

**HAND SANITIZER- alcohol gel
STUDIO 320**

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.

Just Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 73%.

Purpose

Antiseptic

Use

Reduces bacteria on skin. Use when soap and water are not available.

Warnings

Flammable. Keep away from flame.

Purpose

For external use only. If swallowed, seek medical help or contact a Poison Control Center immediately. Keep out of reach of children.

Do Not Use

Do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if rash appears.

Directions

Bend where indicated on package to dispense. Squeeze contents into hands and rub together until dry.

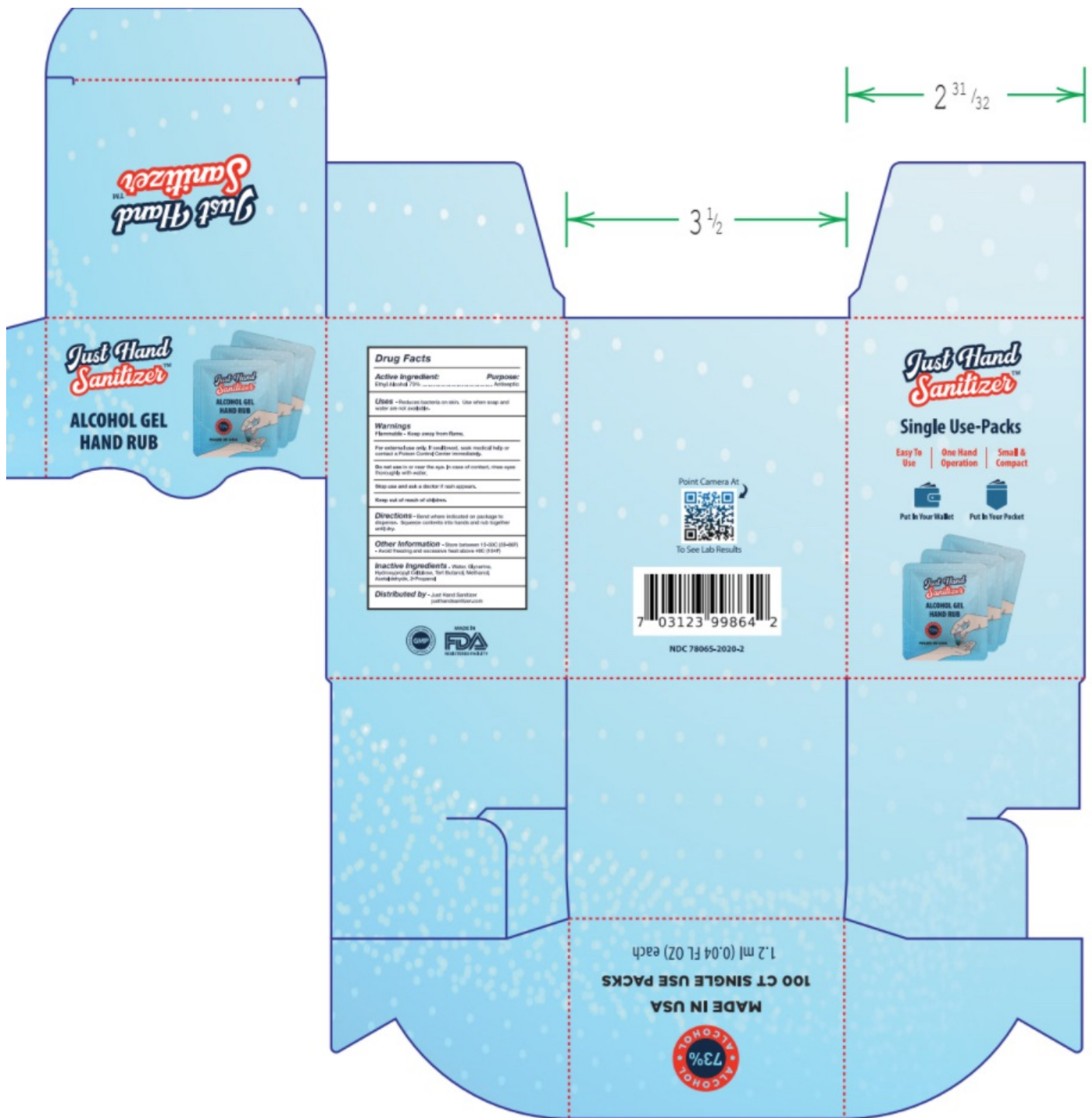
Other information

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

Inactive ingredients

Water, Glycerin, Hydroxypropyl Cellulose

Package Label - Principal Display Panel



Just Hand Sanitizer box

Drug Facts

Active Ingredient

Ethyl Alcohol 73% v/v.....

Purpose

Antiseptic

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

Warnings

Flammable. Keep away from fire or flame.

For external use only

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 right away.

Directions • Put enough products in your palm to cover hands and rub hands together briskly until dry

- Children under 6 years of age should be supervised when using when using this product

Other Information • Store between 15-30C (59-86F)

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

Inactive Ingredients Water, Glycerin, Hydroxypropyl Cellulose

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78065-2020	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	0.876 mL in 1.2 mL	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			0.03 mL in 1.2 mL	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			0.013 mL in 1.2 mL	
WATER (UNII: 059QF0KO0R)			0.277 mL in 1.2 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78065-2020-2	100 in 1 BOX	06/01/2020	
1		1.2 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:78065-2020-1	1.2 mL in 1 POUCH; Type 0: Not a Combination Product	06/01/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/21/2020		

Labeler - STUDIO 320 (066376564)

Registrant - Open Book Extracts (117239295)

Establishment

Name	Address	ID/FEI	Business Operations
Open Book Extracts		117239295	manufacture(78065-2020)

Revised: 6/2020

STUDIO 320