

DR LUCID 70% ETHANOL HAND SANITIZER GEL WITH ROSE- 70% ethanol hand sanitizer gel
KIRANEX 70% ETHANOL HAND SANITIZER GEL WITH EUCALYPTUS- 70% ethanol hand sanitizer gel
COMPASS 70% ETHANOL HAND SANITIZER GEL WITH CITRUS- 70% ethanol hand sanitizer gel
COMPASS 70% ETHANOL HAND SANITIZER GEL WITH LAVENDER- 70% ethanol hand sanitizer gel
DR LUCID 70% ETHANOL HAND SANITIZER GEL- 70% ethanol hand sanitizer gel
DR LUCID 70% ETHANOL HAND SANITIZER- 70% ethanol hand sanitizer liquid
DR LUCID HAND SANITIZER- 65% ethanol gel
DR LUCID 70% IPA SANITIZER- 70% isopropanol liquid
DR LUCID 91% IPA SANITIZER- 91% isopropanol liquid
SAFETY FIRST 70% ETHANOL HAND SANITIZER GEL- 70% ethanol hand sanitizer gel
DR LUCID 70% ETHANOL HAND SANITIZER GEL WITH EUCALYPTUS- 70% ethanol hand sanitizer gel
DR LUCID 70% ETHANOL HAND SANITIZER LIQUID WITH ROSE- 70% ethanol hand sanitizer gel
DR LUCID 70% ETHANOL HAND SANITIZER LIQUID WITH EUCALYPTUS- 70% ethanol hand sanitizer gel
Otto Solutions 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.

Hand Sanitizer

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

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.

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.

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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

For refills contact Kiranex at info@kiranex.com or (443) 914-2994 www.kiranex.com/gelpole

Drug Facts

Active Ingredient Ethyl Alcohol 70%
Purpose Antibacterial

Uses Hand Sanitizer to help reduce bacteria on the skin. 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 • On open skin wounds • When using this product keep out of eyes, ears, mouth • In case of contact with eyes, rinse 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.

Directions Place enough product on hands to cover all surfaces. Rub hands together until dry • Supervise children under age 6 when using this product to avoid swallowing.

Other Information Store between 15-30°C (59-86°F)
• Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients Water, glycerin, carbomer, eucalyptus, triethanolamine, hydrogen peroxide, blue 1, yellow 5

*Kills 99.9% of most common germs



Manufactured in
Miami, FL 33150 NDC#: 78346-019-02



KIRAGEL

ALCOHOL-BASED HAND SANITIZER GEL

**KILLS 99.9%
OF GERMS**

- 70% Ethyl Alcohol
- Kills 99.9% Germs < 15 Secs
- FDA-Registered Facilities
- Meets CDC Guidelines
- Made in the USA
- Fresh Scent
- Eucalyptus Essential Oil



KIRANEX

kiranex.com/gelpole
info@kiranex.com

1 gallon (128 fl oz)

THE LITTLE RIVER CO. PRESENTS



DR LUCID®

Advanced Moisturizing

HAND SANITIZER

Antiseptic Topical Solution

70% ALCOHOL • 3.4 FL OZ

DRUG FACTS

Active Ingredient	Purpose
Ethyl alcohol 70% v/v	Antimicrobial

Uses
To reduce bacteria on the skin that could cause disease

Warnings

- **Keep out of reach of children**
- **For external use only.** If swallowed, get medical help or contact poison control immediately.
- **Flammable. Keep away from flames**
- In case of contact with eyes, flush with plenty of water immediately
- **Consult a doctor** if irritation or redness develops

Directions
Apply just enough to cover hands and rub until dry



Other Ingredients
Water, glycerin, essential oil, hydrogen peroxide

www.doctorlucid.com

Dr Lucid sources the highest quality ingredients on the planet to create our hand sanitizing product. Our priority is to get you the most effective product to protect against germs, bacteria, and viruses. We strive to deliver a product that is healthy and hydrating for your skin using sustainably sourced ingredients.

