

RAREESSENCE GEL WELL HAND SANITIZER- ethyl alcohol gel
rareESSENCE, 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.

Drug Facts

Ethyl Alcohol 70%

Hand and Antiseptic

Hand and skin antiseptic to help decrease pathogens (germs) on the skin

For external use only

Flammable: Keep away from heat and flame

* Avoid contact with eyes. If contact occurs flush eyes thoroughly with clean and cold water

* Do not ingest or inhale

* If irritation or redness develops, and/or you have open wounds or serious burns.

* If irritation or redness develops

* Have open wounds or serious burns

* If swallowed get medical help or contact a Poison Control Center immediately

* Wet hands thoroughly with product and allow to dry without wiping

* Supervise children under 6 years of age

Purified water, Glycerin, Orange Oil, Lemon Oil, Lavender Oil, Lavandin Oil, Vitamin E, Carbomer, Dimethicone, Aminomethyl Propanol

Questions? 800-998-1762

rareESSENCE Gel Well(TM) Hand Sanitizer

Alcohol Antiseptic 70%

with Pure Essential Oils

Lavender orange

Feel good, Do good.

For every bottle you purchase, we will donate a portion of the proceeds to U.S. food shelves

With 100% pure Essential Oils

No Synthetic Fragrances

No Phthalates

No Parabens

Reduces Germs that can potentially cause disease

Washing hands with soap and warm water remains the best way to remove germs.

For use when soap and water are not available

Made in USA

rareEssence, LLC

Minneapolis, MN 55344

www,rareESSENCEaromatherapy.com

xx oz(zzz mL) NDC 78035-002-xx

Feel good. Do good.

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With 100% Pure Essential Oils

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No Parabens

REDUCES GERMS

that can potentially cause disease

Washing hands with soap and warm water remains the best way to remove germs. For use when soap and water are not available.



rareESSENCE.
AROMATHERAPY

Gel Well™

Hand Sanitizer

Alcohol Antiseptic 70%

with
PURE ESSENTIAL OILS

lavender
orange

8 fl oz / 236 ml



Made in USA
rareESSENCE, LLC
Minneapolis, MN 55344
www.rareESSENCEaromatherapy.com

P/N 95810 04-00134 2004



Drug Facts

Active Ingredients: Ethanol 70%
Purpose: Antiseptic

Uses: • Hand sanitizer to help reduce bacteria on the skin. • For use when soap and water are not available.
• Recommended for repeated use.

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 and 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:

• Wet hands thoroughly with product and allow to dry without wiping.
• Supervise children under 6 years of age.

Other Information:

• Store between 59-104F (15-40C)
• May discolor certain fabrics.

Inactive Ingredients: Purified Water, Vegetable Glycerin, Organic Sweet Orange Oil, Organic Lemon Oil, Organic French Lavender Oil, Organic Lavandin Oil, Vitamin E, Carbomer, Dimethicone, Aminomethyl Propanol

NDC 78035-002-10 Questions? 800.998.1762

Feel good. Do good.

For every bottle you purchase, we will donate a portion of the proceeds to U.S. food shelves.

With 100% Pure Essential Oils

No Synthetic Fragrances

No Phthalates

No Parabens

REDUCES GERMS

that can potentially cause disease

Washing hands with soap and warm water remains the best way to remove germs. For use when soap and water are not available.



rareESSENCE.
AROMATHERAPY

Gel Well™

Hand Sanitizer

Alcohol Antiseptic 70%



Made in USA
rareESSENCE, LLC
Minneapolis, MN 55344
www.rareESSENCEaromatherapy.com

P/N 95420 04-00134 2004



with
PURE ESSENTIAL OILS

lavender
orange

4 fl oz / 118 ml

Drug Facts	
Active Ingredients:	Purpose:
Ethanol 70%.....	Antiseptic
Uses: • Hand sanitizer to help reduce bacteria on the skin. • For use when soap and water are not available. • Recommended for repeated use.	
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 and 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:	
• Wet hands thoroughly with product and allow to dry without wiping.	
• Supervise children under 6 years of age.	
Other Information:	
• Store between 59-104 F (15-40C)	
• May discolor certain fabrics.	
Inactive Ingredients: Purified Water, Vegetable Glycerin, Organic Sweet Orange Oil, Organic Lemon Oil, Organic French Lavender Oil, Organic Lavandin Oil, Vitamin E, Carbomer, Dimethicone, Aminomethyl Propanol	

NDC 78035-002-07 Questions? 800.998.1762

RAREESSENCE GEL WELL HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78035-002
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
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ORANGE OIL (UNII: AKN3KSD11B)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LAVANDIN OIL (UNII: 9RES347CKG)	
WATER (UNII: 059QF0K00R)	
LEMON OIL (UNII: I9GRO824LL)	

GLYCERIN (UNII: PDC6A3C00X)

DIMETHICONE 350 (UNII: 2Y53S6ATLU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78035-002-09	48 in 1 CARTON	06/08/2020	
1	NDC:78035-002-08	12 in 1 CASE		
1	NDC:78035-002-07	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:78035-002-11	12 in 1 CARTON	06/08/2020	
2	NDC:78035-002-10	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/08/2020	

Labeler - rareESSENCE, LLC (011585557)

Registrant - rareESSENCE, LLC (011585557)

Establishment

Name	Address	ID/FEI	Business Operations
Diversified Manufacturing Corporation		185073996	manufacture(78035-002) , pack(78035-002) , label(78035-002)

Revised: 6/2020

rareESSENCE, LLC