

BIOSS INSTANT HAND SANITIZER- alcohol liquid GROUPE DISSAN, LE

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel and Drug Facts



BiOSS

INSTANT HAND SANITIZER Lemon scent

- Made with natural ingredients
- Kills bacteria when cleaning hands



DRUG FACTS	
Active Ingredient	Purpose
Ethyl alcohol 75%	Antiseptic skin cleanser
USES	
Effective in killing bacteria (harmful) to provide an antiseptic cleaning. For personal hand hygiene to prevent the spread of bacteria.	
WARNINGS For external use only.	
Flammable. Keep away from heat and flame.	
When using this product avoid contact with eyes. In case of contact, immediately flush eyes with water.	
Stop use and consult a health care practitioner if irritation or redness develops.	
Keep out of reach of children	
Do not use on children/infants under 2 years old (except on the advice of a doctor).	
DIRECTION	
For occasional use for personal household use. Rub well for at least 30 seconds. Let dry.	
OTHER INFORMATION	
Store at 20°C (68° to 77°F) cool place.	
INACTIVE INGREDIENTS	
Acrylates/c10-30, Alkyl Acrylate Copolymer, Triethanolamine, Citrus Aurantium Bergamia (Bergamot) Fruit Extract, Lemon oil.	
QUESTIONS? 1-866-796-8481	

Bloss product code: 001
 Product name: **BiOSS Hand Sanitizer 500 ml - Lemon**
 Format: 500 ml
 Case UPC: 80871920000014
 Unit UPC: 871920000018
 Unit/case: 24

Case dimension
 Length: 45,6 cm (17,9 in)
 Width: 31 cm (12,2 in)
 Height: 21,6 cm (8,5 in)

Case per pallet: 42
 Tie and tier: 6 cases/row and 7 rows/pallet
 Pallets per load: 26

Case weight: 14 kg (30,87 lbs)
 Pallet weight: 630 kg (1388,91 lbs)
 Shelf life: **Unlimited**
 Country of origin: **Canada**

Distributed by: Espace Beton, Blainville, QC CAN J7C 2P3
info@bloss.ca



500 mL NDC: 78306-101-12

BIOSS INSTANT HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78306-101
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
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
CITRUS BERGAMIA WHOLE (UNII: 14YV5375VD)	
LEMON OIL (UNII: I9GRO824LL)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78306-101-12	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	



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Bloss product code: 001
 Product name: **BiOSS Hand Sanitizer 500 ml - Lemon**
 Format: 500 ml
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved drug other	03/30/2020
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Labeler - GROUPE DISSAN, LE (248967291)

Registrant - GROUPE DISSAN, LE (248967291)

Establishment

Name	Address	ID/FEI	Business Operations
GROUPE DISSAN, LE		248967291	label(78306-101) , manufacture(78306-101)

Revised: 5/2020

GROUPE DISSAN, LE