

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.

Delma Hand Sanitizer with Fragrance

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 a 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 the 40C (104 F)

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

Package Label - Principal Display Panel

4107D

8oz label

52x84 mm

Front sticker
Transparent material

Back sticker
Paper material



back

236 mL NDC: 80208-112-03

DELMA

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80208-112
Route of Administration	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 HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80208-112-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	
2	NDC:80208-112-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	
3	NDC:80208-112-03	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2020	
4	NDC:80208-112-04	591 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(80208-112)

Revised: 1/2022

Delma Global, Inc