PROSERA SOOTHING HAND SANITIZER- alcohol liquid
D-Time Limited Liability Company

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.

Prosera Soothing Hand Sanitizer

Active Ingredient

Alcohol 80% v/v.

Purpose

Antiseptic skin cleanser

Use

For personal hand hygiene to help prevent the spread of bacteria

Warning

For external use only
When using this product avoid contact with eyes.
Flammable. Keep away from heat and flame.

Ask doctor

Stop use and consult a healthcare professional if irritation develops.

Keep out of reach of children.

If swallowed, contact a Poison Control Center or , get medical help right away.

Directions

Adults and children over 2 years: • For occasional and personal domestic use • Supervise children when they use this product • Spray onto hands and rub thoroughly for at least 30 seconds. Allow to dry.

Inactive ingredients

Water, Isopropyl alcohol, Glycerin, Hyaluronic Acid, Allantoin, Vitamin E, Vetiver Oil, Sage Oil, Hydrogen Peroxide

Other information

Store at 68 to 70 F (20 to 25 C). May discolor certain fabrics on surfaces

Questions?

1-844-800-6858

PROSERA SOOTHING HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75306-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYALURONIC ACID (UNII: S270N0TRQY)	
ALLANTOIN (UNII: 344S277G0Z)	

.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
VETIVER OIL (UNII: 9M9P32M01L)	
SAGE OIL (UNII: U27K0H1H2O)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75306-004-01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
2	NDC:75306-004-02	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
3	NDC:75306-004-03	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
4	NDC:75306-004-04	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
5	NDC:75306-004-05	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
6	NDC:75306-004-06	150 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
7	NDC:75306-004-07	160 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
8	NDC:75306-004-08	200 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
9	NDC:75306-004-09	250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
10	NDC:75306-004-10	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
11	NDC:75306-004-11	1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
12	NDC:75306-004-12	3785 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
13	NDC:75306-004-13	18927 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
14	NDC:75306-004-14	5000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
15	NDC:75306-004-15	10000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
16	NDC:75306-004-16	15000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	
17	NDC:75306-004-17	20000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/21/2020	

Labeler - D-Time Limited Liability Company (081728006)

Establishment

Name	Address	ID/FEI	Business Operations
D-Time Limited Liability Company		081728006	manufacture(75306-004)