SANIKLEAN E3 HAND SANITIZER- alcohol liquid Bunzl Processor Distribution 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.

Drug Facts

Active Ingredients

Ethyl Alcohol 70% (v/v)

Purpose

Hand Sanitizer

Uses

Hand wash to help reduce bacteria that potentially can cause diseases

Helps prevent cross contamination by hand contact

Helps prevent drying and chafing of skin

Recommended for repeated use

Warnings

For External use only

Flammable, keep away from fire or flame

When using this product

Do not use in or near eyes

Use in well-ventilated area

Discontinue use if irritation and/or redness develops

Keep out of reach of children.

In case of accidental ingestion, seek medical attention or contact Poison Control Center immediately

Directions

Wet hands thoroughly with product, covering entire surface of hands, including fingertips, cuticles, wrists and forearms

Rub vigorously into skin until dry

No rinsing or toweling required

Store in a cool dry place below 104 F

For Food Processing, Food Service and Professional Use Only

NDC 21532-1410-1

Inactive Ingredients

Purified Water, Glycerin

SaniKleen

E3 Hand Sanitizer

Marketed By:

Bunzl

528 East 19th Avenue

North Kansas City, MO 64116

CONTENTS: 1 Gallon

SANIKLEAN E3 HAND SANITIZER

alcohol liquid

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21532-1410

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

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Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		

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	#]	tem Code	Package Description	Marketing Start Date	Marketing End Date
		C:21532- .0-1	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/05/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	0 1/0 1/20 0 6			

Labeler - Bunzl Processor Distribution LLC (007169634)

Establishment				
Name	Address	ID/FEI	Business Operations	
Central Solutions Inc		007118524	manufacture(21532-1410)	

Revised: 12/2018 Bunzl Processor Distribution LLC