

SHINE AND CLEAN HAND SANITIZER- alcohol gel

Maquiladora Miniara 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.

Shine and Clean Hand Sanitizer Gel

Drug facts

Active ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Uses

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

Warnings

For external use only: hands

Flammable. Keep away from heat and flame.

When using this product

- keep out of eyes. In case of contact with eyes, flush thoroughly with water.
- avoid contact with broken skin
- do not inhale or ingest

Stop use and ask a doctor if

- irritation or redness develops
- condition persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- for children under 6, use only under adult supervision
- not recommender for infants

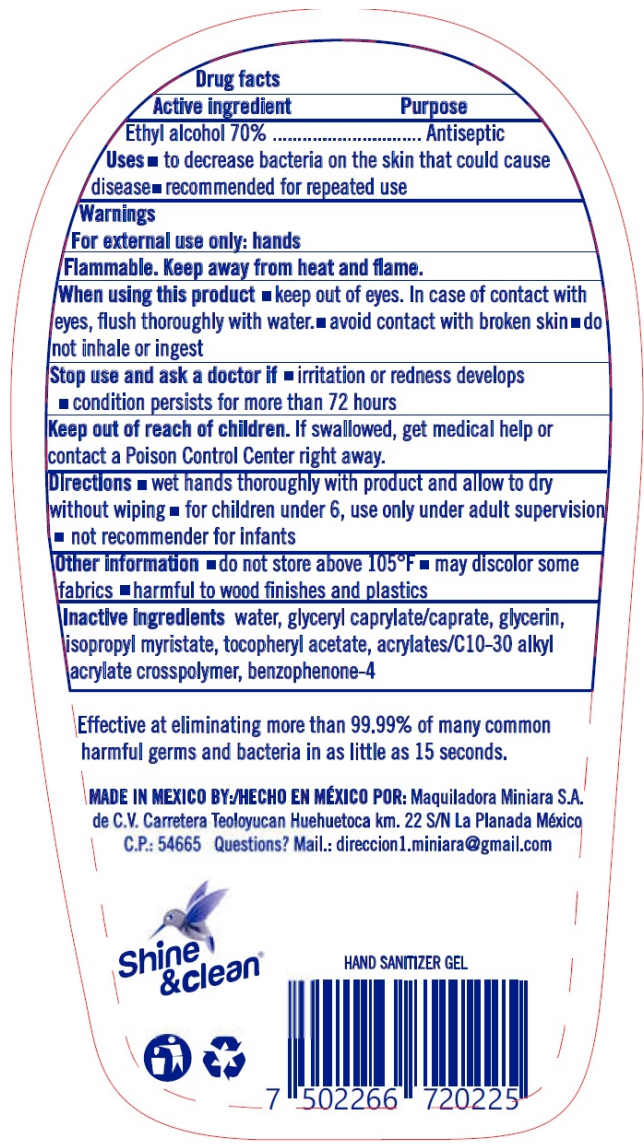
Other information

- do not store above 105°F
- may discolor some fabrics
- harmful to wood finishes and plastics

Inactive ingredients

water, glyceryl caprylate/caprate, glycerin, isopropyl myristate, tocopheryl acetate, acrylates/C10-30 alkyl acrylate crosspolymer, benzophenone-4

Package Labeling:



SHINE AND CLEAN HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76753-001
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)				
GLYCERYL MONOCAPRYLOCAPRATE (UNII: G7515SW10N)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)				
SULISOBENZONE (UNII: 1W6L629B4K)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76753-001-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	04/10/2020		

Labeler - Maquiladora Miniara S.A de C.V. (812802434)

Establishment				
Name	Address	ID/FEI	Business Operations	
Maquiladora Miniara S.A de C.V.		812802434	manufacture(76753-001)	

Revised: 4/2020

Maquiladora Miniara S.A de C.V.