

HS-70 HANDSANITIZER HANDSANITIZER- alcohol gel
Sharp International Services, 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.

HS-70 HANDSANITIZER SHARP INTERNATIONAL

Drug Active

Active Ingredients	Purpose
Ethyl Alcohol 70%v/v	Antiseptic

Uses:

- Hand sanitizer to help reduce bacteria that potentially can cause disease.
- For use when soap and water are not available.

Stop Use and ask a doctor if

- irritation or rash occurs
- condition persists for more than 72 hours

Do not use

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

Keep out of reach of children

If swallowed, get medical help, or contact a Poison Control Center Right Away

Uses:

Handsanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available

Warnings

- For external use only : hands
- Flammable keep away from heat or flame
- Do not ingest or inhale

Stop use and ask a doctor if

- irritation or rash occurs
- condition persists for more than 72 hours
- Store between 15 - 30C (59 - 86 F)
- Avoid freezing and storage above 40C (140F)

Glycerin

Isopropyl Myristate

Polyethylene Glycol/ Acrylates Copolymer

Tocopheryl Acetate

Water

HS 70

HAND SANITIZER GEL

Manufactured By:
Sharp International Services
12936 FM 787 West
Cleveland, TX 77327

Net Volume: 265 Gallons (1003 Liters)

Drug Facts

Active ingredient(s)	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic

Uses: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

- For external use only: hands
- Flammable, keep away from heat or flame
- Do not ingest or inhale

Do not use

- for 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, flush eyes thoroughly with water.

Stop use and ask a doctor if

- irritation or rash occurs
- condition 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

- Place enough product on hands to cover all surfaces and rub hands together until dry
- Supervise children under 6 years of age when using this product

Other information

- Store between 15 – 30C (59 – 86F)
- Avoid freezing and storage above 40C (104F)

Inactive ingredients – Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74221-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 L in 1 L

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MP.A.S) (UNII: T967IEU43C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74221-003-01	1003 L in 1 CONTAINER; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2020	

Labeler - Sharp International Services, LLC (060597488)

Establishment

Name	Address	ID/FEI	Business Operations
Sharp International Services, LLC		060597488	manufacture(74221-003)

Revised: 6/2020

Sharp International Services, LLC