

SIMPLE SANITIZER- isopropyl alcohol gel
SIMPLE SANITIZER- isopropyl alcohol liquid
Compass Coffee 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.

Formula II

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry. The hand sanitizer is manufactured consistent with World Health Organization (WHO) formulation II.

Active Ingredient(s)

Isopropyl Alcohol 70% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial

Use

Hand Sanitizer to help reduce bacteria on the skin.

Warnings

Flammable. Keep away from fire or flame. This product is intended for external use only.

When using this product, do not use in or near the eyes. In case of contact, rinse thoroughly with water.

Discontinue Use

Discontinue use if irritation or redness develops. If condition persists for more than 72 hours consult a doctor.

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

Directions

- Place enough product in your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

glycerin, hydrogen peroxide, purified water USP

Inactive ingredients

Purified Water (Aqua), Hydrogen Peroxide, Glycerol, Aloe, Fragrance

Questions or Comments?

Reach out to hello@compasscoffee.com 24/7

Package Label - Principal Display Panel

473ml NDC: 75333-001-02



**SIMPLE
SANITIZER**

16FL OZ (473mL)

It's a little strange for a coffee company to be making hand sanitizer. But we've always believed in building our city, so when we saw a problem — the world was out of hand sanitizer — we decided to fix it.

We've repurposed our bottling line to bring you Simple Sanitizer. We hope it keeps you clean and healthy in the days ahead.

Michael Hamner



**COMPASS
COFFEE®**



**UNION
KITCHEN**



236ml NDC: 75333-001-01



**SIMPLE
SANITIZER**

8FL OZ (236mL)



**COMPASS
COFFEE®**



**UNION
KITCHEN**





236ml NDC: 75333-002-01





**SIMPLE
SANITIZER**

8 FL OZ (236mL)



**COMPASS
COFFEE®**



**UNION
KITCHEN**





473ml NDC: 75333-002-02



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16FL OZ (473mL)

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COFFEE®**



SIMPLE SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75333-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.4 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.725 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.725 mL in 100 mL
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.1 mL in 100 mL
2,4,5-T-TROLAMINE (UNII: 9007L1DAXM)	0.2 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.3 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75333-002-01	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/08/2020	
2	NDC:75333-002-02	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/08/2020	

SIMPLE SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75333-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.725 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.725 mL in 100 mL
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75333-001-01	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75333-001-02	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Compass Coffee Llc (079255636)

Registrant - Compass Coffee Llc (079255636)

Establishment

Name	Address	ID/FEI	Business Operations
Union Kitchen Llc		079235761	manufacture(75333-001, 75333-002) , pack(75333-001, 75333-002) , label(75333-001, 75333-002)

Revised: 5/2020

Compass Coffee Llc