DOUGLAS - HAND SANITIZER 75 PERCENT- is opropyl alcohol gel Douglas Pads & Sports, 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.

Douglas

ACTIVE INGREDIENT

ISOPROPYL ALCOHOL 75%

PURPOSE

ANTISEPTIC

USES

HEALTH CARE PERSONNEL HAND RUB TO HELP REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE.

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 (58-86°F)
- AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40°C (104°F)

INACTIVE INGREDIENTS

DI WATER, CARBOPOL, PROPYLENE GLYCOL, TEA, FRAGRANCE, POLYSORBATE 20



HAND SANITIZER

ANTISEPTIC HAND RUB NON-STERILE SOLUTION

> **Active Ingredients** Isopropyl Alcohol 75%

> > 2 FL OZ (59 mL) NDC 78510-101-12

DRUG FACTS (CONTINUED)

ACTIVE INGREDIENTS

Isopropyl Alcohol 75%......

USES

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

WARNINGS

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

- 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 medial help or contact 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 (58-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

INACTIVE INGREDIENTS

DI Water, Carbopol, Propylene glycol, TEA, Fragrance, Polysorbate 20

DISTRIBUTED BY Douglas Pads & Sports, Inc. 12325 Cutten Road Houston, TX 77066

Made in Canada

DOUGLAS - HAND SANITIZER 75 PERCENT

isopropyl alcohol gel

Product Information

Product Type HU	UMAN OTC DRUG It	tem Code (Source)	NDC:78510-101
-----------------	------------------	-------------------	---------------

Route of Administration TOPICAL

Active Ingradient/Active Mojety

e ingredient/retive worty		
Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

	TROLAMINE (UNII: 9O3K93S3TK)	
ı	POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging					
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:78510-101-12	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/02/2020	

Labeler - Douglas Pads & Sports, Inc (161798285)

Revised: 6/2020 Douglas Pads & Sports, Inc