GUARDEX HAND SANITIZER ANTISEPTIC GEL- isopropyl alcohol 75% gel
Guardex Labs, Inc.

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.

Guardex Hand Sanitizer Antiseptic Gel

Active Ingredient

Isopropyl Alcohol 75%

Purpose

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

On 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.

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

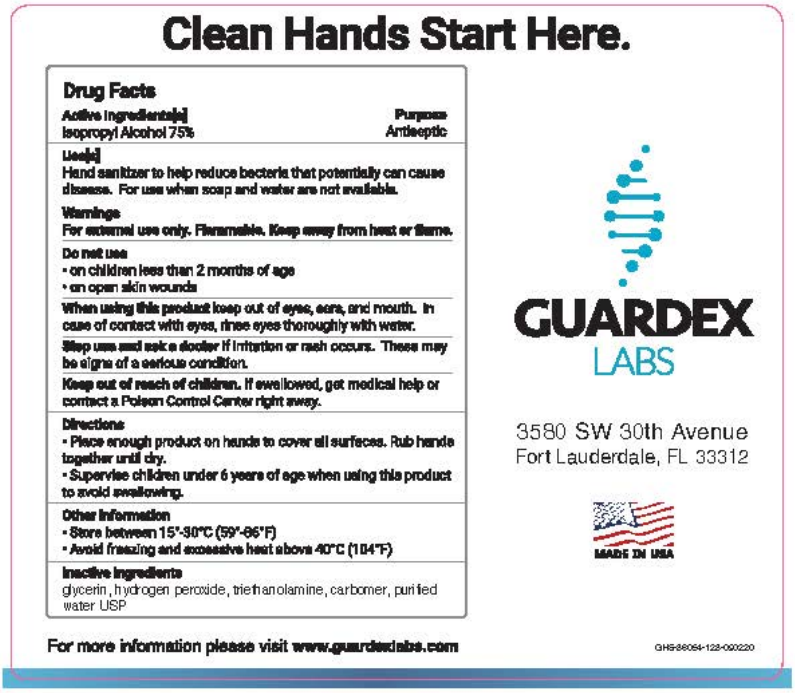
-Store between 15-30C (59-86F).

-Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

glycerin, hydrogen peroxide, Triethanolamine, carbomer, purified water USP

Guardex Hand Sanitizer gel



GUARDEX HAND SANITIZER ANTISEPTIC GEL

isopropyl alcohol 75% gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80307-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	2839 mL in 3785 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TRIETHANOLAMINE TRISTEARATE (UNII: HOM72YRP1F)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	

WATER (UNII: 059QF0KO0R)	
(3-BROMOPROPYL)BENZENE (UNII: 6VX623QN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80307-001-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2020	

Labeler - Guardex Labs, Inc. (117630183)

Registrant - Guardex Labs, Inc. (117630183)

Revised: 9/2020 Guardex Labs, Inc.