

HAND SANITIZER- isopropyl alcohol liquid
SMARKCHEM INDUSTRIES 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.

Hand Sanitizer

Active Ingredient(s)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

- a. Isopropyl Alcohol (75%, v/v)
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. water

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.

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, water

Package Label - Principal Display Panel

3.785 L NDC: 75812-7500-01

Drug Facts	
Active ingredient(s) Isopropyl alcohol 75% v/v	Purpose 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 <ul style="list-style-type: none">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 <ul style="list-style-type: none">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 <ul style="list-style-type: none">Store between 15-30C (59-86F).Avoid freezing and excessive heat above 40C (104F).	
Inactive ingredients: glycerin, hydrogen peroxide, water.	

KEEP OUT OF REACH OF CHILDREN WARNING: FLAMMABLE PRODUCT
READ CAREFULLY OTHER CAUTIONS AND DIRECTIONS ON THIS LABEL BEFORE USE



HAND SANITIZER

A D V A N C E D

ISOPROPYL ALCOHOL ANTISEPTIC 75%
TOPICAL SOLUTION

- HAND SANITIZER
- NON-STERILE SOLUTION

Net Content:
1 Gallon (3.785 L)

NDC: 75812-750-01

SMARKCHEM INDUSTRIES INC - 8636 Otis St, South Gate, CA 90280 - Phone: +1(323)268-8184 - Fax: +1(323)268-8158 - Email: csr@smarkchemicals.com

LIQUID

473 ml NDC: 75812-750-17

LIQUID

HAND SANITIZER

A D V A N C E D

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION

- HAND SANITIZER
- NON-STERILE SOLUTION

NDC: 75812-750-17

**Net Content:
16 fl oz (473 ml)**



Drug Facts	
Active ingredient[s] Isopropyl alcohol 75% v/v.....	Purpose Antiseptic
Purpose: Antiseptic, Hand Sanitizer.	
Use[s]: 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ Store between 15-30C (59-86F). ■ Avoid freezing and excessive heat above 40C (104F). 	
Inactive ingredients: glycerin, hydrogen peroxide, water.	

**KEEP OUT OF REACH OF CHILDREN WARNING: FLAMMABLE PRODUCT
READ CAREFULLY OTHER CAUTIONS AND DIRECTIONS ON THIS LABEL BEFORE USE**



SMARKCHEM INDUSTRIES INC, 8636 Otis St, South Gate, CA 90280
Phone: +1(323)268-8184 - Fax: +1(323)268-8158 - Email: csr@smarkchemicals.com

473 ml NDC 75812-750-16

LIQUID

HAND SANITIZER

A D V A N C E D

ISOPROPYL ALCOHOL ANTISEPTIC 75%
TOPICAL SOLUTION

- HAND SANITIZER
- NON-STERILE SOLUTION

NDC: 75812-750-16

Net Content:
16 fl oz (473 ml)



Drug Facts	
Active ingredient[s] Isopropyl alcohol 75% v/v.....	Purpose Antiseptic
Purpose: Antiseptic, Hand Sanitizer.	
Use[s]: 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ Store between 15-30C (59-86F). ■ Avoid freezing and excessive heat above 40C (104F). 	
Inactive ingredients: glycerin, hydrogen peroxide, water.	

KEEP OUT OF REACH OF CHILDREN WARNING: FLAMMABLE PRODUCT
READ CAREFULLY OTHER CAUTIONS AND DIRECTIONS ON THIS LABEL BEFORE USE



SMARKCHEM INDUSTRIES INC, 8636 Otis St, South Gate, CA 90280
Phone: +1(323)268-8184 - Fax: +1(323)268-8158 - Email: csr@smarkchemicals.com

946 ml NDC 75812-750-32

LIQUID

HAND SANITIZER

A D V A N C E D

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION

- HAND SANITIZER
- NON-STERILE SOLUTION

NDC: 75812-750-32

**Net Content:
32 fl oz (946 ml)**



Drug Facts	
Active ingredient[s] Isopropyl alcohol 75% v/v.....	PurposeAntiseptic
Purpose: Antiseptic, Hand Sanitizer.	
Use[s]: 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ Store between 15-30C (59-86F). ■ Avoid freezing and excessive heat above 40C (104F). 	
Inactive ingredients: glycerin, hydrogen peroxide, water.	

**KEEP OUT OF REACH OF CHILDREN WARNING: FLAMMABLE PRODUCT
READ CAREFULLY OTHER CAUTIONS AND DIRECTIONS ON THIS LABEL BEFORE USE**



SMARKCHEM INDUSTRIES INC, 8636 Otis St, South Gate, CA 90280
Phone: +1(323)268-8184 - Fax: +1(323)268-8158 - Email: csr@smarkchemicals.com

18.927 L NDC: 75812-750-06

LIQUID

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	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F). 	
Inactive ingredients: glycerin, hydrogen peroxide, water.	

HAND SANITIZER

A D V A N C E D

ISOPROPYL ALCOHOL ANTISEPTIC 75%
TOPICAL SOLUTION

- HAND SANITIZER
- NON-STERILE SOLUTION

Net Content:

5 Gallon (18.927 L)

NDC: 75812-750-06

KEEP OUT OF REACH OF CHILDREN WARNING: FLAMMABLE PRODUCT
READ CAREFULLY OTHER CAUTIONS AND DIRECTIONS ON THIS LABEL BEFORE USE



SMARKCHEM INDUSTRIES INC - 8636 Otis St, South Gate, CA 90280 - Phone: +1(323)268-8184 - Fax: +1(323)268-8158 - Email: csr@smarkchemicals.com

18.927 L NDC: 75812-750-05

LIQUID



HAND SANITIZER

A D V A N C E D

ISOPROPYL ALCOHOL ANTISEPTIC 75%
TOPICAL SOLUTION

- HAND SANITIZER
- NON-STERILE SOLUTION

NDC: 75812-750-05

KEEP OUT OF REACH OF CHILDREN WARNING: FLAMMABLE PRODUCT
READ CAREFULLY OTHER CAUTIONS AND DIRECTIONS ON THIS LABEL BEFORE USE

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	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F). 	
Inactive ingredients: glycerin, hydrogen peroxide, water.	



Net Content:
5 Gallon (18.927 L)

SMARKCHEM INDUSTRIES INC - 8636 Otis St, South Gate, CA 90280 - Phone: +1(323)268-8184 - Fax: +1(323)268-8158 - Email: csr@smarkchemicals.com

HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:758 12-750
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75812-750-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2020	
2	NDC:75812-750-06	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/15/2020	
3	NDC:75812-750-32	946.353 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/15/2020	
4	NDC:75812-750-16	473.176 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/15/2020	
5	NDC:75812-750-05	18927 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/15/2020	
6	NDC:75812-750-17	473.176 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/15/2020	

Labeler - SMARKCHEM INDUSTRIES INC (605375166)**Establishment**

Name	Address	ID/FEI	Business Operations
Smarchem Industries INC		605375166	manufacture(75812-750)

Revised: 4/2020

SMARKCHEM INDUSTRIES INC