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

Antiseptic, Hand Rub

Use

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

5 L (5000 mL) NDC: 78555-001-04

Dr. Schutz®

4 001936 008814

4700000500 D/GB 04.20

SaniSchutz Hand Sanitizer

US For the hygienic disinfection of hands, use with caution. Always read the label before using. Contra-indications: not suitable for the disinfection of mucous membranes. Do not use in close proximity of the eyes or of open wounds. Over-sensitivity (allergy) to one of the ingredients. Side-effects: can occasionally lead to slight dryness or irritation of the skin. In such cases the intensification of general skin care is recommended. Warning: should not be used on newly or prematurely born babies. Do not use in the proximity of open flames, sparks, or other sources of ignition. Flammable. When the product is used in accordance with regulations no danger of fire or explosion is to be expected. In the event of spillage of the SaniSchutz hand-disinfectant the following measures are to be taken: immediately wipe up the liquid, dilute the spillage with plenty of water, ventilate the rooms and remove any sources of ignition. Do not smoke. In case of fire, extinguish with water, extinguishing powder, foam or CO2. Danger! Highly flammable liquid and vapor. If medical advice is needed, have product container or label at hand. Keep out of reach of children. Read label before use. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground and bond container and receiving equipment. Use explosion-proof [electrical/ventilating/lighting] equipment. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Dispose of contents/container in accordance with local regulations.

Drug Facts

Active Ingredient(s) — **Purpose**
Alcohol 75% v/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 betwenn 15 30C (59 86F)
- Avoid Freezing and excessive heat above 40C (104F)

Inactive ingredients Hydroxyethylcellulose, Glycerin, Sodium Lactate, Vitamin E, Deionized Water

Active substances: ethyl alcohol
Chemical composition contains:active substances ethylalcohol(75%ig)
Other ingredients:Hydroxyethylcellulose,glycerin, Sodium Latate, Vitamin E, deionized water.
NDC: 78555-001-04

5l

Eine Marke der Dr. Schutz GROUP

Dr. Schutz / Schutz NA LLC 8701 Torresdale Ave #P
Philadelphia PA 19136 USA Tel.: +1 877-272-4889
·info@dr-schutz.us · www.dr-schutz.us

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:78555-001-04	5000 mL in 1 CONTAINER; 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