## SCB-HS-70C- alcohol gel SMK Holdings 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.

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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer 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) (80%, 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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. 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 80% 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

- 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.

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

#### **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

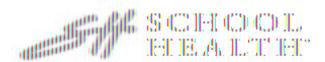
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## **Package Label - Principal Display Panel**

.06L NDC: 77177-002-06



# AMUSENTIC GEL HAND SANITUZER

- Unscented
- Alcohol 7'096 w/w
- W/litth Wiltermin E
- Niom-sticky, no residue
- Quick drying
- Moisturizing



Reonder # 10201.62 SchoolHealth.com | 866-323-5465 Drug Facts

Active Ingredient(s) Ethyl Alcohol 7096 w/w...

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Imactive Ingredients: Gycelin, bop Gycal/Acrylato: Copolymor, Tocaphoryl Ac

Minufactured for School Health Corporation by: Sugar Creek Bottling Co. 5249: Park Plana Ct. Indianapolis, IN-462201

.6L NDC: 77177-002-01



**Drug Facts** 

Active ingredient[s]
Ethyl Alcohol 70%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**

Fragrance(Parfum), Glycerin, Isopropyl Myristate, PEG-6 & AMP Acrylates / Vinyl Isodecanoate Crosspolymer, Tocopheryl Acetate, Water

.12L NDC: 77177-002-02



**Drug Facts** 

Active ingredient[s]
Ethyl Alcohol 70%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.

For external use only. Flammable. Keep away from heat or flame

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- 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)

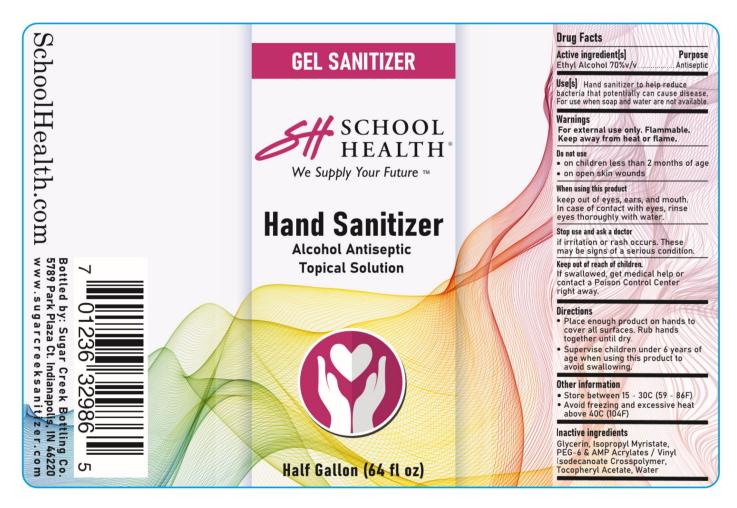
#### **Inactive ingredients**

Fragrance(Parfum), Glycerin, Isopropyl Myristate, PEG-6 & AMP Acrylates / Vinyl Isodecanoate Crosspolymer, Tocopheryl Acetate, Water

3.785L NDC: 77177-002-03



1.89L NDC: 77177-002-04



1.89L NDC: 77177-002-05



#### SCB-HS-70C

alcohol gel

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Prod	nct	Into	rma	tion

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77177-002(NDC:74221-005)

Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)			
.ALPHATO COPHERO L ACETATE, DL- (UNII: WR1WPI7EW8)			
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)			

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:77177-002-01	0.06 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77177-002-02	0.12 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77177-002-03	$3.785\ L$ in $1\ BOTTLE$ ; Type $0$ : Not a Combination Product	03/30/2020	
4	NDC:77177-002-04	1.89 L in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77177-002-05	1.89 L in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77177-002-06	0.06 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	03/30/2020		

## Labeler - SMK Holdings LLC (095712546)

Establishment					
Name	Address	ID/FEI	Business Operations		
SMK Holdings LLC		095712546	repack(77177-002)		

Revised: 7/2020 SMK Holdings LLC