

ELEGANT MAXIMUM FRESH HAND SANITIZER- isopropyl alcohol gel
EPOCH Cosmetics and Toiletries Industries 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.

Active Ingredient(s)

Isopropyl Alcohol 70%

Purpose

Antimicrobial

Use

Hand Sanitizer to help reduce bacteria on the skin

Warnings

For external use only. Flammable. Keep away from heat or flame

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

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

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

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry
- Children under 6 years of age be supervised when using ELEGANT.

Other information

- Store between 110F (43C)
- May discolor certain fabrics

Inactive ingredients

Water (Aqua), Isopropyl Alcohol, Glycol, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Acrylates/ C10-30 Alkyl Acrylate Copolymer, Aminomethyl Propanol, Fragrance (Parfum).

Package Label - Principal Display Panel

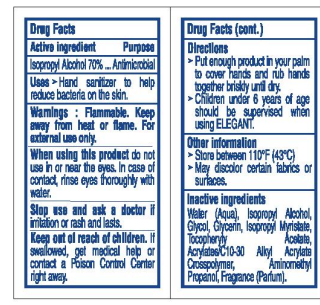
SPECIFICATIONS	
Date:	June 10, 2020
Title:	ELEGANT
Type:	Hand Sanitizer Gel
Can base:	<input checked="" type="checkbox"/> Sticker: <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Transparent <input type="checkbox"/> Board: <input type="checkbox"/> Normal <input type="checkbox"/> Metallized <input type="checkbox"/> Others:
Color(s):	CYMK
Size:	74 X 136.5 MM
Finished:	<input checked="" type="checkbox"/> Glossy <input type="checkbox"/> Semi-Matte <input type="checkbox"/> Matte <input type="checkbox"/> Other(s):



SPECIFICATIONS	
Date:	Jun 11, 2020
Title:	ELEGANT
Type:	Hand Sanitizer
Can base:	<input checked="" type="checkbox"/> Sticker: <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Transparent <input type="checkbox"/> Board: <input type="checkbox"/> Normal <input type="checkbox"/> Metallized <input type="checkbox"/> Others:
Color(s):	CYMK
Size:	57 X 76 MM
Finished:	<input type="checkbox"/> Glossy <input type="checkbox"/> Semi-Matte <input type="checkbox"/> Matte <input type="checkbox"/> Other(s):

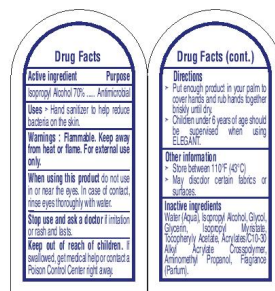


SPECIFICATIONS	
Date:	June 11, 2020
Title:	Elegant
Type:	Hand Sanitizer
Can base:	<input checked="" type="checkbox"/> Sticker: <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Transparent <input type="checkbox"/> Board: <input type="checkbox"/> Normal <input type="checkbox"/> Metallized <input type="checkbox"/> Others:
Color(s):	CYMK
Size:	44 X 82 MM
Finished:	<input type="checkbox"/> Glossy <input type="checkbox"/> Semi-Matte <input type="checkbox"/> Matte <input type="checkbox"/> Other(s):



EPOCH
COSMETICS & TOILETRIES
DESIGN & GRAPHICS DEPARTMENT

SPECIFICATIONS	
Date:	June 8, 2020
Title:	ELEGANT
Type:	Hand Sanitizer
Can base:	<input checked="" type="checkbox"/> Sticker: <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Transparent <input type="checkbox"/> Board: <input type="checkbox"/> Normal <input type="checkbox"/> Metalized <input type="checkbox"/> Others:
Color(s):	CYMK
Size:	34 x 70 MM
Finished:	<input type="checkbox"/> Glossy <input type="checkbox"/> Semi-Matte <input type="checkbox"/> Matte <input type="checkbox"/> Other(s):



EPOCH
COSMETICS & TOILETRIES
DESIGN & GRAPHICS DEPARTMENT

SPECIFICATIONS	
Date:	June 8, 2020
Title:	ELEGANT
Type:	Hand Sanitizer
Can base:	<input checked="" type="checkbox"/> Sticker: <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Transparent <input type="checkbox"/> Board: <input type="checkbox"/> Normal <input type="checkbox"/> Metalized <input type="checkbox"/> Others:
Color(s):	CYMK
Size:	34 x 70 MM
Finished:	<input type="checkbox"/> Glossy <input type="checkbox"/> Semi-Matte <input type="checkbox"/> Matte <input type="checkbox"/> Other(s):



000 ml NDC: 00000-000-00

ELEGANT MAXIMUM FRESH HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80309-001
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)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80309-001-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80309-001-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:80309-001-03	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:80309-001-04	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
5	NDC:80309-001-06	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
6	NDC:80309-001-07	60 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 - EPOCH Cosmetics and Toiletries Industries LLC (561196517)

Establishment			
Name	Address	ID/FEI	Business Operations
EPOCH Cosmetics and Toiletries Industries LLC		561196517	manufacture(80309-001)

Revised: 8/2020

EPOCH Cosmetics and Toiletries Industries LLC