

INSTANT HAND SANITIZER- alcohol solution
Theochem Laboratories

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.

Active Ingredient(s)

Alcohol 70% 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

- on 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.

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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.

Other information

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP, dye, fragrance

INSTANT HAND SANITIZER, 473 ML, NDC: 68878-001-01

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Other Information:

- Store between 15°C - 30°C (59°F - 86°F).
- Avoid freezing and excessive heat above 40°C (104°F).
- Non-Sterile solution.

Inactive Ingredients:
Glycerin, hydrogen peroxide, purified water USP, dye and fragrance.

103600-0520v1



a family company, since 1962

INSTANT HAND SANITIZER

**CLEAN
HYDRATE
PURIFY**

alcohol antiseptic
fresh breeze scent
kills 99.9% of germs

proudly & responsibly manufactured in the USA

Drug Facts

Active Ingredient	Purpose
Alcohol 70% v/v	Antiseptic

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Tampa, FL 33610 • Call 800-237-2591
Net Contents: 16 fl. oz./473 ml



INSTANT HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68878-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0KO0R)	28.425 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68878-001-01	12 in 1 CARTON	05/25/2020	
1	NDC:68878-001-00	0.473 L 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	05/25/2020	

Labeler - Theochem Laboratories (004100038)

Registrant - Theochem Laboratories (004100038)

Establishment

Name	Address	ID/FEI	Business Operations
Theochem Laboratories		004100038	manufacture(68878-001)

Revised: 5/2020

Theochem Laboratories