Let's be Lucid. Sanitation is more important now than ever. Please, sanitize responsibly.



THE LITTLE RIVER CO. PRESENTS



Advanced Moisturizing

HAND SANITIZER

Gel Based - Antiseptic Topical Solution

70% ALCOHOL • 3.4 FL OZ

DRUG FACTS

Active Ingredient Ethyl alcohol 70% v/v	Purpose Antimicrobial
Uses To reduce bacteria on the skin that could cause disease	
Warnings <ul style="list-style-type: none">· Keep out of reach of children· For external use only. If swallowed, get medical help or contact poison control immediately.· Flammable. Keep away from flames· In case of contact with eyes, flush with plenty of water immediately· Consult a doctor if irritation or redness develops	
Directions Apply just enough to cover hands and rub until dry	
Other Ingredients Water, glycerin, triethanolamine, carbomer, essential oil, fragrance, hydrogen peroxide	
www.doctorlucid.com	

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THE LITTLE RIVER CO. PRESENTS



Advanced Moisturizing

HAND SANITIZER

Antiseptic Topical Solution

70% ALCOHOL • 3.4 FL OZ

DRUG FACTS

Active Ingredient	Purpose
Ethyl alcohol 70% v/v	Antimicrobial

Uses
To reduce bacteria on the skin that could cause disease

Warnings

- **Keep out of reach of children**
- **For external use only.** If swallowed, get medical help or contact poison control immediately.
- **Flammable. Keep away from flames**
- In case of contact with eyes, flush with plenty of water immediately
- **Consult a doctor** if irritation or redness develops

Directions
Apply just enough to cover hands and rub until dry



Other Ingredients
Water, glycerin, essential oil, fragrance, hydrogen peroxide

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THE LITTLE RIVER CO. PRESENTS



Advanced Moisturizing

HAND SANITIZER

Gel Based - Antiseptic Topical Solution

70% ALCOHOL • 3.4 FL OZ

DRUG FACTS

Active Ingredient Ethyl alcohol 70% v/v	Purpose Antimicrobial
Uses To reduce bacteria on the skin that could cause disease	
Warnings <ul style="list-style-type: none">· Keep out of reach of children· For external use only. If swallowed, get medical help or contact poison control immediately.· Flammable. Keep away from flames· In case of contact with eyes, flush with plenty of water immediately· Consult a doctor if irritation or redness develops	
Directions Apply just enough to cover hands and rub until dry	
Other Ingredients Water, glycerin, triethanolamine, carbomer, essential oil, hydrogen peroxide	
www.doctorlucid.com	

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Let's be Lucid. Sanitation is more important now than ever. Please, sanitize responsibly.



DR LUCID

Stay Safe
My Friends



THE LITTLE RIVER CO.

73 NW 71st Street
Miami, FL 33150
info@thelittleriverco.com



THE LITTLE RIVER CO. PRESENTS



DR LUCID

First Aid Antiseptic

HYDROGEN PEROXIDE 4%

Topical Solution USP

1 GALLON

DRUG FACTS

Active Ingredient
Hydrogen Peroxide 4%

Purpose
■ First Aid Antiseptic

Uses
■ First aid to help prevent the risk of infection in minor cuts, scrapes and burns

Warnings For external use only.
■ Do not use ■ in the eyes or apply over large areas of the body ■ longer than 1 week ■ Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns ■ Stop use and ask a doctor if ■ the condition persists or gets worse ■ irritation, pain, or redness persists or worsens ■ swelling, rash, or fever develops

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

Directions For use as first aid antiseptic: ■ Clean the affected area ■ Apply a small amount of product on the area 1 to 3 times daily ■ May be covered with a sterile bandage ■ If bandaged, let dry first

■ Children under 12 years of age should be supervised in the use of this product
■ Children under 2 years of age: consult a dentist or doctor

Inactive Ingredient Purified water

Other Information ■ keep tightly closed and in a dark place at room temperature. ■ do not shake bottle. ■ hold away from face when opening.

www.doctorlucid.com

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%.....	Antibacterial

Uses Hand Sanitizer to help reduce bacteria on the skin. 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 • On open skin wounds • When using this product keep out of eyes, ears, mouth • In case of contact with eyes, rinse 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.

