# GEL HAND SANITIZER WINTERGREEN- alcohol gel Sovents and Petroleum 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.

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## Wintergreen Scented Clean All Gel Hand Sanitizer

Active Ingredient(s)

Drug Facts

Active ingredient

Alcohol 65% Ethyl Alcohol\*

Purpose

Purpose \_\_\_\_ Antiseptic

Antiseptic, Hand Sanitizer

Use

Uses

to reduce bacteria on hands

To reduce bacteria on hands. • when soap and water are not available

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 open wounds, avoid eyes, ears and mouth. In case of contact, rinse with water

Warninas

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- 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

Stop use and ask a doctor if irritation or rash occurs., you may report side effects 1-800-315-4467

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you may report side effects to 1-800-315-4467

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

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#### **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.
- Do not use on children less than two months of age

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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 and excessive heat above 40C (104F)

## **Inactive ingredients**

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

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## Questions

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

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Package Label - Principal Display Panel



## **GEL HAND SANITIZER WINTERGREEN**

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75660-124	
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
ACRYLATES/VINYL ISODECANO ATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8 MDB79 NA)	0.5 mL in 100 mL

0.01.........................

DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)	in 100 mL
GAULTHERIA PROCUMBENS LEAF (UNII: 2125M16OWN)	0.01 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.35 mL in 100 mL
HYDROGEN PERO XIDE (UNII: BBX060AN9V)	0.18 mL in 100 mL
WATER (UNII: 059QF0KO0R)	30.95 mL in 100 mL
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	2 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75660-124- 01	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/13/2020	
2	NDC:75660-124- 04	4 in 1 BOX	10/13/2020	
2	NDC:75660-124- 01	$3785.41\mathrm{mL}$ in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:75660-124- 05	18927.05 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/13/2020	
4	NDC:75660-124- 06	6 in 1 BOX	10/13/2020	
4	NDC:75660-124- 01	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:75660-124- 44	118.29 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/13/2020	
6	NDC:75660-124- 08	236.59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/13/2020	
7	NDC:75660-124- 16	473.17 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/13/2020	
8	NDC:75660-124- 25	9463.52 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/13/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	10/13/2020		

## **Labeler** - Sovents and Petroleum Inc (013277454)

Establishment				
Name	Address	ID/FEI	Business Operations	
Clean All		117505240	manufacture(75660-124)	

Revised: 10/2020 Sovents and Petroleum Inc