

ONE STEP- hand sanitizer gel
BELVEDERE INTERNATIONAL 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.

ONE STEP HAND SANITIZER

Active Ingredient

Ethyl Alcohol 70%v/vAntiseptic

Uses

Hand sanitizer to help reduce bacteria on the skin

Warnings

Flammable. Keep away from source of heat, fire or flame.

For external use only.

Stop use and ask a doctor if irritation or redness develops and lasts.

When using this product avoid contact with eyes. if contact occurs, rinse thoroughly with water.

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 and rub hands together until dry.

Children under 6 years should be supervised when using this product.

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, Ext. Violet 2 (CI 60730), Fragrance (Parfum), Polysorbate 20, Tetrahydroxypropyl Ethylenediamine, Water (Aqua).

Store at a temperature below 110 F (43 °C)

may discolor certain fabrics or surfaces.

Children under 6 years should be supervised when using this product

 **One Step**

HAND SANITIZER

with ALOE

KILLS 99.9% OF GERMS WITHOUT WATER

60 mL e 2 U.S. fl. oz.
NDC 60742-400-01

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic

Uses Hand sanitizer to help reduce bacteria on the skin.

Warnings
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Directions
 ■ place enough product in your palm to thoroughly cover your hands and rub hands together until dry.
 ■ children under 6 years should be supervised when using this product.

Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Copolymer, Aloe Barbatenis Leaf Extract, Ext. Violet 2 (CI 60730), Fragrance (Parfum), Polysorbate 20, Tetrahydropropyl Ethylenediamine or Aminomethyl Propanol, Water (Aqua).

Other information
 ■ store at a temperature below 110°F (43°C).
 ■ may discolor certain fabrics or surfaces.

Questions or comments? 1-800-668-1118

MANUFACTURED BY: BELVEDERE INTERNATIONAL INC., MISSISSAUGA, ONTARIO, L5R 3G3
 BELVEDERE INTERNATIONAL INC. MISSISSAUGA, ONTARIO, L5R 3G3
 MADE IN CANADA

 0 65743 24075 5

 **One Step**

FAMILY SIZE

HAND SANITIZER

with ALOE

KILLS 99.9% OF GERMS WITHOUT WATER

473 mL e 16 U.S. fl. oz.
NDC 60742-400-03

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic

Uses Hand sanitizer to help reduce bacteria on the skin.

Warnings
Flammable. Keep away from source of heat, fire or flame.
 For external use only.
 When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
 Stop use and ask a doctor if irritation or redness develops and lasts.
 Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.


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Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Copolymer, Aloe Barbatenis Leaf Extract, Ext. Violet 2 (CI 60730), Fragrance (Parfum), Polysorbate 20, Tetrahydropropyl Ethylenediamine or Aminomethyl Propanol, Water (Aqua).

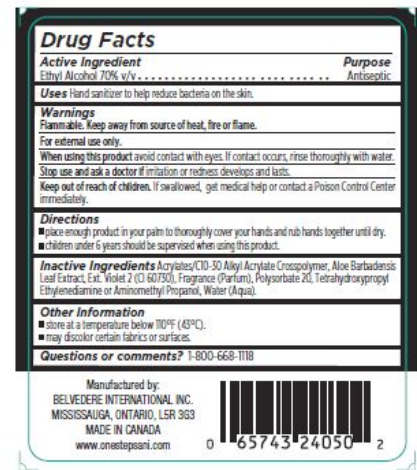
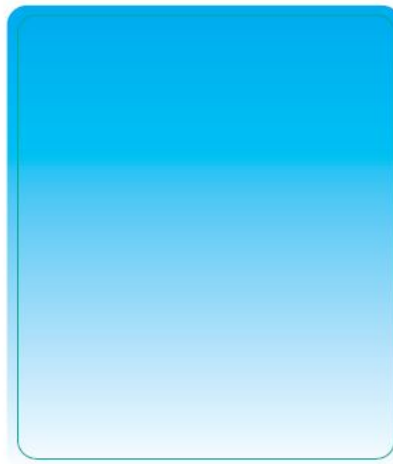
Other information
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 ■ may discolor certain fabrics or surfaces.

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Manufactured by:
 BELVEDERE INTERNATIONAL INC.
 MISSISSAUGA, ONTARIO, L5R 3G3
 MADE IN CANADA
 www.onestepsani.com

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5.250"



ONE STEP

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60742-400
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
EDETOL (UNII: Q4R969U9FR)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60742-400-03	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/03/2020	
2	NDC:60742-400-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2020	
3	NDC:60742-400-04	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/03/2020	

Labeler - BELVEDERE INTERNATIONAL INC. (247836356)

Registrant - BELVEDERE INTERNATIONAL INC. (247836356)

Establishment

Name	Address	ID/FEI	Business Operations
BELVEDERE INTERNATIONAL INC.		247836356	manufacture(60742-400)

Revised: 2/2020

BELVEDERE INTERNATIONAL INC.