

HY-GN QUALITY HAND AND SURFACE SANITIZERS- alcohol gel
TRIFECTA TELECOM HOLDINGS LLC dba HY-GN 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

Ethyl Alcohol 80% v/v

Purpose

Antiseptic

Uses

Use on hands and surfaces as a disinfecting agents to kill viruses and bacteria

Warnings

For external use only. Flammable. Keep away from heat or flame.

H226 Flammable liquid and vapour.

H319 Causes serious eye irritation.

DO NOT USE on children under the age of 2 months old or open skin wounds

WHEN USING THIS PRODUCT Keep out of eyes, ears and mouth. In case of contact with eyes, rinse thoroughly with water

STOP USE AND ASK A DOCTOR If irritation or rash occur. This may be a sign of a serious condition.

KEEP OUT OF REACH OF CHILDREN If swallowed, seek medical help or contact 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 (59-85F)

Avoid Freezing and excessive heat above 40C (104F)

Inactive ingredients

Deionized Water, Glycerin, Hydrogen Peroxide

Package Label - Principal Display Panel

Product label

Drug Facts

Active Ingredient

Ethyl Alcohol 80% v/v.....Antiseptic

Purpose

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 - 85F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Manufactured and packaged in a federally licensed facility in the USA
Distributed by CAPNA Systems, 15148 Bledsoe St, Sylmar, CA 91342
www.capnasanitizer.com



HY-GN QUALITY HAND AND SURFACE SANITIZERS

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76972-001
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
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76972-001-01	72 in 1 CASE	04/01/2020	
1		30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination		

1		Product		
2	NDC:76972-001-02	48 in 1 CASE	04/01/2020	
2		59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:76972-001-03	48 in 1 CASE	04/01/2020	
3		89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:76972-001-04	48 in 1 CASE	04/01/2020	
4		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:76972-001-05	24 in 1 CASE	04/01/2020	
5		236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:76972-001-06	30 in 1 CASE	04/01/2020	
6		375 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:76972-001-07	24 in 1 CASE	04/01/2020	
7		473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:76972-001-08	12 in 1 CASE	04/01/2020	
8		946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
9	NDC:76972-001-09	4 in 1 CASE	04/01/2020	
9		3785 mL in 1 JUG; Type 0: Not a Combination Product		
10	NDC:76972-001-10	18927 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/01/2020	
11	NDC:76972-001-11	18927 mL in 1 DRUM; Type 0: Not a Combination Product	04/01/2020	
12	NDC:76972-001-12	208198 mL in 1 DRUM; Type 0: Not a Combination Product	04/01/2020	
13	NDC:76972-001-13	1022060 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - TRIFECTA TELECOM HOLDINGS LLC dba HY-GN LLC (117505673)

Establishment

Name	Address	ID/FEI	Business Operations
California Spirits Company		080351585	manufacture(76972-001)