

BABY BUM HAND SANITIZER- alcohol liquid
Sun Bum 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.

Baby Bum Hand Sanitizer

Drug Facts

Active ingredient

Ethyl alcohol 62%

Purpose

Antiseptic

Uses

- to help reduce bacteria on the skin
- recommended for repeated use

Warnings

For external use only

Flammable keep away from fire or flame

When using this product

do not use in or near the eyes. In case of eye contact, rinse thoroughly with water.

Stop use and ask a doctor if

irritation or rash appears and lasts. Condition persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- spray enough product in your palms to thoroughly cover your hands
- rub hands together briskly until dry
- children under 6 years of age should be supervised when using this product

Other information

- do not store above 104° F/40°C
- may discolor some fabrics or surfaces

Inactive ingredients

water, fragrance, glycerin, aloe barbadensis leaf juice, cucumis sativus (cucumber) fruit extract, musa sapientum (banana) fruit extract, hedychium coronarium root extract, gardenia taitensis flower extract, cocos nucifera (coconut) oil, sea salt, ethylhexylglycerin

Questions?

1-877-978-6286

Package Labeling:

Antibacterial Hand Sanitizer

Kills 99.9% of Germs
Plant-Based Ingredients
Vegan • Hypoallergenic
Pediatrician Tested

Green Coconut

2 FL OZ / 59 mL

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BABY BUM HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-614
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C00X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CUCUMBER (UNII: YY7C30VXJT)	
BANANA (UNII: 4AJZ4765R9)	
HEDYCHIUM CORONARIUM ROOT (UNII: 92A6N0IQN9)	
GARDENIA TAITENSIS FLOWER (UNII: T0OCU8201Y)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SEA SALT (UNII: 87GE52P74G)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-614-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/01/2020	

Labeler - Sun Bum LLC (028642574)**Establishment**

Name	Address	ID/FEI	Business Operations
Formulated Solutions, LLC		143266687	manufacture(69039-614)

Revised: 2/2022

Sun Bum LLC