Distributed by FairFromBoring Promotions™

SAFETYTM FIRST Hand Sanitizer



with Eucalyptus Leaf
Vitamin E & Aloe

Kills 99.9% of Germs*

1 Gallon (3875ml)

Directions Place enough product on hands to cover all surfaces. Rub hands together until dry • Supervise children under age 6 when using this product to avoid swallowing.

Other Information Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients Water, glycerin, isopropyl alcohol, acrylates/C10-30 alkyl acrylate crosspolymer, eucalyptus oil, aminomethyl propanol, hydrogen peroxide, aloe vera, tocopheryl acetate (vitamin E)

*Kills 99.9% of most common germs



Manufactured in
Miami, FL 33150

NDC#: 78346-010-01

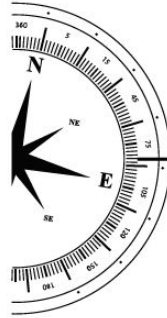




COMPASS
Of Miami Services, INC.

Compass of Miami Services, Inc.
13061 NW 43 Avenue
Opa Locka FL 33054

T: 305-318-7619
info@compassofmiami.com



COMPASS
Of Miami Services, INC.

Advanced Moisturizing

HAND SANITIZER
Lemon Scented Gel

Topical Antiseptic

70% ALCOHOL • 1 GALLON

DRUG FACTS

Active Ingredient
Ethyl alcohol 70% v/v

Purpose
Antimicrobial

Uses
To reduce bacteria on the skin that could cause disease

Warnings
• **Keep out of reach of children**
• **For external use only.** If swallowed, get medical help or contact poison control immediately.
• **Flammable. Keep away from flames**
• In case of contact with eyes, flush with flush with plenty of water immediately
• **Consult a doctor** if irritation or redness develops

Directions
Apply just enough to cover hands and rub until dry

Other Ingredients
Water, glycerin, triethanolamine, carbomer, limonene, hydrogen peroxide

www.compassofmiami.com



Made and bottled by
THE LITTLE RIVER CO.

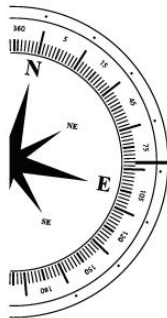
73 NW 71st Street
Miami, FL 33150



COMPASS
Of Miami Services, INC.

Compass of Miami Services, Inc.
13061 NW 43 Avenue
Opa Locka FL 33054

T: 305-318-7619
info@compassofmiami.com



COMPASS
Of Miami Services, INC.

Advanced Moisturizing

HAND SANITIZER
Lavender Scented Gel

Topical Antiseptic

70% ALCOHOL • 1 GALLON

DRUG FACTS

Active Ingredient
Ethyl alcohol 70% v/v

Purpose
Antimicrobial

Uses
To reduce bacteria on the skin that could cause disease

Warnings
• **Keep out of reach of children**
• **For external use only.** If swallowed, get medical help or contact poison control immediately.
• **Flammable. Keep away from flames**
• In case of contact with eyes, flush with flush with plenty of water immediately
• **Consult a doctor** if irritation or redness develops

Directions
Apply just enough to cover hands and rub until dry

Other Ingredients
Water, glycerin, triethanolamine, carbomer, lavender, hydrogen peroxide

www.compassofmiami.com



Made and bottled by
THE LITTLE RIVER CO.

73 NW 71st Street
Miami, FL 33150

DR LUCID

*Stay Safe
My Friends*

Dr Lucid sources the highest quality ingredients on the planet to create our hand sanitizing product. Our priority is to get you the most effective product to protect against germs, bacteria, and viruses. We strive to deliver a product that is healthy and hydrating for your skin using sustainably sourced ingredients.

Let's be Lucid. Sanitation is more important now than ever. Please, sanitize responsibly.



THE LITTLE RIVER CO.

