HAND SANITIZER- hand sanitizer gel
1201258 Ontario Inc.

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.

Alcorub Sanitizer

a. Alcohol (ethanol)- USP (66.5%, volume/volume (v/v))
b. Sterile distilled water or boiled cold water.

Active Ingredient(s)

Alcohol 66.5% 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

Isopropyl alcohol 3.5%v/v, Carbomer 941, Glyceryl acrylated/acrylic acid copolymer, Lime Oil, PEG-40 Hydrogenated Castor Oil, Aloe Vera Juice, Triethanolamine, Purified Water

Package Label - Principal Display Panel

Example of Plastic Bottle

20ML NDC: 80129-005-01

50ML NDC: 80129-005-02

60ML NDC: 80129-005-03

100ML NDC: 80129-005-04

250ML NDC: 80129-005-05

500ML NDC: 80129-005-06

1000ML NDC: 80129-005-07

2000ML NDC: 80129-005-08

3785ML NDC: 80129-005-09

5000ML NDC: 80129-005-10

HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83254-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	66.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	0.3 g in 100 mL
LIME OIL (UNII: UZH29XGA8G)	0.3 g in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.6 g in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	3.5 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.75 g in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.55 g in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.5 g in 100 mL
WATER (UNII: 059QF0KO0R)	100 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83254-005-02	20 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2023	
2	NDC:83254-005-05	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2023	
3	NDC:83254-005-06	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2023	
4	NDC:83254-005-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2023	
5	NDC:83254-005-25	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2023	
6	NDC:83254-005-50	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2023	
7	NDC:83254-005-10	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2023	
8	NDC:83254-005-20	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2023	
9	NDC:83254-005-37	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2023	
10	NDC:83254-005-55	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2023	
11	NDC:83254-005-12	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2020	

12	NDC:83254-005-36	360 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/24/2020	

Labeler - 1201258 Ontario Inc. (256906595)

Registrant - 1201258 Ontario Inc. (256906595)

Establishment

Name	Address	ID/FEI	Business Operations
1201258 Ontario Inc.		256906595	manufacture(83254-005) , pack(83254-005) , label(83254-005)

Revised: 7/2023 1201258 Ontario Inc.