AUGUSTINUS BADER THE HAND SANITIZER- augustinus bader the hand sanitizer solution ASC REGENITY LIMITED

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.

DRUG FACTS

Active Ingredient(s)

Alcohol 68%

Purpose

Antiseptic

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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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

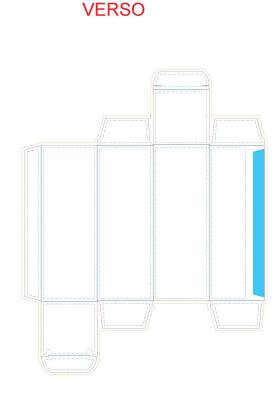
- Store between 15-30C (59-86F)
 - Avoid freezing and excessive heat above 40C (104F)

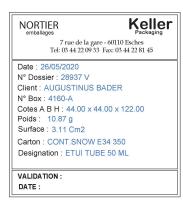
Inactive ingredients

Water, Glycerin, Ammonium Polyacryloyldimethyl Taurate, T-Butyl Alcohol, Denatonium Benzoate

Principal Display Panel









AUGUSTINUS BADER THE HAND SANITIZER

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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79322-010	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	68 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371)	
WATER (UNII: 059QF0KO0R)	
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	

I	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79322-010-50	1 in 1 CARTON	06/29/2020		
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/29/2020		

Labeler - ASC REGENITY LIMITED (222266461)

Revised: 6/2020 ASC REGENITY LIMITED