

HAND SANITIZER- alcohol gel
Ni Hau Industrial Co., Ltd.

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.

Ni Hau Industrial Co., Ltd. 77189-001-45

Active Ingredient(s)

Ethyl Alcohol 75% Purpose: Antiseptic

Purpose

Antiseptic

Use

For hand sanitizing to reduce bacteria on the skin

Warnings

For external use only. Flammable, keep away for fire and flames.

Do not use

When using this product keep out of eyes. In case of eye contact, flush with water. Do not inhale or ingest. Stop use and ask a doctor if skin irritation develops. Keep out of reach of children

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Keep out of reach of children.

Directions

Squeeze a small amount into your palm and briskly rub together until dry.

Inactive ingredients

Water (Aqua), Propanediol, Polyacrylic Acid, Triethanolamine Cyclohexane

Package Label - Principal Display Panel

Drug Facts

Active Ingredient	Purpose
Urea (Ammonium Carbamate)	Antipruritic

Urea - For hand sanitizing to reduce bacteria on the skin.

Warnings For external use only. Flammable. Keep away from fire and flames.

When using this product Keep out of eyes. In case of eye contact, flush with water. Do not breathe or ingest. Stop use and ask a doctor if skin irritation develops. Keep out of reach of children.

Directions Dispense small amount in your palm and briefly rub hands together until dry.

Inactive Ingredients Water (Aqua), Propylene Glycol, Polyacrylic Acid, Hexylcetyl Alcohol, Triethyl Citrate, Triethylamine, Cyclohexane



45 mL NDC: 77189-001-45

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77189-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
TRIETHANOLAMINE 2-CYCLOHEXYL-4,6-DINITROPHENOLATE (UNII: N2TK31JIAH)	
PROPANEDIOL (UNII: 5965N8W85T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77189-001-45	45 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/07/2020	

Labeler - Ni Hau Industrial Co., Ltd. (658274464)

Establishment

Name	Address	ID/FEI	Business Operations
Ni Hau Industrial Co., Ltd.		658274464	manufacture(77189-001)

Revised: 5/2020

Ni Hau Industrial Co., Ltd.