyl myristate, propylene glycol, tocopheryl acetate, water, fragrance

## Package Label - Principal Display Panel

# 4106D

8oz label

52×84 mm

Front sticker  
Transparent material

Back sticker  
Paper material



236 mL NDC: 80208-111-03

## DELMA

hand sanitizer gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80208-111
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80208-111-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	
2	NDC:80208-111-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	
3	NDC:80208-111-03	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	
4	NDC:80208-111-04	591 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	
5	NDC:80208-111-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/27/2020	

**Labeler** - Delma Global, Inc (131110987)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ningbo Pasco United Industry Co., Ltd.		529035953	manufacture(80208-111)

Revised: 8/2020

Delma Global, Inc