

GERMS BE GONE ANTIBACTERIAL SCENTED- antiseptic hand cream cream BRANDS INTERNATIONAL CORPORATION

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.

Germ Be Gone Antibacterial Hand Sanitizing cream- Scented

Active Ingredient(s)

Benzalkonium chloride 0.05 %.

Purpose

Antiseptic skin cleanser

Use

To help reduce bacteria on hands.

Warnings

For external use only.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Rub thoroughly on hands for at least 30 seconds and allow to dry
- Supervise children when using this product to avoid swallowing.
- Adults and children over 2 years

- For occasional and domestic use

Other information

- Store between 15-30C (59-86F)
- May discolor certain fabrics or surfaces

Inactive ingredients

Aqua (Water), Propylene Glycol, Isopropyl Myristate, Isopropyl Palmitate, Stearyl Alcohol, Ceteareth-20, Glycerin, Glyceryl Stearate, Caprylic/Capric Triglyceride, Stearic Acid, Glycol Stearate, Helianthus Annuus (Sunflower) Seed Oil, Cocos Nucifera Oil (Coconut), Petroleum Jelly, Vitamin E (Tocopherol), DMDM Hydantoin, Allantoin, Aloe Barbadensis Leaf Extract, Perfume

Package Label - Principal Display Panel



Drug Facts / Info-médicament	
Active ingredient (w/w) / Ingrédient actif (p/p) Benzalkonium chloride 0.13 % / Chlorure de benzalkonium 0,13 %	Purpose / Utilité Antiseptic skin cleanser / Nettoyant antiseptique pour la peau
Use / Usage Effective in destroying harmful bacteria to provide antiseptic cleansing / Efficace pour détruire les bactéries nocives et procurer un nettoyage antiseptique	
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. Lorsque vous utilisez ce produit évitez tout contact avec les yeux. En cas de contact, bien rincer avec de l'eau. Stop use and ask a doctor if irritation develops Cessez d'utiliser et consultez un médecin si une irritation se développe Keep out of reach of children. If swallowed, call a poison control centre 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. ■ 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 between 15° C - 30° C / Conserver entre 15° C et 30° C ■ May discolor certain fabrics or surfaces. / Peut décolorer certains tissus ou surfaces.	
Inactive ingredients / Ingrédients inactifs Aqua (Water), Propylene Glycol, Isopropyl Myristate, Isopropyl Palmitate, Stearyl Alcohol, Ceteareth-20, Glycerin, Glyceryl Stearate, Caprylic/Capric Triglyceride, Stearic Acid, Glycol Stearate, Helianthus Annuus (Sunflower) Seed Oil, Cocos Nucifera Oil (Coconut), Perfume, Petroleum Jelly, Vitamin E (Tocopherol), DMDM Hydantoin, Allantoin, Aloe Barbadosensis Leaf Extract.	
Questions? 1-866-234-2345	
Manufactured by Brands International Corporation 594 Newmarket Blvd, Newmarket, ON L3X 2S2 Canada www.brandsicorp.com	
<div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; padding: 5px;">BAR CODE</div> <div>EXP YYYY-MM-DD Lot No. XXXX</div> </div>	

GERMS BE GONE ANTIBACTERIAL SCENTED

antiseptic hand cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50157-524
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
COCONUT OIL (UNII: Q9L0O73W7L)	
PETROLATUM (UNII: 4T6H12BN9U)	
TRICAPRYLIN (UNII: 6P92858988)	
ALLANTOIN (UNII: 344S277G0Z)	
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-524-50	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/14/2021	

Labeler - BRANDS INTERNATIONAL CORPORATION (243748238)

Establishment

Name	Address	ID/FEI	Business Operations
BRANDS INTERNATIONAL CORPORATION		243748238	manufacture(50157-524)

Revised: 8/2021

BRANDS INTERNATIONAL CORPORATION