DERMO REAL- ethyl alcohol gel Saflos a 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



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.

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Care Mx

When usung this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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🔘 @Real Skin (

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.

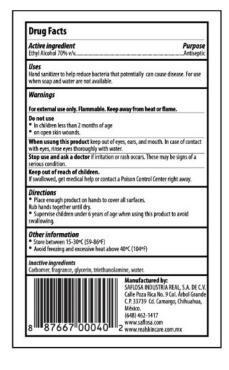
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Manufactured by: SAFLOSA INDUSTRIA REAL, S.A. DE C.V. 33739 Camargo, Chihuahua, México. Tels.: (648)462-1417

960 mL package







Drug Facts	
Active ingredient	Purpose





1 Gallon package



Active ingredient Purpose Ethyl Alcohol 70% v/v. Hand sanitizer to help reduce bacteria on the skin could cause disease. For use when soap and water are not available. 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 usung 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. 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. Manufactured by: SAFLOSA INDUSTRIA REAL, S.A. DE C.V. Galle Poza Rica No. 9 Col. Árbol Grande C.P. 33739 Cd. Camargo, Chihuahua, México. (648) 462-1417 www.saflosa.com www.realskincare.com.mx

Drug Facts

DERMO REAL

ethyl alcohol gel

	Product Information			
	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78009-110
l	Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
TROLAMINE (UNII: 9O3K93S3TK)			
WATER (UNII: 059QF0KO0R)			

P	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.