HAND SANITIZER- isopropyl alcohol spray
Ibex Chemicals

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. Isopropyl Alcohol (75%, 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)

Xtra Hand Sanitizer

Ibex Chemicals, Inc.
12950 Emmett Rd.
Houston, TX 77041
Emergency Telephone (713) 937-4533

Isopropyl Alcohol Antiseptic 75% Topical Solution
Hand Sanitizer
NON-Sterile Solution

Drug Facts	
Active ingredient[s]	*Purpose*
Isopropyl alcohol 75% v/v...Antiseptic	

Use[s]
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 15-30C (59-86F)
• Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

NET CONTENTS:
16 fl.oz.

LOT NUMBER: 022150

MADE IN USA

IBEX CHEMICALS, INC.

Purpose

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.

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Xtra Hand Sanitizer

IBEX

Ibex Chemicals, Inc.
12950 Emmett Rd.
Houston, TX 77041
Emergency Telephone (713) 937-4533

Isopropyl Alcohol Antiseptic 75% Topical Solution
Hand Sanitizer
NON-Sterile Solution

Drug Facts

Active ingredient[s] **Purpose**
Isopropyl alcohol 75% v/v...Antiseptic

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

NET CONTENTS:
16 fl.oz.

LOT NUMBER: 022150

MADE IN USA

IBEX CHEMICALS, INC.

IBEX

473 ml NDC: 78693-123-01

HAND SANITIZER

isopropyl alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78693-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78693-123-01	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	

IBEX

Xtra Hand Sanitizer

Ibex Chemicals, Inc.
12950 Emmett Rd.
Houston, TX 77041
Emergency Telephone (713) 937-4533

Isopropyl Alcohol Antiseptic 75% Topical Solution
Hand Sanitizer
NON-Sterile Solution

Drug Facts

Active ingredient[s] — **Purpose**
Isopropyl alcohol 75% v/v...Antiseptic

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

NET CONTENTS:
16 fl.oz.

LOT NUMBER: 022150

MADE IN USA

IBEX CHEMICALS, INC.

IBEX

Marketing Information

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

Labeler - Ibex Chemicals (789850088)

Registrant - Ibex Chemicals (789850088)

Establishment

Name	Address	ID/FEI	Business Operations
Ibex Chemicals		789850088	manufacture(78693-123)

Revised: 5/2020   Ibex Chemicals