

DUDAS HAND SANITIZER GEL- alcohol gel

Duda Energy 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.

Active Ingredient(s)

Duda's Hand Sanitizer Gel

High Potency Revitalizing Gel

Relaxing Lavender Scent

Manufactured and Packaged in an FDA registered facility

Warning! Flammable
See side panel for additional information

Net Volume: 1 Gallon

FDA APPROVED

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Drug Facts	
Active Ingredient	Purpose
Alcohol 80%	Antiseptic
Use: -Hand sanitizer to help reduce bacteria that 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 on children less than 2 months of age or 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 might be signs of a serious condition. Keep out of reach of children and pets. 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.	
Other information: - Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F).	
Inactive ingredients: Water, Glycerin, Hydroxypropyl Cellulose, Fragrance Please visit DudaEnergy.com for product information.	

Duda Energy LLC
1112 Brooks St.
Decatur, AL 35601
256.340.4866
DUDAENERGY.COM

4 0 24 12051 2

Purpose

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Inactive ingredients

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- 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.
- store in a well-ventilated place and keep cool.

Package Label - Principal Display Panel

Duda's Hand Sanitizer Gel

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Relaxing Lavender Scent

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Inactive Ingredients Water, Glycol, Hydroxypropyl Cellulose, Fragrance Please visit DudaEnergy.com for product information.	

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Net Volume: 5 Gallons

Drug Facts	
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Duda's Hand Sanitizer Gel

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Net Volume: 950 ml

Warning! Flammable
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Drug Facts

Active Ingredient	Purpose
Alcohol 60%	Antiseptic
Uses - Hand sanitizer to help reduce bacteria that can cause disease. For use when soap and water are not available.	
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DUDAS HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77209-3291
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
LAVENDER OIL (UNII: ZBP1YXW0H8)	
GLYCERIN (UNII: PDC6A3C0OX)	2.5 L in 100 L
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	1.1 L in 100 L
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77209-3291-1	0.95 L in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
2	NDC:77209-3291-2	3.785 L in 1 JUG; Type 0: Not a Combination Product	05/08/2020	
3	NDC:77209-3291-3	18.9 L in 1 PAIL; Type 0: Not a Combination Product	05/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/08/2020	

Labeler - Duda Energy LLC (023793705)

Registrant - Duda Energy LLC (023793705)

Establishment

Name	Address	ID/FEI	Business Operations
Duda Energy LLC		023793705	manufacture(77209-3291) , pack(77209-3291)

Revised: 5/2020

Duda Energy LLC