

DERMO REAL- ethyl alcohol gel
Saflosa Industria Real, S.A. de C.V.

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.

Dermo Real® SKIN CARE Moisturising Hand Sanitizer

Drug Facts

Active ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Uses

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.

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

Inactive ingredients

Carbomer, fragrance, glycerin, triethanolamine, water.

Kills 99.9% of Most Illness Causing Germs

with Glycerin

@Real Skin Care Mx

Manufactured by:

SAFLOSA INDUSTRIA REAL, S.A. DE C.V.
Calle Poza Rica No. 9 Col. Arbol Grande C.P. 33739
Cd. Camargo, Chihuahua, México.

Tels.: (648) 462-1417

www.saflosa.com

www.realskincare.com.mx

Packaging

30 mL package



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Care Mx
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@RealSkin
www.realskincare.co
www.saflosa.com

960 mL package



Drug Facts	
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8 87667 00035 8	

1 Gallon package



Drug Facts	
Active ingredient Ethyl Alcohol 70% v/v.....	Purpose Antiseptic
Uses Hand sanitizer to help reduce bacteria on the skin could cause disease. For use when soap and water are not available.	
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Do not use • In children less than 2 months of age • on open skin wounds.	
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DERMO REAL

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78009-110
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
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78009-110-06	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2020	
2	NDC:78009-110-02	960 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/24/2020	
3	NDC:78009-110-03	960 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2020	
4	NDC:78009-110-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/24/2020	

Labeler - Saflosa Industria Real, S.A. de C.V. (821354313)

Establishment

Name	Address	ID/FEI	Business Operations
Saflosa Industria Real, S.A. de C.V.		821354313	manufacture(78009-110)

Revised: 5/2020

Saflosa Industria Real, S.A. de C.V.