

NUDESTIX HAND SANITIZER- alcohol gel
HEALKINBIO CO.

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(s)

alcohol

Purpose

Purpose: Antiseptic

Use

☐ Hand sanitizing to help reduce bacteria on the skin

Warnings

- ☐ For external use only.
- ☐ Flammable, keep away from fire or flame.
- ☐ When using this product, avoid contact with the eyes. In case of contact, rinse eyes thoroughly with water.
- ☐ Stop use and ask a doctor if irritation or redness appears and lasts.
- ☐ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

☐ Take suitable amount of sanitizer in the hand. Wet thoroughly and rub hands together until dry
aqua, caprylyl glycol, carbomer, dipropylene glycol, glycerin, hydroxyacetophenone, triethanolamine



NUDESTIX

NUDESTIX^{TM/MC}
ANTIBACTERIAL HAND GEL 75%
GEL ANTIBACTÉRIEN POUR LES MAINS 75%

KILLS HARMFUL BACTERIA / GERMS
TUE DES BACTÉRIES ET MICROBES NOCIFS

250 ML / 8.45 FL. OZ

DISTRIBUTED BY: NUDESTIX USA, INC., 3411 SILVERSIDE ROAD,
RODNEY BUILDING #104, WILMINGTON, DE 19810, UNITED STATES
MANUFACTURED BY: HESUNBIOL, 35 HONGHONGUANG-RO SIBONG-GU,
MANGYANG-KU, INCHON, REPUBLIC OF KOREA
MADE IN KOREA



Drug Facts

ACTIVE INGREDIENT	PURPOSE
Alcohol 75% v/v	Antiseptic

USE(S)

• Antiseptic (skin) cleanser • Medicated (skin) cleanser • Antibacterial (skin) cleanser • Effective in destroying (harmful) bacteria to provide antiseptic cleansing • For personal hand hygiene to help prevent the spread of bacteria

WARNINGS • For external use only. Flammable. Keep away from heat or flame.

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.

DIRECTIONS • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.

OTHER INFORMATION • Store between 15° - 30° C (59° - 86° F) out of direct sunlight • Avoid freezing and excessive heat above 40° C (104° F).

Do not use this product if tamper-resistant seal is broken when opened.

INACTIVE INGREDIENTS aqua, caprylyl glycol, carbomer, dipropylene glycol, glycerin, hydroxyacetophenone, triethanolamine.



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TUE DES BACTÉRIES ET MICROBES NOCIFS

250 ML / 8.45 FL. OZ
NPN 80098392

DIST. BY/PAR: NUDESTIX INC.,
TORONTO, CANADA M8H 5T5
MADE IN KOREA / FABRIQUE EN CORÉE



Antiseptic Skin Cleanser/ Nettoyant antiseptique pour la peau
Active Ingredients / Ingrédients actifs Ethanol 75% / Éthanol 75%

Uses / Usage • Antiseptic (skin) cleanser • Medicated (skin) cleanser • Antibacterial (skin) cleanser • Effective in destroying (harmful) bacteria to provide antiseptic cleansing • For personal hand hygiene to help prevent the spread of bacteria

• Nettoyant antiseptique (pour la peau) • Nettoyant médicamenteux (pour la peau) • Nettoyant antibactérien (pour la peau) • Efficace pour détruire des bactéries (nocives) afin de procurer un nettoyage antiseptique • 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.

Lorsque vous utilisez ce produit éviter tout contact avec les yeux. Le cas échéant, 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 portée des enfants.** En cas d'ingestion, appeler immédiatement un centre antipoison ou obtenir une assistance médicale.

Flammability warning Keep away from open flame and sources of heat.

Avvertissement – Inflammabilité tenir loin des flammes et sources de chaleur.

Directions / Mode d'emploi

Adults and children two years of age and older: rub thoroughly into hands for at least 30 seconds. For occasional and personal domestic use. Supervise children when they use this product.

Adultes et enfants d'au moins deux (2) ans : Bien frotter pendant au moins 30 secondes. Laisser sécher. Pour une utilisation occasionnelle pour usage domestique et personnel. Superviser les enfants durant l'utilisation de ce produit.

Non-medicinal Ingredients / Ingrédients non médicinaux
aqua, glycerin, dipropylene glycol, carbomer, hydroxyacetophenone, triethanolamine, caprylyl glycol.

Questions? www.nudestix.com

NUDESTIX HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76586-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	75 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
TROLAMINE (UNII: 9O3K93S3TK)				
DIPROPYLENE GLYCOL (UNII: E107L85C40)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76586-111-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	07/01/2020	

Labeler - HEALKINBIO CO. (694039685)

Establishment

Name	Address	ID/FEI	Business Operations
HEALKINBIO CO.		694039685	manufacture(76586-111)

Revised: 7/2020

HEALKINBIO CO.