

DELAMO HAND SANITIZING GEL- alcohol gel
Guard Products 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.

Del Amo Hand Sanitizing Gel

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% 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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, aloe vera, vitamin e acetate, carbomer, purified water USP

[undefined] 3.785 L NDC: 77668-004-01

<p>DELAMO HAND SANITIZING GEL is a hand sanitizer including >70% v/v Ethyl Alcohol & carefully selected emollients such as Vitamin E & Aloe Vera Moisturizers.</p> <p>HAZARD STATEMENTS May cause eye irritation. May be harmful if swallowed.</p> <p>PRECAUTIONARY STATEMENTS Forms smooth, Slippery surface on floors, posing a slip and fall accident risk.</p> <p>STORAGE AND HANDLING Store in a dry and well-ventilated place. Store in a closed container. Keep cool. Use / follow appropriate industrial practice.</p> <p>SPILL RESPONSE Wipe away or for larger spills, dike area in front / around spill and contain for appropriate disposal.</p> <p>SHIPPING DESCRIPTION ORM-D, Consumer Commodity, in accordance with 49CFR (HMR 181), 173.150 and 173.156. In QTY > 8 US GAL/PKG, UN1170, Ethanol Solution, PG II</p> <p style="text-align: center;">ORM-D</p>	 <div style="background-color: red; color: white; padding: 10px; border-radius: 15px; font-weight: bold; font-size: 1.2em;">HAND SANITIZING GEL</div> <p>>70% ETHYL ALCOHOL LIGHTLY SCENTED & INFUSED WITH VITAMIN E & ALOE VERA</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>✓ PARABEN FREE</p> <p>✓ SULFATE FREE</p> <p>✓ GLUTEN FREE</p> </div>  </div> <div style="background-color: red; color: white; padding: 5px; border-radius: 10px; font-weight: bold; font-size: 0.8em;">NO WATER REQUIRED • WORKS WITH MOST AUTOMATED DESPENSING SYSTEMS</div> <div style="background-color: red; color: white; padding: 5px; border-radius: 10px; font-weight: bold; font-size: 0.8em;">NET CONTENTS • 3785 mL (1 US GALLON - 128 US FL OZ)</div>	<p>DRUG FACTS</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">ACTIVE INGREDIENT</th> <th style="text-align: left;">PURPOSE</th> </tr> </thead> <tbody> <tr> <td>Ethyl Alcohol >70% v/v</td> <td>Antimicrobial</td> </tr> </tbody> </table> <p>USES For handwashing to decrease bacteria on skin when water is not available.</p> <p>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 or persists. Keep out of reach of children. If swallowed, get medical help or contact Poison Control immediately.</p> <p>DIRECTIONS</p> <ul style="list-style-type: none"> • Apply enough product to your palm to completely wet / cover both hands. • Rub hands together briskly for up to 30 seconds until dry, covering all surfaces. <p>INACTIVE INGREDIENTS Purified Water (Aua) Glycerith-26 PEG-40 Hydrogenated Castor Oil Carbomer Vitamin E Acetate Aloe Vera Fragrance</p> <p>OTHER INFORMATION</p> <ul style="list-style-type: none"> • Store below 110°F (43°C) • May discolor certain fabrics or surfaces <p style="text-align: center;">DELAMO MANUFACTURING INC.</p> <p style="font-size: 0.8em;">©2020 Delamo Manufacturing Inc. ALL RIGHTS RESERVED. Transportation / Spill 24 - Hour Emergency Phone Number: 1-800-424-9300</p>	ACTIVE INGREDIENT	PURPOSE	Ethyl Alcohol >70% v/v	Antimicrobial
ACTIVE INGREDIENT	PURPOSE					
Ethyl Alcohol >70% v/v	Antimicrobial					
<p>Consult SDS for Full Statements of Health, Safety, & Environmental Information</p> <p style="text-align: center;">DISTRIBUTED BY: Delamo Manufacturing Inc. 1-888-711-8011</p>						
 <p style="font-size: 0.8em;">8 92034 96100 2</p>						

DELAMO HAND SANITIZING GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77668-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	70 L in 100 L
Inactive Ingredients				
Ingredient Name				Strength
GLYCERIN (UNII: PDC6A3C0OX)				1.42 L in 100 L
WATER (UNII: 059QF0KO0R)				27.61 L in 100 L
PEG-40 HYDROGENATED LANOLIN (UNII: 959P5CXE48)				0.3 L in 100 L
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)				0.01 L in 100 L
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				0.5 L in 100 L
ALOE VERA FLOWER (UNII: 575DY8C1ER)				0.01 L in 100 L
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)				0.15 L in 100 L
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77668-004-01	3.785 L in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/20/2020		

Labeler - Guard Products Inc (116830285)

Registrant - Custom Blenders (057505117)

Establishment

Name	Address	ID/FEI	Business Operations
custom blenders		057505117	manufacture(77668-004)

Revised: 10/2020

Guard Products Inc