DUGEL- sanitizer gel DUTRIEC S.A.

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.

DUTRIEC SA-DUGEL Sanitizer Pouch

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce the 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.

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Directions

• Put enough product in your palm to cover your hands and rub your hands together briskly until is 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)

Inactive ingredients

carbomer interpolymer, citrus, Tocopherol, glycerin, trolamine, purified water

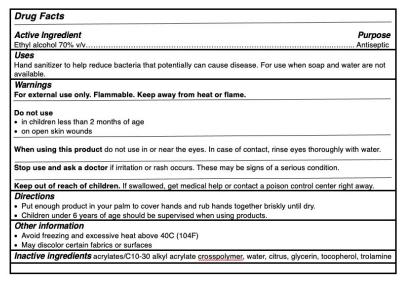
Package Label - Principal Display Panel



HAND SANITIZER

ETHYL ALCOHOL 70%

Net: 2mL / 0.07 fl. Oz.



Manufactured for & Distributed by :

Mid Atlantic Medical Services LLC Address: 3801 PGA Blvd. Ste. 600, Palm Beach Gardens, FL 33410

Made in Paraguay

2 mL NDC: 80549-111-12

DUGEL

sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80549-111
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	
GLYCERIN (UNII: PDC6A3C0OX)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		
TOCOPHEROL (UNII: ROZB2556P8)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		
ORANGE OIL (UNII: AKN3KSD11B)		

	Packaging				
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:80549-111-	2.5 mL in 1 POUCH; Type 0: Not a Combination Product	09/17/2020		
:	NDC:80549-111- 12	2 mL in 1 POUCH; Type 0: Not a Combination Product	02/03/2021		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/17/2020	

Labeler - DUTRIEC S.A. (955048863)

Establishment				
Name	Address	ID/FEI	Business Operations	
DUTRIEC S.A.		955048863	manufacture(80549-111)	

Revised: 12/2021 DUTRIEC S.A.