

ANTIBACTERIAL HAND SANITIZING- alcohol gel

Grupo Rodeh 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.

ANTIBACTERIAL HAND SANITIZING GEL

Drug Facts

Active Ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Use

- Antibacterial hand sanitizing gel to help killing bacteria and germs as antiseptic on the skin. For use when soap and water are not available.

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product

keep out of eyes and mouth. In case of contact with eyes, immediately rinse eyes thoroughly with water

Stop use and ask doctor

If irritation, rash or allergy 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

- Apply. Put enough product on hands to cover all surfaces. Rub hands together, until hands feel dry. This should take around 20 seconds. recommended for repeated use.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients

- Deionized Water. Carbomer. Panthenol. D-Limonene. DMDM Hydantoin. Disodium EDTA Triethanolamine.

Package Labeling



**ANTIBACTERIAL
HAND SANITIZING GEL**

KILLS 99.9% OF BACTERIA

- NO STICKY FEELING
- EASY ABSORPTION
- FAST DISTRIBUTION
- FRAGRANCE-FREE
- RINSE-FREE

MOISTURIZED,
PROTECTED
AND SOFT

WITH
PANTHENOL



SKIN

CAUTION



**FLAMMABLE
PRODUCT**

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ETHYL ALCOHOL 70%

EXTERNAL USE ONLY

e 8.45 fl. oz. (250 ml)

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US-PM000002

ANTIBACTERIAL HAND SANITIZING

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77710-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PANTHENOL (UNII: WV9CM0O67Z)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77710-001-00	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/07/2020	

Labeler - Grupo Rodeh S.A. de C.V. (951576890)

Revised: 5/2020

Grupo Rodeh S.A. de C.V.