### 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

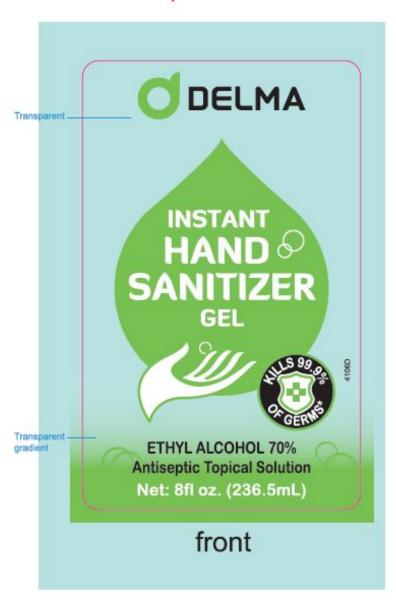
Package Label - Principal Display Panel

4106D

8oz label 52×84 mm

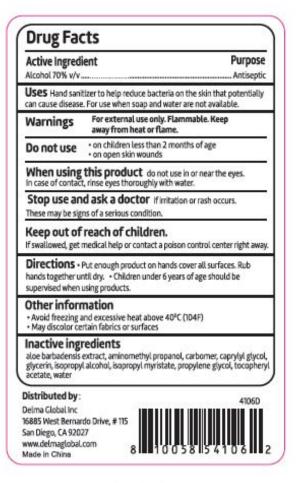
# Front sticker

Transparent material



# Back sticker

## Paper material



back

236 mL NDC: 80208-111-03

#### **DELMA**

hand sanitizer gel

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80208-111

Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL (DIVII: 3K9958V90M) ALCOHOL 70 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
GLYCERIN (UNII: PDC6A3C0OX)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
WATER (UNII: 059QF0KO0R)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	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