

ONKOHEALTH HAND AND SURFACE SANITIZER- alcohol liquid
ONKO PHARMACEUTICALS USA 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.

Active Ingredient

Alcohol 80% v/v.

Purpose

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. Flammable. Keep away from heat or flame.

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

Product Labels

HAND SANITIZER

ALCOHOL ANTISEPTIC 80%

Drug Facts	
Active ingredient(s) Alcohol 80% w/v	Purpose Antiseptic
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 • 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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Manufactured by
CALDINI KIMYA SANAYI VE TICARET LIMITED SIRKETI
NO.32 PELULI KOYU MERKEZ MEVKII MAHALLESİ SANAYİ SOKAK
Gebze/ KOCAELİ, TURKEY 41400
90-262-751-0099

Distributed by
ONKO PHARMACEUTICALS USA INC.
450 ALTON RD UNIT 2602 MIAMI BEACH, FL USA 33139
onkohealthcare.com
NDC 77283-001-01

3.4FL OZ (100 mL)

Lot No:
MM/YYYY

HAND SANITIZER

FDA & WORLD HEALTH ORGANIZATION RECOMMENDED FORMULA

 **ONKOHEALTH**
Since 1987



HAND SANITIZER

ALCOHOL ANTISEPTIC 80%

TOPICAL SOLUTION
NON-STERILE SOLUTION

- ♥ Liquid Strong Formula
- ♥ Paraben Free
- ♥ Sulfate Free
- ♥ Scent Free
- ♥ Vegan



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Distributed by
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450 ALTON RD UNIT 2602 MIAMI BEACH, FL USA 33139
onkohealthcare.com
NDC 77283-001-02

5.1 FL OZ (150 mL)

Lot No:
MM/YYYY

HAND SANITIZER

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NDC 77283-001-03

Lot No:
MM/YYYY

8FL OZ (236 mL)

HAND SANITIZER

FDA & WORLD HEALTH ORGANIZATION RECOMMENDED FORMULA



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NDC 77283-001-03

Lot No:
MM/YYYY

16FL OZ (473 mL)

FDA & WORLD HEALTH ORGANIZATION
RECOMMENDED FORMULA

HAND SANITIZER

FDA & WORLD HEALTH ORGANIZATION RECOMMENDED FORMULA



ONKOHEALTH
Since 1987

HAND SANITIZER

ALCOHOL ANTISEPTIC 80%

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16FL OZ (473 mL)

HAND & SURFACE SANITIZER

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Gebze / KOCAELİ, TÜRKİYE 41400
90-262-791-0099

Distributed by
ONKO PHARMACEUTICALS USA INC.
450 AITON RD UNIT 2802 N. BAY BEACH, FL USA 33139
onkohealthcare.com
NDC 77283-001-05

Lot No:
MM/YYYY

33.8FL OZ (1000 mL)

HAND & SURFACE SANITIZER

FDA & WORLD HEALTH ORGANIZATION RECOMMENDED FORMULA

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Since 1987



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ALCOHOL ANTISEPTIC 80%

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33.8FL OZ (1000 mL)

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NO.32 PEUTLU KOFU MERKEZ MEVK II MAHALLESİ SANAYİ SOKAK
Gebze/ KOCAELİ, TÜRKİYE 41400
90-262-751-0099

Distributed by
ONKO PHARMACEUTICALS USA INC.
450 ALTON RD UNIT 2602 MIAMI BEACH, FL USA 33139
onkohealthcare.com
NDC 77283-001-06

1 GALLON (3785mL)

Lot No:
MM/YYYY

HAND & SURFACE SANITIZER

FDA & WORLD HEALTH ORGANIZATION RECOMMENDED FORMULA



ONKOHEALTH
Since 1987

HAND & SURFACE SANITIZER

ALCOHOL ANTISEPTIC 80%

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FDA & WORLD HEALTH ORGANIZATION RECOMMENDED FORMULA

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Since 1987



HAND & SURFACE SANITIZER

ALCOHOL ANTISEPTIC 80%

TOPICAL SOLUTION
NON-STERILE SOLUTION

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- ♥ Sulfate Free
- ♥ Scent Free
- ♥ Vegan



Manufactured by
GALDINI KAMYA SANAYI VE TICARET LIMITED SIRKETI
NO.33 PEJLITI KÖYÜ ABRİSİZ MEYDANI MAHALLESİ SAKARYA SOKAKI
Gölcük / KOCASEN, TÜRKİYE 41400
90-262-751-0099

Distributed by
ONKO PHARMACEUTICALS USA INC.
450 AUTUMN RD UNIT 2602 MIAMI BEACH, FL USA 33139
onkohealthcare.com
NDC 77283-001-07

Lot No:
MM/YYYY

2.6 GALLON (10000 mL)

2.6 GALLON (10000 mL)

ONKOHEALTH
Since 1987



HAND & SURFACE SANITIZER

ALCOHOL ANTISEPTIC 80%

TOPICAL SOLUTION
NON-STERILE SOLUTION

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5.3 GALLON (20000 mL)

HAND & SURFACE SANITIZER

ALCOHOL ANTISEPTIC 80%

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Active ingredient(s)	Purpose
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



Manufactured by
CALDINI KIAYA SANAYI VETICI CARET LIMITED SIRKETI
NO.32 PEUTU KOYU MERKEZ MEVKII MAHALLESİ SANAYİ SOKAKI
Gebze/ KOCAELİ, TURKEY 41400
90-262-751-0099

Distributed by
ONKO PHARMACEUTICALS USA INC.
450 ALTON RD UNIT 2602 MIAMI BEACH, FL USA 33139
onkohealth@onko.com.tr
NDC 77283-001-08

Lot No:
MMV11111

5.3 GALLON (20000 mL)

ONKOHEALTH HAND AND SURFACE SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77283-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77283-001-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	
2	NDC:77283-001-02	150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	
3	NDC:77283-001-03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	
4	NDC:77283-001-04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	
5	NDC:77283-001-05	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	
6	NDC:77283-001-06	3790 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	
7	NDC:77283-001-07	10000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	
8	NDC:77283-001-08	20000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/11/2020	

Labeler - ONKO PHARMACEUTICALS USA INC. (114603246)**Establishment**

Name	Address	ID/FEI	Business Operations
CALDINI KIMYA SANAYI VE TICARET LIMITED SIRKETI		504596538	manufacture(77283-001)

Revised: 5/2020

ONKO PHARMACEUTICALS USA INC.