

**CREME 21 HAND SANITIZER GERM PROTECTION WITH ALOE VERA AND GLYCERIN-
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 70% v/v..... antimicrobial

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

Do not use

In children less than 2 months of age

On open skin wounds

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

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 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), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Caprylyl Glycol, Fragrance, Glycerin, Isopropyl alcohol, Isopropyl Myristate, Tocopheryl acetate.

Place enough products on hands to cover all surfaces. Rubs hands together until dry.

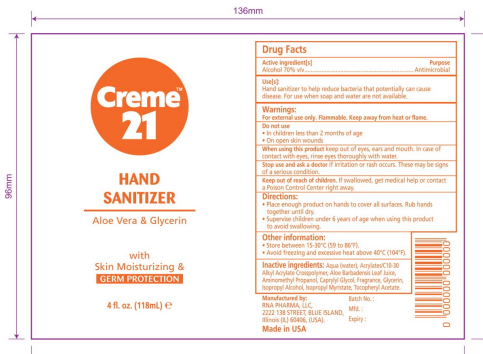
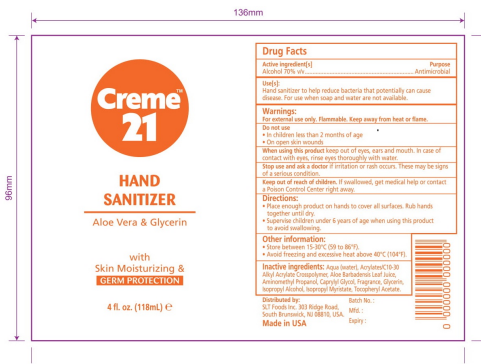
Supervise children under 6 years of age when using this products to avoid swallowing.

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

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

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.



CREME 21 HAND SANITIZER GERM PROTECTION WITH ALOE VERA AND GLYCERIN

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73797-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	7 mL in 10 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

ALOE VERA LEAF (UNII: ZY81Z83H0X)

GLYCERIN (UNII: PDC6A3C0OX)

CAPRYLYL GLYCOL (UNII: 00YIU5438U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73797-103-07	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
2	NDC:73797-103-08	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
3	NDC:73797-103-09	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
4	NDC:73797-103-10	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/03/2020	

Labeler - Creme 21 GmbH (315190250)

Registrant - Creme 21 GmbH (315190250)

Establishment

Name	Address	ID/FEI	Business Operations
RNA PHARMA, LLC		079103999	manufacture(73797-103)

Revised: 5/2020

Creme 21 GmbH