HAND SANITIZER- alcohol gel REALITY PHARMA, 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.

HAND SANITIZER GEL

DOSAGE

Place enough product on hands to cover all surfaces. Rub hands together until dry.

INACTIVE INGREDIENTS

Inactive ingredients Water (Aqua), Glycerin, Carbomer, Triethanolamine

DIRECTIONS

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

PURPOSE

PURPOSE ANTIMICROBIAL

WARNINGS

Warnings

For external use only. Flammable. Keep away from heat or flame

ACTIVE INGREDIENT

Active ingredient. Ethyl Alcohol 70% v/v

STOP USE ASK A DOCTOR

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

PRINCIPAL DISPLAY



Hand Sanitizer

ANTIMICROBIAL FORMULA

4.25 FL OZ / 125 mL

Drug Facts

Active Ingredient

Purpose

Ethyl Alchohol 70% v/v......Antimicrobial

Use Hand sanitizer to help reduce bacteria on skin.

Warnings:

Flammable. Keep away from fire of flame.

For external use only.

When using this product do no use in or near the eyes In case of contact, flush thoroughly with water. Stop use and ask a doctor it irritation or rash appears and lasts. Keep out of reach of children. It swallowed, ge medical help or contact a Poison Control Center inmediately.

Directions: Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using.

Other Information: Store below 110°F (43°C)

Inactive Ingredients: Water(Aqua), Glycerin, Carbomer,

Triethanolamine

MADE IN MEXICO

Distributed by SBL Brands, LLC



Las Vegas, NV 89119 MedicallyMinded.us



Alcohol Antiseptic 70%

Topical Solution

Hand Sanitizer Gel Non-sterile Solution

250 mL (8.45 fl. oz.)

kctive ingredient. thyl Alcohol 70% v/v	PurposeAntmicrobial
Use[s] land Sanitizer to help reduce bacteria on skin.	
Warnings For external use only. Flammable. Keep away from hea	t or flame
When using this product keep out of eyes, ears, and mo	uth. In case of contact with eyes, rinse eyes thoroughly with water.
Stop use and ask a doctor if irritation or rash occurs. The	ese 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. F 	
 Supervise children under 6 years of age when using th 	is product to avoid swallowing.
Other information Store below 110°F (43°C)	

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SBL Brands, LLC

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MADE IN MEXICO

NET CONTENTS

250 mL

(8.45 fl. oz.)

Alcohol Antiseptic 70%

Topical Solution

Hand Sanitizer Gel Non-sterile Solution

1000 mL (33.8 fl. oz.)

Drug Facts Active ingredient. Ethyl Alcohol 70% v/v... Purpose

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

For external use only. Flammable. Keep away from heat or flame

• 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 below 110°F (43°C)

Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients Water (Aqua), Glycerin, Carbomer, Triethanolamine

Datos del Producto

Ingrediente Activo

Propósito

Desinfectante para manos empleado para reducir la cantidad de bacterias en la piel que pueden causar enfermedades. Utilice este producto cuando no haya jabón y agua disponibles.

Advertencias Sólo para uso externo. Inflamable. Mantenga este producto alejado del fuego o calor.

No Usar

• en niños menores a 2 meses de edad

· en heridas expuestas

Al utilizar este producto, evitar el contacto con los ojos, oídos y boca. En caso de caso de contacto con los ojos, enjuagar completamente con agua.

Dejar de usar el producto y consultar a un médico si aparece y persiste una irritación o erupción cutánea. Estas pueden ser señales de una condición médica seria.

Mantener fuera del alcance de los niños. En caso de ingestión, acudir de inmediato a un médico o

ponerse en contacto con un Centro de Control de Sustancias Tóxicas

- Poner suficiente cantidad de producto en la palma de la mano para cubrir las manos completamente. Frotarse las manos vigorosamente hasta que se sequen.
- El empleo de este producto por niños menores a 6 años deberá ser supervisado

Información Adicional

- Almancenar a temperaturas inferiores a 110°F (43°C)
- Evitar congelar el producto o exponerio a temperaturas superiores a 40C (104F)

Ingredientes Inactivos Agua, Glicerina, carbomero, trietanolamina,

NET CONTENTS

1000 mL

(33.8 fl. oz.)

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MADE IN MEXICO

Alcohol Antiseptic 70%

Topical Solution

Hand Sanitizer Gel Non-sterile Solution

500 mL (16.9 fl. oz.)

Drug Facts Active ingredient. Purpose Ethyl Alcohol 70% v/v. 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

Distributed by SBL Brands, LLC

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MADE IN MEXICO

HAND SANITIZER

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 below 110°F (43°C)

Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients Water (Aqua), Glycerin, Carbomer, Triethanolamine

Datos del Producto

Ingrediente Activo Propósito pholetilico 70% v/v

Desinfectante para manos empleado para reducir la cantidad de bacterias en la piel que pueden causar enfermedades. Utilice este producto cuando no haya jabón y agua disponible:

Sólo para uso externo. Inflamable. Mantenga este producto alejado del fuego o calor.

No Usar

en niños menores a 2 meses de edad

en heridas expuestas

Al utilizar este producto, evitar el contacto con los ojos, oídos y boca. En caso de caso de contacto con los ojos, enjuagar completamente con agua.

Dejar de usar el producto y consultar a un médico si aparece y persiste una irritación o erupción cutánea. Estas pueden ser señales de una condición médica seria.

Mantener fuera del alcance de los niños. En caso de ingestión, acudir de inmediato a un médico o ponerse en contacto con un Centro de Control de Sustancias Tóxicas

Modo de Uso

 Poner suficiente cantidad de producto en la palma de la mano para cubrir las manos completamente. Frotarse las manos vigorosamente hasta que se sequen.

El empleo de este producto por niños menores a 6 años deberá ser supervisado

Información Adicional

Almancenar a temperaturas inferiores a 110°F (43°C)

Evitar congelar el producto o exponerio a temperaturas superiores a 40C (104F)

Ingredientes Inactivos Agua, Glicerina, carbomero, trietanolamina,

NET CONTENTS

500 mL

(16.9 fl. oz.)

alcohol gel

Product Information

Route of Administration

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78525-2000

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients						
Ingredient Name	Strength					
TRIETHANO LAMINE CAPRO YL GLUTAMATE (UNII: 0 F2FO57253)	$0.002\ mL$ in $1\ mL$					
CARBOMER 940 (UNII: 4Q93RCW27E)	$0.002\ mL$ in $1\ mL$					
WATER (UNII: 059QF0KO0R)	$0.2585\ mL\ in\ 1\ mL$					
GLYCERIN (UNII: PDC6A3C0OX)	$0.0375 \; mL \; in \; 1 \; mL$					

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78525-2000-2	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
2	NDC:78525-2000-3	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
3	NDC:78525-2000-4	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
4	NDC:78525-2000-5	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph not finalpart333A06/02/2020

Labeler - REALITY PHARMA, S.A. DE C.V. (951578646)

Registrant - REALITY PHARMA, S.A. DE C.V. (951578646)

Establishment						
Name	Address	ID/FEI	Business Operations			
REALITY PHARMA, S.A. DE C.V.		951578646	manufacture(78525-2000)			

Revised: 6/2020 REALITY PHARMA, S.A. DE C.V.