

SATORI HAND SANITIZER- alcohol liquid
US Continental

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(s)

Ethanol 80% v/v.

Purpose

Antimicrobial

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. Recommended for repeated use.

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.

Stop use and ask a doctor if irritation or rash appears or lasts.

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.

Other information

- Store below 21C (70F); Flash point 25C (77F)
- may discolour certain fabrics or surfaces

Inactive ingredients

glycerin, hydrogen peroxide, water

Package Label - Principal Display Panel

Please read this proof carefully and indicate any corrections or errors found.

APPROVAL FOR ATTACHED JOB

U.S. Continental is not responsible for any errors or omissions not indicated at this time. Alterations will be charged extra according to time involved in making necessary changes. Please check that all areas have been reviewed and approved, sign and return.

All text has been proof-read. All bar codes have been scanned for accuracy. Any appropriate warnings are correct.

Customer Signature		Date	
Colors:	Printed Size:	Material:	
<input checked="" type="checkbox"/> BLACK <input checked="" type="checkbox"/> PMS 485C	6.325 x 5"	GLOSSY LAMINATE	<input checked="" type="checkbox"/> Laminated <input type="checkbox"/> UV Coating
	Comments:	Bottle Base:	Bottle Lid:
	<input type="checkbox"/> Square <input checked="" type="checkbox"/> Round		

SATORI[®]
HAND
SANITIZER

8 FLUID OUNCES, FOR EXTERNAL USE ONLY
FLAMMABLE
KEEP AWAY FROM FIRE, FLAME OR ANY HEAT SOURCE
USE CAUTION IF LEFT IN AN ENCLOSED VEHICLE
Recyclable Packaging if Label Removed

DRUG FACTS	
ACTIVE INGREDIENT	PURPOSE
Ethanol 80% w/v	Antimicrobial
USES Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.	
⚠ WARNINGS Flammable. Keep away from fire, flame or any heat source. When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
DIRECTIONS • Place enough product in your palm to thoroughly cover your hands. • Rub hands together briskly until dry.	
OTHER INFORMATION • Store below 21C (70F); Flash point 25C (77F) • May discolor certain fabrics or surfaces.	
INACTIVE INGREDIENTS Water, Glycerol, Hydrogen Peroxide.	

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Questions or Comments?
Call 1.810.776.5844
Monday thru Friday
8am-5pm.



Formulation consistent with World Health Organization (WHO) guidelines:
http://who.int/gpsc/5may/Guide_to_Local_Production.pdf

The statements made regarding this product have not been evaluated by the Food and Drug Administration. The efficacy of this product has not been confirmed by FDA approved research. This product is not intended to diagnose, treat, cure or prevent any disease. All information presented here is not meant as a substitute for or alternative to information from health care practitioners. Please consult your health care professional about potential interactions or other possible complications before using any product, especially an alcohol based product. Do not use this product if you are allergic or have adverse reactions to any of the ingredients listed herein. Alcohol is a known carcinogen. Women who are pregnant should take extra precautions when using this product or avoid using this product altogether. The Federal Food, Drug and Cosmetic Act requires this notice.

LBL405

SATORI HAND SANITIZER
alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76533-004
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76533-004-01	236 mL in 1 BOTTLE; 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 - US Continental (793141912)**Establishment**

Name	Address	ID/FEI	Business Operations
US Continental		793141912	manufacture(76533-004)

Revised: 7/2020

US Continental