

ALCOHOL ANTISEPTIC- alcohol solution
J & S Chemical Corporation

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.

Drug Facts

Active ingredient[s]

Alcohol 80% v/v

Purpose

Antiseptic

Use[s]

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 15-30C (59-86F)

- Avoid freezing and excessive heat above 40C (104F)
- **Inactive Ingredients** glycerin, hydrogen peroxide, purified water USP

Principal Display Panel -

J&S Chemical™

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer

Non-sterile Solution

Manufactured in Compliance to FDA Guidelines



Alcohol Antiseptic 80% Topical Solution		
Hand Sanitizer Non-sterile Solution <i>Manufactured in Compliance to FDA Guidelines</i>		
 	DANGER	UN 1987
<small> DOT Name: UN 1987, Ethanol, N.O.S., 3 PG 2 Hazard Statement: Highly flammable liquid and vapor. Causes serious eye irritation. May cause damage to organs. Precautionary statements: Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/Bond Container and receiving equipment. Use explosion proof Electrical/Ventilating equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/footwear. IF SWALLOWED, Immediately call a POISON CENTER or doctor/physician. IF ON SKIN, Take off immediately all contaminated clothing. Rinse skin with water/shower. IF IN EYES, Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do so. Continue rinsing. If eye irritation persists, get medical advice/attention. In case of fire use sand, dry chemical or alcohol-resistant foam to extinguish. Store in a well-ventilated place. Keep cool. Dispose of contents and container to an approved waste facility. </small>		<small> Drug Facts Active ingredient(s) Alcohol 80% v/v Purpose Antiseptic Uses 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. </small>
<small> 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 45°C (105°F) • Inactive ingredients: glycerin, hydrogen peroxide, purified water USP </small>		
Lot#:		Volume:
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ALCOHOL ANTISEPTIC

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76948-0005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	800 mL in 1 L

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Hydrogen Peroxide (UNII: BBX060AN9V)	
Denatonium Benzoate (UNII: 4YK5Z54AT2)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76948-0005-1	19 L in 1 PAIL; Type 0: Not a Combination Product	03/27/2020	
2	NDC:76948-0005-2	208 L in 1 DRUM; Type 0: Not a Combination Product	03/27/2020	
3	NDC:76948-0005-3	1041 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/27/2020	
4	NDC:76948-0005-4	3.78 L in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/27/2020	
5	NDC:76948-0005-5	.946 L in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/27/2020	

Labeler - J & S Chemical Corporation (074551862)

Establishment

Name	Address	ID/FEI	Business Operations
J & S Chemical Corporation		074551862	MANUFACTURE(76948-0005)

Revised: 4/2020

J & S Chemical Corporation