CREME 21 HAND SANITIZER- alcohol gel
Creme 21 GmbH

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.

ALCOHOL 65% v/v..... antimicrobial

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.

Keep out of children. If swallowed, get medical help or contact a poison control centre right away.

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of serious condition.

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

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

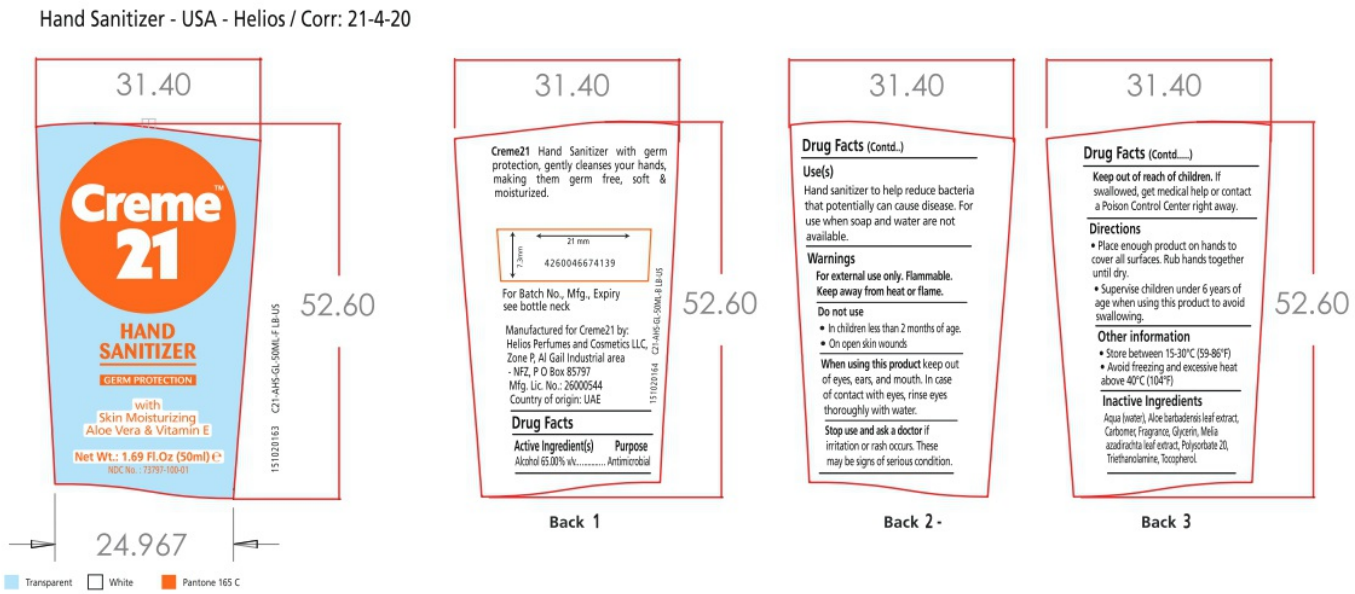
Aqua (water), Aloe barbadensis leaf extract, Carbomer, Fragrance, Glycerin, Melia azadirachta leaf extract, Polysorbate 20, Triethanolamine, Tocopherol.

Place enough products on hands to cover all surfaces. Rubs hands together until dry.
Supervise children under 6 years of age when using this products to avoid swallowing.

USES: Hand sanitizer to help reduce bacteria that potentially cause disease. For use when soap and water are no available.

Dosage-Gel

Route of administration-Topical



CREME 21 HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73797-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	6.5 mL in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
MELIA AZEDARACH LEAF (UNII: 8194E3H7D4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73797-100-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2020	
2	NDC:73797-100-02	59 mL in 1 TUBE; Type 0: Not a Combination Product	04/01/2020	
3	NDC:73797-100-03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2020	

Labeler - Creme 21 GmbH (315190250)

Registrant - Creme 21 GmbH (315190250)

Establishment

Name	Address	ID/FEI	Business Operations
Helios Perfumes and Cosmetics LLC		851721102	manufacture(73797-100) , analysis(73797-100) , pack(73797-100)

Establishment

Name	Address	ID/FEI	Business Operations
ACCRA PAC (INDIA) PRIVATE LIMITED		859652454	manufacture(73797-100)

Revised: 4/2020

Creme 21 GmbH