

TAPATIAS- hand sanitizer gel gel

TAPATIAS

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.

TAPATIAS-SOLIS SANITIZER GEL

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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.

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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)

Inactive ingredients

glycerin, hydrogen peroxide, purified water, ethylcellulose, aloe vera

Package Label - Principal Display Panel

BIODEGRADABLE PRODUCT
Keeps hands protected and soft

GEL Hand Sanitizer

WITH 80% ALCOHOL

With *aloe vera*

KILLS 99.9% GERMS

Antiseptic Hand Rub
Non-sterile Solution

Alcohol Antiseptic 80%
Topical Solution
KILLS MOST GERMS
6.76 FL OZ (200 mL)

During the sanitary public health emergency, Tapatias® offers a product that complies with the FDA guidelines for alcohol-based hand sanitizers in accordance with 21 CFR 10.115(g)(2) code, published on March 27, 2020.

Active ingredient (s)	Purpose
Ethyl alcohol 80% v/v	Antiseptic

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Inactive ingredients
Purified water USP, glycerin, H. ethylcellulose, aloe vera, hydrogen peroxide.

Imported and Distributed by:
6656 Rosecrans Ave SPC 17
Paramount CA 90723-3169
Tel (323) 403-93-79

0 85000 1 72732 4

200 mL NDC: 77751-123-01

TAPATIAS

hand sanitizer gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77751-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name			Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77751-123-01	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020	
2	NDC:77751-123-02	450 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020	
3	NDC:77751-123-03	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	05/12/2020	

Labeler - TAPATIAS (092606000)

Establishment			
Name	Address	ID/FEI	Business Operations
Solis piedras Lizbette Berenice		951577575	manufacture(77751-123)

Revised: 5/2020

TAPATIAS