

CRYSTAL RIDGE HAND SANITIZER- hand sanitizer liquid

Crystal Ridge Distillery

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.

Hand sanitizer

Alcohol 80 % v/v

Antiseptic

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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

- In children less than 2 months of age
- On open skin wounds

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 40 C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Hand Sanitizer

1. 750 mL size bottle NDC 74207-010-07



2. Back Label

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% v/v.....	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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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. 	
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3.78 L plastic jug, NDC 7207-010-40

Hand Sanitizer



18.9L bucket label with handwritten batch number included on bucket:

CRYSTAL RIDGE HAND SANITIZER

hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74207-010
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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	155 L in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74207-010-07	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2020	
2	NDC:74207-010-40	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2020	
3	NDC:74207-010-80	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/28/2020	

Labeler - Crystal Ridge Distillery (029126883)**Establishment**

Name	Address	ID/FEI	Business Operations
Crystal Ridge Distillery		029126883	manufacture(74207-010)

Revised: 3/2020

Crystal Ridge Distillery