73 NW 71st Street
Miami, FL 33150
info@thelittleriverco.com

THE LITTLE RIVER CO. PRESENTS



DR LUCID

Advanced Moisturizing

HAND SANITIZER

Gel Based - Antiseptic Topical Solution

65% ALCOHOL • 10 FL OZ

DRUG FACTS

Active Ingredient
Ethyl alcohol 65% v/v

Purpose
Antimicrobial

Uses
To reduce bacteria on the skin that could cause disease

Warnings

- Keep out of reach of children
- For external use only. If swallowed, get medical help or contact poison control immediately.
- Flammable. Keep away from flames
- In case of contact with eyes, flush with plenty of water immediately
- Consult a doctor if irritation or redness develops

Directions
Apply just enough to cover hands and rub until dry

Other Ingredients
Water, glycerin, hydrogen peroxide

www.doctorlucid.com



3 78346 00110 5



DR LUCID

STAY SAFE MY FRIENDS

Dr Lucid sources the highest quality ingredients on the planet to create the best rubbing alcohol. Let's be lucid.



THE LITTLE RIVER CO.

73 NW 71st Street
Miami, FL 33150
info@thelittleriverco.com



3 78346 00301 7

THE LITTLE RIVER CO. PRESENTS



DR LUCID

First Aid Antiseptic

RUBBING ALCOHOL

70% ISOPROPYL

10 fl oz

DRUG FACTS

Active ingredient (by volume)
Isopropyl alcohol (70% conc.)

Purpose
first aid antiseptic

Uses
first aid to help prevent the risk of infection in minor cuts, scrapes and burns

Warnings

For external use only

- flammable, keep away from fire or flame
- if taken internally serious gastric disturbances will result
- use only in a well-ventilated area; fumes may be toxic

Ask a doctor before use if you have

- deep or puncture wounds, animal bites or serious burns

When using this product

- do not get into eyes
- do not apply over large areas of the body
- do not use longer than one week unless directed by a doctor

Stop use and ask a doctor if

- condition persists or gets worse

Keep this out of the reach of children.
In case of accidental ingestion, seek medical assistance or contact a Poison Control Center immediately.

Directions

- clean affected area
- apply small amount of this product on the area 1-3 times daily
- if bandaged, let dry first
- may be covered with a sterile bandage

Other information

- store at room temperature
- does not contain, nor is intended as a substitute for grain or ethyl alcohol

Inactive ingredient purified water

Made in an FDA registered facility

www.doctorlucid.com

DR LUCID

STAY SAFE MY FRIENDS

Dr Lucid sources the highest quality ingredients on the planet to create the best rubbing alcohol. Let's be lucid.



THE LITTLE RIVER CO.

73 NW 71st Street
Miami, FL 33150
info@thelittleriverco.com



THE LITTLE RIVER CO. PRESENTS



DR LUCID

First Aid Antiseptic

RUBBING ALCOHOL

91% ISOPROPYL

10 fl oz

DRUG FACTS

Active ingredient (by volume)
Isopropyl alcohol (91% conc.)

Purpose
first aid antiseptic

Uses
· first aid to help prevent the risk of infection in minor cuts, scrapes and burns

Warnings
For external use only
· flammable, keep away from fire or flame
· if taken internally serious gastric disturbances will result
· use only in a well-ventilated area; fumes may be toxic

Ask a doctor before use if you have
· deep or puncture wounds, animal bites or serious burns

When using this product
· do not get into eyes
· do not apply over large areas of the body
· do not use longer than one week unless directed by a doctor

Stop use and ask a doctor if
· condition persists or gets worse

Keep this out of the reach of children.
In case of accidental ingestion, seek medical assistance or contact a Poison Control Center immediately.

