

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.

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

- 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

DuGel

Practical and Easy

HAND SANITIZER

ETHYL ALCOHOL 70%

Net: 2mL / 0.07 fl. Oz.

Drug Facts	
Active Ingredient	Purpose
Ethyl alcohol 70% v/v.....	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	
<ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds 	
When using this product do not use in or near the eyes. In case of contact, 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	
<ul style="list-style-type: none"> • 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 products. 	
Other information	
<ul style="list-style-type: none"> • Avoid freezing and excessive heat above 40C (104F) • May discolor certain fabrics or surfaces 	
Inactive ingredients acrylates/C10-30 alkyl acrylate <u>crosspolymer</u> , water, citrus, glycerin, tocopherol, trolamine	

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: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ORANGE OIL (UNII: AKN3KSD11B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80549-111-11	2.5 mL in 1 POUCH; Type 0: Not a Combination Product	09/17/2020	
2	NDC:80549-111-12	2 mL in 1 POUCH; Type 0: Not a Combination Product	02/03/2021	

Marketing Information

Marketing Category	Application Number or Monograph 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.