

**SANI SCHUTZ- alcohol solution**  
**Schutz NA LLC**

*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.*

-----

**Hand Sanitizer Gel**

The hand rub is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (0.56% v/v).
- c. Hydroxyethylcellulose (2.23% v/v).
- d. Sodium Lactate (0.50% v/v).
- e. Vitamin E (0.44% v/v)
- f. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 75% v/v. Purpose: Antiseptic

**Purpose**

Bulk Antiseptic, Hand Rub

**Use**

Bulk Hand Sanitizer, not for individual use

**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

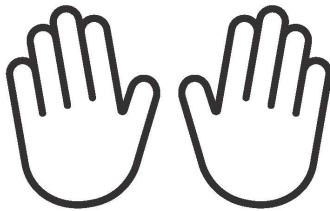
glycerin, hydroxyethylcellulose, vitamin e, purified water

## Package Label - Principal Display Panel

100 mL NDC: 78555-001-03



**SaniSchutz**  
Hand Sanitizer



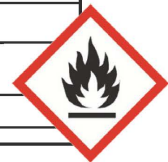
Dr. Schutz US /Schutz NA · 8701 Torresdale  
#P-Philadelphia PA 19136 · Tel.: 877-272-4889  
info@dr-schutz.us · www.dr-schutz.us



**100 ml**

**Active substances:** Active ingredients: ethyl alcohol.  
Composition: 100g solution contain: Active ingredients ethyl alcohol (99%) 75g,  
Inactive: Glycerin, Hydroxyethylcellulose, Sodium Lactate, Vitamin E purified water.  
Very good tolerability even with long-term use. Excellent immediate effect. Effective  
against enveloped viruses. Helps to moisturize the skin with repeated use. (official  
**BauA German registration number N-90280). FDA NDC: 78555-001-03**  
Before use always read the product information and observe the labelling!  
**Application:** Before disinfection, hands and wrists must be washed well with soap  
and free of coarse dirt. The SaniSchutz Hand Sanitizer is applied to the dry palms -  
rub hands twice with about 3 ml of the solution and keep them moist for 30 seconds,  
rub them inside and outside on both hands, especially fingertips, thumbs, nail folds  
and wrists must be included.

Drug Facts	
Active Ingredient(s)	Purpose
Alcohol 75% w/v	Antiseptic
Use(s)	
Antiseptic, Bulk hand sanitizer for rebottling	
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 wound	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes rinse eyes thoroughly with water	
Stop use ask a Doctor if irritation or rash occurs. These may be sign of serious condition.	
Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away	
Directions	
• DO NOT USE, Bulk Hand Sanitizer. Not for individual use	
Other Information	
• Store between 15 -30C (59 - 86F)	
• Avoid Freezing and excessive heat above 40C (104F)	
Inactive ingredients Hydroxyethylcellulose, Glycerin, Sodium Lactate, Vitamin E, Deionized Water	



## SANI SCHUTZ

alcohol solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78555-001
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	21.267 mL in 100 mL
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	2.233 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	.56 mL in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT)	.50 mL in 100 mL
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	.44 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78555-001-03	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/08/2020	

**Labeler** - Schutz NA LLC (014008554)**Establishment**

Name	Address	ID/FEI	Business Operations
Schutz NA LLC		014008554	manufacture(78555-001)

Revised: 6/2020

Schutz NA LLC