Directions
· clean affected area
· apply small amount of this product on the area 1-3 times daily
· if bandaged, let dry first
· may be covered with a sterile bandage

Other information
· store at room temperature
· does not contain, nor is intended as a substitute for grain or ethyl alcohol

Inactive ingredient purified water

Made in an FDA registered facility

www.doctorlucid.com

DR LUCID

Stay Safe My Friends

Dr Lucid sources the highest quality ingredients on the planet to create our hand sanitizing product. Our priority is to get you the most effective product to protect against germs, bacteria, and viruses. We strive to deliver a product that is healthy and hydrating for your skin using sustainably sourced ingredients.

Let's be Lucid. Sanitation is more important now than ever. Please, sanitize responsibly.



THE LITTLE RIVER CO.

73 NW 71st Street
Miami, FL 33150
info@thelittleriverco.com

THE LITTLE RIVER CO. PRESENTS



DR LUCID

Advanced Moisturizing

HAND SANITIZER

Gel Based - Antiseptic Topical Solution

70% ALCOHOL • 10 FL OZ

DRUG FACTS

Active Ingredient
Ethyl alcohol 70% v/v

Purpose
Antimicrobial

Uses
To reduce bacteria on the skin that could cause disease

Warnings
· **Keep out of reach of children**
· **For external use only.** If swallowed, get medical help or contact poison control immediately.
· **Flammable. Keep away from flames**
· In case of contact with eyes, flush with plenty of water immediately
· **Consult a doctor** if irritation or redness develops

Directions
Apply just enough to cover hands and rub until dry

Other Ingredients
Water, glycerin, triethanolamine, carbomer, hydrogen peroxide

www.doctorlucid.com



DR LUCID

*Stay Safe
My Friends*

Dr Lucid sources the highest quality ingredients on the planet to create our hand sanitizing product. Our priority is to get you the most effective product to protect against germs, bacteria, and viruses. We strive to deliver a product that is healthy and hydrating for your skin using sustainably sourced ingredients.

Let's be Lucid. Sanitation is more important now than ever. Please, sanitize responsibly.



THE LITTLE RIVER CO.
73 NW 71st Street
Miami, FL 33150
info@thelittleriverco.com

THE LITTLE RIVER CO. PRESENTS



DR LUCID

Advanced Moisturizing

HAND & SURFACE SANITIZER

Antiseptic Topical Solution

70% ALCOHOL • 10 FL OZ

DRUG FACTS

Active Ingredient
Ethanol 70% v/v

Purpose
Antimicrobial

Uses
To reduce bacteria on the skin that could cause disease

Warnings

- Keep out of reach of children
- For external use only. If swallowed, get medical help or contact poison control immediately.
- Flammable. Keep away from flames
- In case of contact with eyes, flush with plenty of water immediately
- Consult a doctor if irritation or redness develops

Directions
Apply just enough to cover hands and rub until dry

Other Ingredients
Water, glycerin, hydrogen peroxide

www.doctorlucid.com



DR LUCID 70% ETHANOL HAND SANITIZER GEL WITH ROSE

70% ethanol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-017
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
FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
ROSE OIL (UNII: WUB68Y35M7)	

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-017-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
2	NDC:78346-017-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
3	NDC:78346-017-03	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
4	NDC:78346-017-04	6000 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
5	NDC:78346-017-05	6033 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
6	NDC:78346-017-06	400 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
7	NDC:78346-017-07	1600 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
8	NDC:78346-017-08	600 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
9	NDC:78346-017-09	2400 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
10	NDC:78346-017-10	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
11	NDC:78346-017-11	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
12	NDC:78346-017-12	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/14/2021	

KIRANEX 70% ETHANOL HAND SANITIZER GEL WITH EUCALYPTUS

70% ethanol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-019
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-019-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
2	NDC:78346-019-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
3	NDC:78346-019-03	15142 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
4	NDC:78346-019-04	8000 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
5	NDC:78346-019-05	22712 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
6	NDC:78346-019-06	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
7	NDC:78346-019-07	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
8	NDC:78346-019-08	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
9	NDC:78346-019-09	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
10	NDC:78346-019-10	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/14/2021	

COMPASS 70% ETHANOL HAND SANITIZER GEL WITH CITRUS

70% ethanol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-008
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
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-008-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2020	
2	NDC:78346-008-02	15142 mL in 1 CASE; Type 0: Not a Combination Product	11/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/09/2020	

