PROSERA HAND SANITIZER- ethyl alcohol spray
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.

Active Ingredient

Ethyl alcohol 80%

Purpose

Antiseptic skin cleanser

Uses

For personal hand hygiene to help prevent the spread of bacteria

Warnings

For external use only

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and consult a healthcare professional if irritation develops.

Flammable. Keep away from open flame and sources of heat

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 •
- Rub thoroughly into hands for at least 30 seconds. Allow to dry.

Inactive ingredients

Aqua, Glycerin, Vitamin E, Sage Oil, Hydrogen peroxide, Sodium pyruvate

Other Information

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

Label

PROSERA HAND SANITIZER

ethyl alcohol spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75306-008
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
SAGE OIL (UNII: U27K0H1H2O)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
SODIUM PYRUVATE (UNII: POD38AIF08)	

Packaging				
			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75306-008-01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
2	NDC:75306-008-02	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
3	NDC:75306-008-03	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
4	NDC:75306-008-04	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
5	NDC:75306-008-05	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
6	NDC:75306-008-06	150 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
7	NDC:75306-008-07	160 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
8	NDC:75306-008-08	200 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
9	NDC:75306-008-09	250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
10	NDC:75306-008-10	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
11	NDC:75306-008-11	1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
12	NDC:75306-008-12	3785 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
13	NDC:75306-008-13	18927 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
14	NDC:75306-008-14	5000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
15	NDC:75306-008-15	10000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
16	NDC:75306-008-16	15000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	
17	NDC:75306-008-17	20000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - D-Time Limited Liability Company (081728006)

Establishment

Name	Address	ID/FEI	Business Operations
D-Time Limited Liability Company		081728006	manufacture(75306-008)

Revised: 11/2021 D-Time Limited Liability Company