

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
Désinfectant pour les mains

80% Alcohol
80% d'alcool

Vitamin E
vitamine E

Sodium Pyruvate
pyruvate de sodium

Clary Sage Oil
huile de sauge sciarée

60ml

Shake well before use
Bien secouer avant utilisation

Made in USA by
Fabrique aux
Etats-Unis par
Prosera
28 Chamberlain Rd,
Oak Ridge, NJ 07438

USA NDC
00000-000-0

Canada NPN
00000000

CRUELTY FREE
PARABEN FREE
SLS FREE
SULFATE FREE

0 650003 855178

Drug Facts / Info-médicament
Active Ingredient / Ingrédient actif
Ethyl Alcohol 80% Antiseptic skin cleanser
Alcool éthylique 80% Nettoyant antiseptique pour la peau

Purpose / Utilité
Antiseptic skin cleanser

Use / Usage
For personal hand hygiene to help prevent the spread of bacteria. / Pour l'hygiène personnelle des mains afin de prévenir la propagation de bactéries.

Warnings / Mises en garde
For external use only. / Pour usage externe seulement.
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and consult health care professional if irritation develops. / Lorsque vous utilisez ce produit évitez tout contact avec les yeux. Le cas échéant, bien rincer avec de l'eau. Cessez d'utiliser et consultez professionnel de la santé si une irritation se développe.

Flammability warning - Keep away from open flame and sources of heat.
Avertissement - Inflammable tenir loin des flammes et sources de chaleur.

Keep out of reach of children. If swallowed, contact a Poison Control Center or get medical help right away. / Garder hors de la portée des enfants. En cas d'ingestion, appeler immédiatement un centre antipoison ou obtenir une assistance médicale.

Directions / Mode d'emploi
Adults and children over 2 years. For occasional and personal domestic use. Rub hands together when they use this product. Rub thoroughly into hands for at least 30 seconds. Allow to dry. / Adultes et enfants de plus de 2 ans. Pour une utilisation occasionnelle pour usage domestique personnel. Superposer les mains durant l'utilisation de ce produit. Bien frotter pendant au moins 30 secondes. Laisser sécher.

Other information / Autres renseignements
Store at 68° to 70° F (20° to 25° C). May discolor certain fabrics or surfaces. / Conserver entre 20°C et 25°C (68°F et 70°F). Peut décolorer certains tissus et surfaces.

Inactive ingredients / Ingrédients inactifs
Aqua, Glycerin, Vitamin E, Clary Sage Oil, Hydrogen peroxide, Sodium Pyruvate, Aqua, glycerine, vitamine E, huile de sauge sciarée, peroxyde d'hydrogène, pyruvate de sodium

Questions? 1-844-800-6958
www.prosera.com

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)