COMPASS 70% ETHANOL HAND SANITIZER GEL WITH LAVENDER

70% ethanol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-009
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
LAVENDER OIL (UNII: ZBP1YXW0H8)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

TROLAMINE (UNII: 903K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-009-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2020	
2	NDC:78346-009-02	15142 mL in 1 CASE; Type 0: Not a Combination Product	11/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/09/2020	

DR LUCID 70% ETHANOL HAND SANITIZER GEL

70% ethanol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-006
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 903K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-006-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2020	
2	NDC:78346-006-03	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2020	

3	NDC:78346-006-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2020	
4	NDC:78346-006-02	15142 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
5	NDC:78346-006-06	6000 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
6	NDC:78346-006-04	5915 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
7	NDC:78346-006-08	5920 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
8	NDC:78346-006-07	296 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/11/2020	
9	NDC:78346-006-09	600 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
10	NDC:78346-006-10	2400 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
11	NDC:78346-006-11	1774 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
12	NDC:78346-006-12	7098 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
13	NDC:78346-006-13	1774 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
14	NDC:78346-006-14	7098 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
15	NDC:78346-006-15	2400 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
16	NDC:78346-006-16	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2020	
17	NDC:78346-006-17	6000 mL in 1 CASE; Type 0: Not a Combination Product	11/02/2020	
18	NDC:78346-006-18	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2020	
19	NDC:78346-006-19	6000 mL in 1 CASE; Type 0: Not a Combination Product	11/02/2020	
20	NDC:78346-006-20	250000 mL in 1 DRUM; Type 0: Not a Combination Product	11/17/2020	
21	NDC:78346-006-21	208000 mL in 1 DRUM; Type 0: Not a Combination Product	11/17/2020	
22	NDC:78346-006-22	1000000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	11/17/2020	
23	NDC:78346-006-23	400 mL in 1 CASE; Type 0: Not a Combination Product	11/17/2020	
24	NDC:78346-006-24	1600 mL in 1 CASE; Type 0: Not a Combination Product	11/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/11/2020	

DR LUCID 70% ETHANOL HAND SANITIZER

70% ethanol hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-007
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-007-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2020	
2	NDC:78346-007-03	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2020	
3	NDC:78346-007-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2020	
4	NDC:78346-007-02	15142 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
5	NDC:78346-007-06	6000 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
6	NDC:78346-007-04	5920 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
7	NDC:78346-007-07	1774 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
8	NDC:78346-007-08	7098 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
9	NDC:78346-007-09	600 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
10	NDC:78346-007-10	2400 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
11	NDC:78346-007-11	2400 mL in 1 CASE; Type 0: Not a Combination Product	09/11/2020	
12	NDC:78346-007-12	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2020	
13	NDC:78346-007-13	6000 mL in 1 CASE; Type 0: Not a Combination Product	11/02/2020	
14	NDC:78346-007-14	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2020	
15	NDC:78346-007-15	6000 mL in 1 CASE; Type 0: Not a Combination Product	11/02/2020	
16	NDC:78346-007-16	1500 mL in 1 CASE; Type 0: Not a Combination Product	11/02/2020	
17	NDC:78346-007-17	400 mL in 1 CASE; Type 0: Not a Combination Product	11/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/11/2020	

DR LUCID HAND SANITIZER

65% ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	1.3 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-001-34	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78346-001-10	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78346-001-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78346-001-02	15142 mL in 1 CASE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78346-001-11	5920 mL in 1 CASE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78346-001-35	6033 mL in 1 CASE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:78346-001-69	5920 mL in 1 CASE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:78346-001-77	296 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

DR LUCID 70% IPA SANITIZER

70% isopropanol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-003-01	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2020	
2	NDC:78346-003-00	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2020	
3	NDC:78346-003-10	5920 mL in 1 CASE; Type 0: Not a Combination Product	09/09/2020	
4	NDC:78346-003-24	12000 mL in 1 CASE; Type 0: Not a Combination Product	09/09/2020	
5	NDC:78346-003-02	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2020	
6	NDC:78346-003-03	15142 mL in 1 CASE; Type 0: Not a Combination Product	09/09/2020	

