

HAND SANITIZER- alcohol liquid

Seatex, 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.

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.

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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

710 Ml 76250-351-00



Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-Sterile Solution

LOT #:
EXP. DATE:

INFOTRAC# 16351

In Case of Emergency, Contact Infotrac 1-800-535-5053

NET CONTENTS: 710 mL (24 OUNCES)



Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-Sterile Solution

LOT #:
EXP. DATE:

INFOTRAC# 16351

In Case of Emergency, Contact Infotrac 1-800-535-5053

NET CONTENTS: 710 mL (24 OUNCES)

3785 mL 76250-351-01

Drug Facts

Active Ingredient(s) **Purpose**
Alcohol 80% v/vAntiseptic

Use(s)
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Inactive Ingredients
glycerin, hydrogen peroxide, purified water USP

Seatex, LLC. 445 TX Hwy 36 Rosenberg, TX 77471
(713) 357-5300 | seatexcorp.com

REV:033120

Drug Facts

Active Ingredient(s) **Purpose**
Alcohol 80% v/vAntiseptic

Use(s)
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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REV:033120

Información del Medicamento	
Ingrediente Activo Alcohol 80% v/v	Propósito Antiséptico
Usos Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar la enfermedad. Para usar cuando no hay agua y jabón disponibles.	
Advertencias Sólo para uso externo. Inflamable. Mantener alejado del calor o llamas. No utilice • en niños menores de 2 meses de edad • en heridas de piel abierta Al utilizar este producto manténgase fuera de los ojos, los oídos y la boca. En caso de contacto con los ojos, enjuague con agua. Dejar de usar y consultar a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una afección grave. Mantener fuera del alcance de los niños. Si se ingiere, obtener ayuda médica o contactar al Servicio Toxicológico de inmediato.	
Instrucciones • Coloque suficiente producto en las manos para cubrir todas las superficies. Frotar las manos juntas hasta que se sequen. • Supervise a los niños menores de 6 años cuando usar este producto para evitar que se lo traguen.	
Otra Información • Almacenar entre 15 y 30°C (59 y 86°F) • Evite la congelación y el calor excesivo por encima de 40°C (104°F)	
Ingredientes Inactivos: glicerina, peróxido de hidrógeno, agua purificada USP	



Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution

LOT #: EXP. DATE:

INFOTRAC# 16351
In Case of Emergency, Contact Infotrac 1-800-535-5053



NET CONTENTS: 3.785 L (1 GALLON)

Seatex, LLC. 445 TX Hwy 36 Rosenberg, TX 77471 | (713) 357-5300 | seatexcorp.com

Drug Facts	
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Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
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Inactive Ingredients: glycerin, hydrogen peroxide, purified water USP	

18900 ml 76250-351-02



Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution

LOT #: EXP. DATE:

UN1170
Ethanol Solutions, 3, PGII



NET CONTENTS: 18.9 L (5 GALLONS)

Seatex, LLC. 445 TX Hwy 36 Rosenberg, TX 77471
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Drug Facts	
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INFOTRAC# 16351 | In Case of Emergency, Contact Infotrac 1-800-535-5053

208000 76250-351-03



Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution

LOT #: EXP. DATE:

UN1170
Ethanol Solutions, 3, PGII



NET CONTENTS: 208 L (55 GALLONS)

Seatex, LLC. 445 TX Hwy 36 Rosenberg, TX 77471
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Drug Facts	
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Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
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Inactive Ingredients: glycerin, hydrogen peroxide, purified water USP	

INFOTRAC# 16351 | In Case of Emergency, Contact Infotrac 1-800-535-5053

1041000 ml 76250-351-04



**Alcohol Antiseptic 80%
Topical Solution**

**Hand Sanitizer
Non-Sterile Solution**

LOT #:
EXP. DATE:

UN1170
Ethanol Solutions, 3, PGII



NET CONTENTS: 1041 L (275 GALLONS)

Seatex, LLC, 445 TX Hwy 36 Rosenberg, TX 77471
(713) 357-5300 | seatexcorp.com

1249000 ml 76250-351-05



**Alcohol Antiseptic 80%
Topical Solution**

**Hand Sanitizer
Non-Sterile Solution**

LOT #:
EXP. DATE:

UN1170
Ethanol Solutions, 3, PGII



NET CONTENTS: 1249 L (330 GALLONS)

Seatex, LLC, 445 TX Hwy 36 Rosenberg, TX 77471
(713) 357-5300 | seatexcorp.com

Drug Facts

Active Ingredient(s) Alcohol 80% v/v	Purpose Antiseptic
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Inactive Ingredients: glycerin, hydrogen peroxide, purified water USP	

INFOTRAC# 16351 | In Case of Emergency, Contact Infotrac 1-800-535-5053

REF:033120

Drug Facts

Active Ingredient(s) Alcohol 80% v/v	Purpose Antiseptic
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INFOTRAC# 16351 | In Case of Emergency, Contact Infotrac 1-800-535-5053

REF:033120

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76250-351
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)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76250-351-00	710 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76250-351-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76250-351-02	18900 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76250-351-03	208000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
5	NDC:76250-351-05	1249000 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
6	NDC:76250-351-04	1041000 mL in 1 TANK; 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	

Labeler - Seatex, LLC (026647404)

Establishment

Name	Address	ID/FEI	Business Operations
Seatex, LLC		026647404	manufacture(76250-351)

Revised: 4/2020

Seatex, LLC