

F(X)L SKIN CARE HAND SANITIZER- alcohol gel
G.S. COSMECEUTICAL USA, 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.

f(x)l™ Skin Care Hand Sanitizer

Drug Facts

Active Ingredient

Ethanol 70% v/v

Purpose

Antiseptic

Use

Hand sanitizer to reduce the germs on skin

Warnings

For external use only.

Flammable, keep away from fire or flame.

When using this product

- keep out of eyes. In case of contact with eyes, rinse eyes thoroughly with water.
- do not inhale or ingest.

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

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

Directions

- wet hands thoroughly with product and allow to dry without wiping
- for children under 6, use only under adult supervision

Other Information

- do not store above 104° F (40° C)
- may discolor certain fabrics or surfaces

Inactive Ingredients

Aminomethyl Propanol, Aqua (Water), Carbomer, Glycerin

Distributed by:

G.S. Cosmeceutical USA, Inc.

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

f(x)l™

skincare

Hand Sanitizer

Kills 99.9% of Germs

Unscented Gel

16 FL OZ / 473 mL

<p>f(x)l™ skincare</p> <p>Hand Sanitizer</p> <p>Kills 99.9% of Germs</p> <p><u>Unscented Gel</u></p> <p>16 FL OZ / 473 mL</p>	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active Ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Ethanol 70% v/v</td><td>Antiseptic</td></tr></tbody></table> <p>Use: Hand sanitizer to reduce the germs on skin</p> <p>Warnings: For external use only.</p> <p>Flammable, keep away from fire or flame.</p> <p>When using this product: ■ keep out of eyes. In case of contact with eyes, rinse eyes thoroughly with water. ■ do not inhale or ingest.</p> <p>Stop use and ask a doctor if irritation or rash occurs and lasts.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions: ■ wet hands thoroughly with product and allow to dry without wiping ■ for children under 6, use only under adult supervision</p> <p>Other information: ■ do not store above 104° F (40° C) ■ may discolor certain fabrics or surfaces</p> <p>Inactive Ingredients: Aminomethyl Propanol, Aqua (Water), Carbomer, Glycerin</p> <p>Distributed by: G.S. Cosmeceutical USA, Inc. Made in USA.</p>  <p>8 60000 23171 8</p>	Active Ingredient	Purpose	Ethanol 70% v/v	Antiseptic
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F(X)L SKIN CARE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65113-1001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Glycerin (UNII: PDC6A3C0OX)	
Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked) (UNII: 59TL3WG5CO)	
Semuloparin (UNII: 4QW4AN84NQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65113-1001-1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
2	NDC:65113-1001-2	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
3	NDC:65113-1001-3	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
4	NDC:65113-1001-4	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	05/15/2020	

Labeler - G.S. COSMECEUTICAL USA, INC. (017014734)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(65113-1001)

Revised: 1/2022

G.S. COSMECEUTICAL USA, INC.