

HAND SANITIZER- hand sanitizer gel
Xiamen Afgamarine Biotechnology Co., Ltd.

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.

Store below 110°F (43°C). May discolor certain fabrics or surfaces.

WATER

GLYCERIN

PEG-40 Hydrogenated Castor Oil

CARBOMER

TRIETHANOLAMINE

Phenoxyethanol

Parfum (Fragrance)

Aminomethy propanol

- Place enough product on your palm to thoroughly cover your hands.
- Rub hands together biskly until dry.
- Children under 6 years of age should be supevised when using this product.

Alcohol

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

Disinfection

Sterilization

No Rinseing

For external use only, Flammable. Keep product away from fire or flame.

<p style="text-align: center;">AROMATHERAPY RITUALS™</p> <hr/> <p style="text-align: center;">VANILLA BEAN</p> <hr/> <p style="text-align: center;"><i>Hand Sanitizer</i></p>  <p style="text-align: center;">Contains 70% Alcohol</p> <p style="text-align: center;">Antibacterial, reduces bacteria on skin.</p> <p style="text-align: center;">1.99 fl. oz. (59 mL)</p> <p style="font-size: small;">LBN 20200107 EXP: 20220107</p>	<p>Drug Facts</p> <table border="1"> <tr> <th style="text-align: left;">Active ingredient</th> <th style="text-align: left;">Purpose</th> </tr> <tr> <td>Alcohol 70% w/w.....</td> <td>Antiseptic</td> </tr> </table> <p>Use</p> <ul style="list-style-type: none"> • Antiseptic Cleanser, helps decrease bacteria on skin. <p>Warnings</p> <p>For external use only. Flammable. Keep product away from fire or flame.</p> <p>When using this product</p> <ul style="list-style-type: none"> • Avoid contact with the eyes; in case of contact, flush eyes with water. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • Irritation or redness develops and persists. ▶ <p>UPPER CANADA SOAP Mississauga, Canada L5R 3L9 1-800-548-4097 www.uppercanadasoap.com Developed in Canada / Made in China</p>	Active ingredient	Purpose	Alcohol 70% w/w.....	Antiseptic	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> • Place enough product on your palm to thoroughly cover your hands. • Rub hands together briskly until dry. • Children under 6 years of age should be supervised when using this product. <p>Other information</p> <ul style="list-style-type: none"> • Store below 110°F (43°C). May discolor certain fabrics or surfaces. <p>Inactive ingredients Water (Aqua), Glycerin, PEG-40 Hydrogenated Castor Oil, Carbomer, Triethanolamine, Phenoxyethanol, Fragrance (Parfum), Aminomethyl Propanol.</p> <p>Questions? Call 1-800-548-4097</p>
Active ingredient	Purpose					
Alcohol 70% w/w.....	Antiseptic					

HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77607-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	41.3 mL in 59 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77607-004-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/08/2020	

Labeler - Xiamen Afgamarine Biotechnology Co., Ltd. (420485152)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(77607-004)

Revised: 12/2020

Xiamen Afgamarine Biotechnology Co., Ltd.