Marketing Information

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

final	part333A	09/09/2020	
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DR LUCID 91% IPA SANITIZER

91% isopropanol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	91 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-004-00	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2020	
2	NDC:78346-004-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2020	
3	NDC:78346-004-20	5920 mL in 1 CASE; Type 0: Not a Combination Product	09/09/2020	
4	NDC:78346-004-10	12000 mL in 1 CASE; Type 0: Not a Combination Product	09/09/2020	
5	NDC:78346-004-02	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2020	
6	NDC:78346-004-03	15142 mL in 1 CASE; Type 0: Not a Combination Product	09/09/2020	

Marketing Information

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

SAFETY FIRST 70% ETHANOL HAND SANITIZER GEL

70% ethanol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-010
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-010-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2020	
2	NDC:78346-010-02	15142 mL in 1 CASE; Type 0: Not a Combination Product	11/09/2020	
3	NDC:78346-010-05	208000 mL in 1 DRUM; Type 0: Not a Combination Product	11/17/2020	
4	NDC:78346-010-06	250000 mL in 1 DRUM; Type 0: Not a Combination Product	11/17/2020	
5	NDC:78346-010-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2020	
6	NDC:78346-010-04	5678 mL in 1 CASE; Type 0: Not a Combination Product	11/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/09/2020	

DR LUCID 70% ETHANOL HAND SANITIZER GEL WITH EUCALYPTUS

70% ethanol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-013
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-013-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
2	NDC:78346-013-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
3	NDC:78346-013-03	296 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
4	NDC:78346-013-04	6000 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
5	NDC:78346-013-05	6033 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
6	NDC:78346-013-06	2400 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
7	NDC:78346-013-07	600 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
8	NDC:78346-013-08	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
9	NDC:78346-013-09	1600 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
10	NDC:78346-013-10	5920 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
11	NDC:78346-013-11	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
12	NDC:78346-013-12	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/14/2021	

DR LUCID 70% ETHANOL HAND SANITIZER LIQUID WITH ROSE

70% ethanol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-018
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
ROSE OIL (UNII: WUB68Y35M7)	
FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-018-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
2	NDC:78346-018-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
3	NDC:78346-018-03	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
4	NDC:78346-018-04	6000 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
5	NDC:78346-018-05	6033 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
6	NDC:78346-018-06	400 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
7	NDC:78346-018-07	1600 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
8	NDC:78346-018-08	600 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	

9	NDC:78346-018-09	2400 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
10	NDC:78346-018-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
11	NDC:78346-018-11	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/14/2021	

DR LUCID 70% ETHANOL HAND SANITIZER LIQUID WITH EUCALYPTUS

70% ethanol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78346-014
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78346-014-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
2	NDC:78346-014-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
3	NDC:78346-014-03	296 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
4	NDC:78346-	6000 mL in 1 CASE; Type 0: Not a Combination	06/14/2021	

4	014-04	Product	06/14/2021	
5	NDC:78346-014-05	6000 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
6	NDC:78346-014-06	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
7	NDC:78346-014-07	1600 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
8	NDC:78346-014-08	600 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
9	NDC:78346-014-09	2400 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
10	NDC:78346-014-10	1000 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	
11	NDC:78346-014-11	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2021	
12	NDC:78346-014-12	15140 mL in 1 CASE; Type 0: Not a Combination Product	06/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/14/2021	

Labeler - Otto Solutions LLC (117519859)

Establishment

Name	Address	ID/FEI	Business Operations
Otto Solutions LLC		117519859	manufacture(78346-001, 78346-003, 78346-004, 78346-006, 78346-007, 78346-008, 78346-009, 78346-010, 78346-019, 78346-013, 78346-014, 78346-018, 78346-017)

Revised: 8/2022

Otto Solutions LLC