VOP.1 SAFETY SANITIZER- alcohol gel Crown United

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.

ACTIVE INGREDIENT

ALCOHOL 70% w/w

INACTIVE INGREDIENTS

Water, Herb aroma HF-31002, Triethanolamine, Glycerin, Propylene glycol, Carbomer, Polygamma glutamic acid

Purpose

ANTISEPTIC

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.

Uses

- •instant hand antiseptic to decrease bacteria on the skin
- recommended for repeated use

Directions

- Apply to clean, dry hands. Apply sufficient amount to thoroughly wet all surfaces of hands and fingers. Rub onto hands until dry.
- Supervise children in the use of this product.

Other information

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

- May discolor some fabrics
- Harmful to wood finishes and plastics

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



VOP.1 SAFETY SANITIZER

alcohol gel

Product	Inform	nation
Product	INIAFE	narinn

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:778 15-0 10

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)ALCOHOL350 g in 500 mL

Inactive Ingredients Ingredient Name Strength Water (UNII: 059QF0KO0R) TROLAMINE (UNII: 9O3K93S3TK) Glycerin (UNII: PDC6A3C0OX) Propylene glycol (UNII: 6DC9Q167V3) CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:77815-010-	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination	05/01/2020	

01 F	Product	03/01/2020			
Marketing Information					
Marketing Catego	ry Application Number or Monograph Citatio	n Marketing Start Date	Marketing End Date		
OTC monograph not fin	nal part333E	05/01/2020			

Labeler - Crown United (694803095)

Registrant - Crown United (694803095)

Establishment						
Name	Address	ID/FEI	Business Operations			
Samhyun pharma		694185214	manufacture(77815-010)			

Revised: 5/2020 Crown United