EQUINOX- alcohol liquid
ATA FOOD LTD LIABILITY CO

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 Ingredients

Alcohol 70% v/v.

Purpose

Antiseptic

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.

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^{o}C (59-86^{o}F).
- Avoid freezing and excessive heat above 40^{o}C (104^{o}F).

Inactive ingredients

Deionized water, glycerin, hydrogen peroxide.

Package Label - Principal Display Panel

EQUINOX

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79229-001
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)	
WATER (UNII: 059QF0KO0R)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79229-001-01	100 mL in 1 DRUM; Type 0: Not a Combination Product	06/01/2020	
2	NDC:79229-001-02	200 mL in 1 DRUM; Type 0: Not a Combination Product	06/01/2020	
3	NDC:79229-001-03	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
4	NDC:79229-001-04	1000 mL in 1 DRUM; Type 0: Not a Combination Product	06/01/2020	
5	NDC:79229-001-05	5000 mL in 1 DRUM; Type 0: Not a Combination Product	06/01/2020	
6	NDC:79229-001-06	10000 mL in 1 DRUM; Type 0: Not a Combination Product	06/01/2020	
7	NDC:79229-001-07	20000 mL in 1 DRUM; Type 0: Not a Combination Product	06/01/2020	
8	NDC:79229-001-08	30000 mL in 1 DRUM; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - ATA FOOD LTD LIABILITY CO (074004291)

Revised: 6/2020 ATA FOOD LTD LIABILITY CO