

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

80% Alcohol / 80% d'alcool
Hyaluronic Acid / Acide hyaluronique
Vitamin E / vitamine E
Allantoin / allantoiné

60ml
Shake well before use
Bien secouer avant utilisation
www.proseraco.com

Made in USA by
Fabriqué aux
Etats-Unis par
Prosera
26 Park Street
Suite 2035
Montclair, NJ 07042

NDC
00000-000-0
NPN
000000000

QUALITY FREE
PARABEN FREE
SULFATE FREE
SANS
CHARGE PARABEN SULFATE

0 650003 855208

Drug Facts / Info-médicament
Active Ingredient / Ingrédient actif: Antiseptic skin cleanser
Etiquetage bilingue 80% Nettoyant antiseptique pour la peau

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 de produit, 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. Supervise children 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. Superviser les enfants 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 discolorer certains tissus et surfaces.

Inactive ingredients / Ingrédients inactifs
Aqua (isopropyl) Alcohol, Glycerin, Hyaluronic acid, Allantoin, Vitamin E, Vetyver oil, Sage oil, Hydrogen peroxide / Aqua, alcool isopropylique, glycerine, acide hyaluronique, allantoiné, vitamine E, huile de vétiver, huile de sauge, peroxyde d'hydrogène

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)

Revised: 11/2021

D-Time Limited Liability Company