PDI SANI-HANDS FOR KIDS ANTIMICROBIAL ALCOHOL GEL HAND WIPESalcohol cloth

Professional Disposables International, Inc.

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.

PDI SANI-HANDS FOR KIDS ANTIMICROBIAL ALCOHOL GEL HAND WIPES

Uses

- For hand washing to decrease bacteria on the skin.
- Recommended for repeated use.
- Dries in seconds.

Warnings

- Flammable, keep away from fire or flame.
- For external use only.
- Do not use in or contact the eyes.
- Discontinue use if irritation and redness develop. If condition persist for more than 72 hours consult a physician.
- If swallowed, get medical help or contact a Poison Control Center immediately.
- **Keep this out of reach of children** unless under adult supervision.

Directions

- To start feed: Remove cover and discard seal from container. From center of wipe roll, pull up wipe corner; tear off first wipe for use. Twist next wipe into a point and thread through the hole in the container cover. Pull through about one inch. Replace cover. Pull out wipes as needed and snap off at 90° angle. Keep center cap closed to prevent moisture loss.
- Wipe hands, fingers, interdigital areas and wrists thoroughly with towelette. Be sure to utilize the entire wipe surface. Allow to dry.
- For dirty hands, use first wipe to clean hands, then discard wipe; sanitize with second wipe.
- Discard after single use.

Other information

Lot No. and Expiration Date can be found on canister

Dosage

For dirty hands, use first wipe to clean hands, then discard wipe; sanitize with a second wipe. Discard after single use.

Inactive ingredients

Water, Propylene Glycol, Glycerin, Carbomer, Aminometyl Propanol, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate

Professional Disposables International, Inc. Orangeburg, NY 10962-1376 - USA - 1-800-999-6423 www.pdipdi.com

Principal Display Panel - 220 Count Canister

SANI-HANDS^(R) FOR KIDS Antimicrobial Alcohol Gel Hand Wipes Kills 99.99% of Germs

Cleans and Moisturizes

Suitable for use prior to eating 135 Wipes 6.0 x 7.5 in (15.24 x 19.05 cm) Front Canister Label



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Back Canister Label



Drug Facts

Active ingredient Alcohol 65.9% by volume

Purpose Antiseptic

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3BP21701

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Drug Facts (continued)

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Purpose

Antiseptic

PDI SANI-HANDS FOR KIDS ANTIMICROBIAL ALCOHOL GEL HAND WIPES

alcohol cloth

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:10819-5004

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
	Alcohol (INII: 3K9958V90M) (Alcohol - INII: 3K9958V90M)	Alcohol	0.650 ml in 1 ml	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q 16 7 V3)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
AMINO METHYL PRO PANEDIO L (UNII: CZ7BU4QZJZ)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
ALPHA-TO CO PHEROL ACETATE (UNII: 9E8 X80 D2L0)		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10819-5004-1	814 mL in 1 CANISTER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	0 1/0 1/20 0 9	

Labeler - Professional Disposables International, Inc. (800777117)

Establishment			
Name	Address	ID/FEI	Business Operations
Professional Disposables International, Inc.		800777117	manufacture

Revised: 1/2012 Professional Disposables International, Inc.