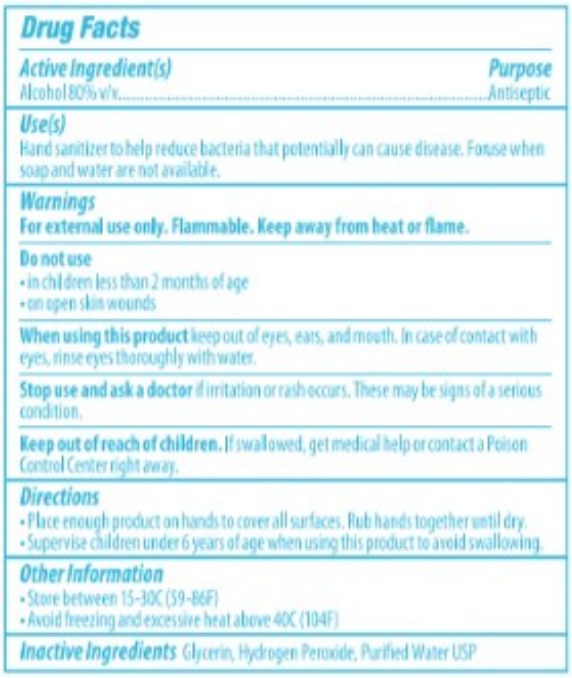
AMERICAN DENTAL- touch hand sanitizer solution
Nutrix International, LLC.

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.

Active Ingredient[s]

Alcohol 80%v/v

Purpose



Antiseptic

Use[s]

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

When using this product keep out of eyes, ears, mouth. In case of contact with eyes, rinse 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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients

Glycerin, Hydrogen Peroxide, Purified water USP

Package

Front Label

AMERICAN DENTAL
touch hand sanitizer solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73333-473
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8334 g in 473 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	0.14845 g in 473 g
GLYCERIN (UNII: PDC6A3C0OX)	0.0145 g in 473 g
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.00365 g in 473 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73333-473-01	473 g in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/21/2020	

Labeler - Nutrix International, LLC. (117341868)

Establishment

Name	Address	ID/FEI	Business Operations
Nutrix International, LLC.		117341868	manufacture(73333-473) , pack(73333-473) , label(73333-473)

Revised: 5/2020 Nutrix International, LLC.