

HAND SANITIZER- alcohol gel
Solents and Petroleum Service 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.

Charcoal Filtered Gel Hand Sanitizer

Active Ingredient(s)

Drug Facts

Active ingredient

65% Ethyl Alcohol*

Purpose

.....
Purpose
..... Antiseptic

Purpose... Antiseptic

Use

Uses

- to reduce bacteria on hands
- when soap and water are not available

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Warnings

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- **for external use only**
- flammable, keep away from heat and flame
- **do not use** on open wounds
- avoid eyes, ears and mouth. In case of contact, rinse thoroughly with water

Warnings

Stop and ask doctor if

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- irritation or rash occurs
- you may report side effects to 1-800-315-4467

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Keep out of reach of children

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

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Other information

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- Store between 59 - 86°F (15 - 30°C).
- Avoid freezing 32°F (0°C)
- Avoid excessive heat above 104°F (40°C).

Store between 15-30C (59-86F)
Avoid freezing 32 F (0 C)
Avoid excessive heat above 140 F (40 C)

Inactive ingredients

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acrylate polymer, bittering agent, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, water

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Directions

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- Place enough product on hands to cover all areas
- Rub hands together until dry
- Supervise children under 6 years of age when using this product to avoid swallowing
- Do not use on children less than 2 months of age

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Questions?

Questions? ☎ 1-800-315-4467, Monday through Friday 8am to 5pm EST

Questions? 1-800-315-4467 Monday through Friday 8am to 5pm ES

Package Label - Principal Display Panel



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75660-054
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2460.52 mL in 3785.41 mL
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Inactive Ingredients

Ingredient Name	Strength
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPAS NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	18.93 mL in 3785.41 mL
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	0.38 mL in 3785.41 mL
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	75.71 mL in 3785.41 mL
GLYCERIN (UNII: PDC6A3C0OX)	51.1 mL in 3785.41 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	6.81 mL in 3785.41 mL
WATER (UNII: 059QF0KO0R)	1172.34 mL in 3785.41 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75660-054-04	4 in 1 BOX	09/01/2020	
1	NDC:75660-054-01	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:75660-054-05	18927.05 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/30/2020	
3	NDC:75660-054-44	118.29 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/30/2020	
4	NDC:75660-054-08	239.58 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/30/2020	
5	NDC:75660-054-16	473.17 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/30/2020	
6	NDC:75660-054-25	9463.52 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/30/2020	
7	NDC:75660-054-01	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
8	NDC:75660-054-06	6 in 1 BOX	03/30/2020	
8	NDC:75660-054-01	3785.41 mL in 1 BOTTLE; 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	03/01/2020	

Labeler - Solents and Petroleum Service INC (013277454)

Establishment

Name	Address	ID/FEI	Business Operations
Clean All		117505240	manufacture(75660-054)

