

SPARKLE- isopropyl alcohol gel
NBA General Corporation 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.

Active Ingredient(s)

Isopropyl Alcohol 65% 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

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

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 occurs.

Directions

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

Other information

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

Inactive ingredients

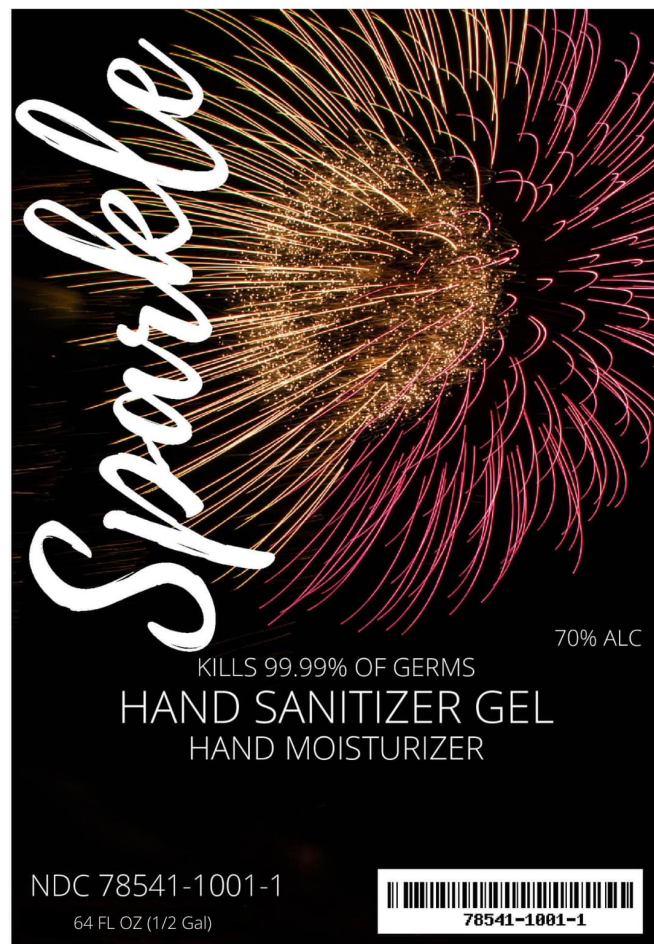
glycerin, purified water, carbomer, triethanolamine, fragrance

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

Antiseptic, Hand Sanitizer

Package Label - Principal Display Panel

Drug Facts	
Active ingredient Isopropyl Alcohol 70%, 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	
For external use only, flammable, keep away from heat or flame	
Do not use	
with children less than 2 months of age, on open skin wounds	
When using	
<ul style="list-style-type: none"> - keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. - 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 occurs	
Directions	
Place enough product on hands to cover all surfaces. Rub hands together until dry.	
Other information	
Store between 15-30°C (59-86° F) Avoid freezing and excessive heat above 40°C (104° F)	
Inactive ingredients	
Carbomer, fragrance, glycerin, purified water, triethanolamine	
Questions or comments?	
Call toll free (877) 517- 3367 Visit our website www.sparklesanitizer.com	



64 fl oz, 1/2 gal NDC: 78541-1001-1

SPARKLE

isopropyl alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:78541-1001

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)

Basis of Strength

ISOPROPYL ALCOHOL

Strength

70 mL in 100 mL

Inactive Ingredients

Ingredient Name

CARBOMER 940 (UNII: 4Q93RCW27E)

Strength

2.5 mL in 100 mL

Ingredient Name

TROLAMINE (UNII: 9O3K93S3TK)

Strength

0.95 mL in 100 mL

Ingredient Name

GLYCERIN (UNII: PDC6A3C0OX)

Strength

1.45 mL in 100 mL

WATER (UNII: 059QF0KO0R)			24.6 mL in 100 mL	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)			0.5 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78541-1001-2	1893 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/30/2020	

Labeler - NBA General Corporation INC (043707019)

Establishment			
Name	Address	ID/FEI	Business Operations
NBA General Corporation INC		043707019	manufacture(78541-1001)

Revised: 9/2020

NBA General Corporation INC