HAND SANITIZER- alcohol gel
Charlotte Products Ltd.

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.

Enviro Solutions Gel 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) (71%, 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 (0.12% v/v).
d. DI water.
e. Acrylates crosspolymer
f. 2,4-D diethylethanolamine

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 71% 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, acrylates crosspolymer, 2,4-D diethylethanolamine

Package Label - Principal Display Panel

1250 mL NDC: 64646-043-04

ES43US-6 **USA Version**

ENVIRO Solutions

WASHROOM CARE & ODOR CONTROL

ES43

GEL HAND SANITIZER

Alcohol Antiseptic 71%
Topical
Hand Sanitizer
Non-sterile Gel

NDC 64646-043-04

Net Contents:
1250 mL (42 fl oz)

Drug Facts
Active ingredient[s] Purpose
Alcohol 71% v/v ..... Antiseptic

Use[s]
Antiseptic, Hand Sanitizer
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.

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 15-30ºC (59-86ºF)
- Avoid freezing and excessive heat above 40ºC (104ºF)

Inactive ingredients
water USP, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.

HOW TO APPLY

Charlotte Products Ltd.
2060 Fisher Dr Peterborough
Ontario K9J 6X6
Tel: 1-877-745-2880

PSL1787A

877502004306

R368B Perflex Die - 5" x 2.5" - Rewind #3 **PSL 1787A**

500 ml NDC: 64646-043-12

Drug Facts
Active ingredient[s] Purpose
Alcohol 71% v/v ..... Antiseptic

Use[s]
Antiseptic, Hand Sanitizer

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.

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ENVIRO Solutions®

WASHROOM CARE & ODOR CONTROL

ES43

GEL HAND SANITIZER

Alcohol Antiseptic 71%
Topical
Hand Sanitizer
Non-sterile Gel

NDC 64646-043-12

Net Contents:
500 mL (16.9 fl oz)

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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients
water USP, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.

UPC Code

Charlotte Products Ltd.
2060 Fisher Dr Peterborough
Ontario K9J 6X6
Tel: 1-877-745-2880

2L NDC:64646-043-02

Drug Facts
Active ingredient[s] Purpose
Alcohol 71% v/v ..... Antiseptic

Use[s]
Antiseptic, Hand Sanitizer

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.

ENVIRO Solutions®

WASHROOM CARE & ODOR CONTROL

ES43

GEL HAND SANITIZER

Alcohol Antiseptic 71%
Topical
Hand Sanitizer
Non-sterile Gel

NDC 64646-043-02

Net Contents:
2 L (0.52 gallon)

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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients
water USP, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.

UPC Code

Charlotte Products Ltd.
2060 Fisher Dr Peterborough
Ontario K9J 6X6
Tel: 1-877-745-2880

3.78L NDC: 64646-043-03

Drug Facts
Active ingredient[s] Purpose
Alcohol 71% v/v ..... Antiseptic

Use[s]
Antiseptic, Hand Sanitizer

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.

ENVIRO Solutions®

WASHROOM CARE & ODOR CONTROL

ES43

GEL HAND SANITIZER

Alcohol Antiseptic 71%
Topical
Hand Sanitizer
Non-sterile Gel

NDC 64646-043-03

Net Contents:
3.78 L (1 gallon)

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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients
water USP, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.

UPC Code

Charlotte Products Ltd.
2060 Fisher Dr Peterborough
Ontario K9J 6X6
Tel: 1-877-745-2880

18.9L NDC: 64646-043-20

Drug Facts
Active ingredient[s] Purpose
Alcohol 71% v/v ..... Antiseptic

Use[s]
Antiseptic, Hand Sanitizer

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.

ENVIRO Solutions®

WASHROOM CARE & ODOR CONTROL

ES43

GEL HAND SANITIZER

Alcohol Antiseptic 71%
Topical
Hand Sanitizer
Non-sterile Gel

NDC 64646-043-20

Net Contents:
18.9 L (5 gallon)

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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients
water USP, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.

UPC Code

Charlotte Products Ltd.
2060 Fisher Dr Peterborough
Ontario K9J 6X6
Tel: 1-877-745-2880

55L NDC: 64646-043-21

Drug Facts
Active ingredient[s] Purpose
Alcohol 71% v/v ..... Antiseptic

Use[s]
Antiseptic, Hand Sanitizer

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.

ENVIRO Solutions®

WASHROOM CARE & ODOR CONTROL

ES43

GEL HAND SANITIZER

Alcohol Antiseptic 71%
Topical
Hand Sanitizer
Non-sterile Gel

NDC 64646-043-21

Net Contents:
55 L (14.5 gallon)

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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients
water USP, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.

HOW TO APPLY

UPC Code

Charlotte Products Ltd.
2060 Fisher Dr Peterborough
Ontario K9J 6X6
Tel: 1-877-745-2880

208L NDC: 64646-04-22

Drug Facts
Active ingredient[s] Purpose
Alcohol 71% v/v ..... Antiseptic

Use[s]
Antiseptic, Hand Sanitizer

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.

ENVIRO Solutions®

WASHROOM CARE & ODOR CONTROL

ES43

GEL HAND SANITIZER

Alcohol Antiseptic 71%
Topical
Hand Sanitizer
Non-sterile Gel

NDC 64646-043-22

Net Contents:
208 L (55 gallon)

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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients
water USP, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.

HOW TO APPLY

UPC Code

Charlotte Products Ltd.
2060 Fisher Dr Peterborough
Ontario K9J 6X6
Tel: 1-877-745-2880

1000L NDC: 64646-043-23

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64646-043
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.12 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
2,4-D DIETHYLETHANOLAMINE (UNII: S070272I1T)	0.21 mL in 100 mL
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)	0.3 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64646-043-04	1250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/10/2021	
2	NDC:64646-043-12	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/10/2021	

3	NDC:64646-043-03	37800 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2021	
4	NDC:64646-043-20	18900 mL in 1 PAIL; Type 0: Not a Combination Product	09/10/2021	
5	NDC:64646-043-21	55000 mL in 1 DRUM; Type 0: Not a Combination Product	09/10/2021	
6	NDC:64646-043-22	208000 mL in 1 DRUM; Type 0: Not a Combination Product	09/10/2021	
7	NDC:64646-043-23	1000 mL in 1 DRUM; Type 0: Not a Combination Product	09/10/2021	
8	NDC:64646-043-02	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/10/2021	

Labeler - Charlotte Products Ltd. (248293359)

Establishment

Name	Address	ID/FEI	Business Operations
Charlotte Products Ltd.		248293359	manufacture(64646-043)

Revised: 9/2021 Charlotte Products Ltd.