CROOKED CREEK DISTILLERY INC HAND SANITIZER- alcohol liquid
Crooked Creek Distillery 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.

Front Label50ml

CROOKED CREEK DSITLLERY

HAND SANITIZER

Alcohol Antiseptic 80% - Topical Solution

Hand Sanitizer - Non-sterile Solution - [50mL]

Produced to World Health Organization (WHO) formulas and to production and labeling requirements as established and approved by the Federal Drug Administration (FDA)

FDA Label ID – 74072

DUNS 096927542

Alcohol Antiseptic 80% - Topical Solution

Hand Sanitizer - Non-sterile Solution - [50mL]

Produced to World Health Organization (WHO) formulas and to production and labeling requirements as established and approved by the Federal Drug Administration (FDA)

FDA Label ID – 74072 **DUNS 096927542**

Back Label50ml

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

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- 30C (59- 86F)
Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

FDA encourages consumers and health care professionals to report adverse events experienced with the use of hand sanitizers to FDA's MedWatch Adverse Event Reporting program:

Complete and submit the report online; or
Download and complete the form, then submit it via fax at 1-800-FDA-0178.

Batch ID: Date Produced:

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

- 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- 30C (59- 86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

FDA encourages consumers and health care professionals to report adverse events experienced with the use of hand sanitizers to FDA's MedWatch Adverse Event Reporting program:

- *Complete and submit the report online; or*
- *Download and complete the form, then submit it via fax at 1-800-FDA-0178.*

Batch ID: Date Produced:

Purpose

Purpose

Antiseptic

Active Ingredients

Active ingredient[s]
Alcohol 80% v/v

Warnings

Warnings

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

Do Not Use

Do not use

in children less than 2 months of age
on open skin wounds

Stop use and ask a doctor

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Inactive Ingredients

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Questions and Concerns

FDA encourages consumers and health care professionals to report adverse events experienced with the use of hand sanitizers to FDA's MedWatch Adverse Event Reporting program:

Complete and submit the report online; or
Download and complete the form, then submit it via fax at 1-800-FDA-0178.

Batch Tracking and Production Date

Batch ID:

Date Produced:

Usage

Use[s]

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

When Using

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Indications and Usage

Use[s]

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.

Directions

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.

Storage

Other information

Store between 15- 30C (59- 86F)
Avoid freezing and excessive heat above 40C (104F)

Dosage and Administration

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)

CROOKED CREEK DISTILLERY INC HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74072-100
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)	4.17 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74072-100-07	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/25/2020	

Labeler - Crooked Creek Distillery Inc (096927542)

Registrant - Crooked Creek Distillery Inc (096927542)

Establishment

Name	Address	ID/FEI	Business Operations
Crooked Creek Distillery Inc		096927542	manufacture(74072-100)

Revised: 3/2020 Crooked Creek Distillery Inc