CALIDAD PREMIUM FRESH ANTIBACTERIAL- alcohol gel Distribuidora de Sistemas Didacticos , 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.

Calidad Premium Fresh Gel Antibacterial

DRUG FACTS

Active ingredient[s]

Alcohol 70% v/v

Purpose

Antiseptic

INACTIVE INGREDIENTS

Distilled Water, Glycerin, Carbomer, Triethanolamine, EDTA, Without fragrance.

USE[S]

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

Questions or Comments:

52 (55) 3686-0416 / 52 (55) 4741-7431 direccion@distribuidoradesistemas.com.mx

Package Labeling:

ADVERTENCIAS: Solo para uso externo. INFLAMABLE. Mantener aleiado del calor o llamas.

NÓ USAR • EN NIÑOS MENORES DE 2 MESES DE EDAD • EN HERIDAS DE PIEL ABIERTA

Evite el contacto con los ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien los ojos con agua. Suspenda su uso y consulte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una afección grave. Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.

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.

INFORMACIÓN DEL MEDICAMENTO

Ingrediente activo Propósito Alcohol 70% v/v Antiséptico

DRUG FACTS

INGREDIENTES INACTIVOS

Agua destilada, glicerina, carbómero, Trietanolamina, EDTA, sin fragancia.

INACTIVE INGREDIENTS

Distilled Water, Glycerin, Carbomer, Triethanolamine, EDTA, without fragrance.





USOS: Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua y jabón disponibles.

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

INSTRUCCIONES: Coloque suficiente producto en las manos para cubrir todas las superficies. Frotar las manos juntas hasta que se sequen. Supervise a los niños menores de 6 años cuando use este producto para evitar que se lo traquen.

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.

OTRA INFORMACIÓN:

Almacenar entre 15-30°C (59-86F) Evite la congelación y el calor excesivo por encima de 40°C (104F)

OTHER INFORMATION

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



HECHO EN MÉXICO por/ MADE IN MÉXICO by DISTRIBUIDORA DE SISTEMAS DIDÁCTICOS S.A. DE C.V. Cedros 40, Santa Martha Acatitla Norte, Álcaldía Iztapalapa, CDMX, México.

Contacto/Questions or Comments: 52 (55) 3686-0416 / 52 (55) 4741-7431

direccion@distribuidoradesistemas.com.mx

CALIDAD PREMIUM FRESH ANTIBACTERIAL

alcohol gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:79728-000 Route of Administration 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	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
TROLAMINE (UNII: 903K93S3TK)		
EDETIC ACID (UNII: 9G34HU7RV0)		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:79728-000-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/29/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/29/2020	
final			

Labeler - Distribuidora de Sistemas Didacticos , S.A. de C.V. (589811236)

Revised: 9/2022 Distribuidora de Sistemas Didacticos , S.A. de C.V.