

INSTANT HAND SANITIZER - alcohol liquid
Evonik Stockhausen, LLC

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.

Drug Facts

Active Ingredient

Ethanol (62%)

Purpose

Hand Antiseptic

Uses

Hand antiseptic to decrease bacteria on the skin.

Warnings

Flammable, For external use only.

Avoid contact with eyes. In case of accidental eye contact, flush eyes thoroughly with water.

Discontinue use if irritation and redness develops.

Stop use and ask doctor if

Skin or eye irritation persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Dispense an adequate amount (approx. 5 mL), rubbing all surfaces of both hands for at least 15 seconds.
- Allow to dry without wiping.

Inactive Ingredients

Deionized Water, Isopropanol, Hydrogenated Starch Hydrolysate, Carbomer, THP Ethylendiamine, Fragrance


Principal Display Panel

NDC 64064-002-06

NPN 80023556

Instant Hand

Sanitizer
 No Rinsing
 Desinfectant
 Instantane Pour Les Mains
 Sans Rincage
 Clinishield
 Net Contents 16 Fl. Oz.
 Contenu Net 473mL
 Stock No. 33245
 No. De Stock 33245
 Manufactured in U.S.A./Fabrique Aux E.-U.
 Evonik Stockhausen, Inc.
 Greensboro, NC 27406
 1-800-334-0242 www.CliniShield.com
 Imported by Trans Canada Distribution Inc.
 Mississauga, ON L5L 5Y7

NDC 64064-002-06		NPN 80023556	
<p>Instant Hand SANITIZER NO RINSING</p> <p>DÉSINFECTANT Instantané Pour Les Mains SANS RINÇAGE</p> 			
<p>NET CONTENTS 16 FL OZ CONTENU NET 473ml STOCK NO. 33245 No. De STOCK 33245</p>		<p>Manufactured in U.S.A./Fabriqué aux É.-U. Evonik Stockhausen, Inc. Greensboro, NC 27406 1-800-334-0242 www.CliniShield.com</p>	
<p>Imported by Trans Canada Distribution Inc. Mississauga, ON L5L 5Y7</p>		<p>©2000 Stockhausen, Inc.</p>	

Drug Facts

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Uses Hand antiseptic to decrease bacteria on the skin.	
Warnings <i>Flammable, For external use only.</i> Avoid contact with eyes. In case of accidental eye contact, flush eyes thoroughly with water. Discontinue use if irritation and redness develops. Stop use and ask doctor if Skin or eye irritation persists for more than 72 hours. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ Dispense an adequate amount (approx. 5 mL), rubbing over all surfaces of both hands for at least 15 seconds. ■ Allow to dry without wiping.	
Inactive Ingredients Deionized Water, Isopropanol, Hydrogenated Starch Hydrolysate, Carbomer, THP Ethylenediamine, Fragrance.	

Medicinal ingredient: Ethyl Alcohol 62% v/v

Recommended use or purpose: Antiseptic cleanser to decrease bacteria on the skin.

Directions for use: Use as part of your daily cleansing routine. Pump product into hands and rub thoroughly until dry. Do not rinse.

Risk information: For external use only. Avoid contact with eyes. In case of accidental eye contact, flush eyes thoroughly with water. Discontinue use and consult a health care practitioner if irritation develops. Flammable. Keep away from open flame and sources of heat. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Centre right away.

Non Medicinal Ingredients: Deionized Water, Isopropanol, Hydrogenated Starch Hydrolysate, Tetrahydroxypropyl (THP) Ethylenediamine, Polyacrylic Acid (Carbomer), Fragrance.

Ingrédient médicamenteux: Alcool éthylique 62 % v/v

Utilisation ou usage recommandé : Nettoyant antiseptique diminuant la quantité de bactéries sur la peau.

Mode d'emploi : Utiliser dans le cadre de votre routine de nettoyage quotidienne. Enduire de produit la paume des mains et bien se frotter les mains jusqu'à ce qu'elles soient sèches. Ne pas rincer.

Information relative aux risques : Pour usage externe seulement. Éviter le contact avec les yeux. En cas de contact accidentel avec les yeux, les rincer à fond avec de l'eau. En cas d'irritation, cesser l'utilisation et consulter un médecin. Inflammable. Tenir à l'écart des flammes nues et des sources de chaleur. Tenir hors de portée des enfants. Si le produit est ingéré, immédiatement obtenir de l'aide médicale ou communiquer avec un centre antipoison.

Ingrédients non médicamenteux : Eau déminéralisée, alcool isopropylique, hydrolysat d'amidon hydrogéné, tétrahydroxypropyl éthylenediamine, acide polyacrylique (carbomère), fragrance.



INSTANT HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64064-002
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	62 mL in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Isopropyl Alcohol (UNII: ND2M416302)	
Carbomer Homopolymer Type C (UNII: 4Q93RCW27E)	
Edetol (UNII: Q4R969U9FR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64064-002-06	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/06/2011	

Labeler - Evonik Stockhausen, LLC (089906614)

Establishment

Name	Address	ID/FEI	Business Operations
Evonik Stockhausen, LLC		089906614	manufacture

Revised: 9/2011

Evonik Stockhausen, LLC