

NIC GPE 80- alcohol liquid
North Industrial Chemicals, 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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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. 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.

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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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

NIC GPE 80 Alcohol Antiseptic 80%		UN1170 Ethanol Solution 3, PG II
Topical Solution		
Drug Facts		
Active ingredient[s]	Purpose	
Alcohol 80% v/v.....	Antiseptic	
Use[s]		
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		
Warnings		
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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.		
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DANGER

Highly flammable liquid and vapor. Causes skin and eye irritation. Toxic to aquatic life.

Store in a well ventilated place. Keep container tightly closed. Dispose of contents / container in accordance with local / regional / national / international regulations

Precautions:

Keep away from heat/sparks/open flames/hot surfaces. Keep container tightly closed. Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wash skin thoroughly after handling. Avoid release to the environment. Wear protective gloves/protective clothing/face protection/eye protection.

First Aid:

If on Skin: Remove/take off immediately all contaminated clothing. Rinse skin with water/shower.

If in Eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention.

For Industrial Use Only. Observe Label Instructions and consult SDS before handling

260 Gal NDC: 77889-180-01

NIC GPE 80

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77889-0180
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 g in 100 g
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 g in 100 g
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77889-0180-2	260 g in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - North Industrial Chemicals, Inc (015153901)**Establishment**

Name	Address	ID/FEI	Business Operations
North Industrial Chemicals, Inc		015153901	manufacture(77889-0180)

Revised: 6/2020

North Industrial Chemicals, Inc