

LXR HEALTHCARE- hand sanitizer gel gel
LXR Biotech 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.

LXR-Sanitizer Gel Red-Label

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 59-86F (15-30C)

Avoid freezing and excessive heat above 104F (40C)

May discolor certain fabrics or surfaces

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP, acrylate, copolymer

Package Label - Principal Display Panel

Destroys 99.99% of Germs

HAND SANITIZER
EXTRA STRENGTH Gel
 FRAGRANCE-FREE Antiseptic

ETHYL 80% ALCOHOL

LXR Healthcare

1.93 FL OZ MADE IN USA

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v	Antiseptic

Uses ■ 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.
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Stop use and consult 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.

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.

Inactive ingredients ■ Purified Water, Acrylate Copolymer, Glycerin, Hydrogen Peroxide

Other Information ■ Store between 59-86°F (15-30°C) ■ Avoid freezing and excessive heat above 104°F (40°C) ■ May discolor certain fabrics or surfaces.

Manufactured by **LXR Biotech, LLC.**
 Auburn Hills, MI, 48326
 www.lxrbio.com

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NO TEXT

57 mL NDC: 78299-122-11

LXR HEALTHCARE			
hand sanitizer gel gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78299-122
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			

WATER (UNII: 059QF0K00R)

BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78299-122-11	57 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/12/2020	

Labeler - LXR Biotech LLC (117520926)

Establishment

Name	Address	ID/FEI	Business Operations
LXR Biotech LLC		117520926	manufacture(78299-122)

Revised: 9/2020

LXR Biotech LLC