

**SUNBEAM WASH-FREE HAND SANITIZER/DISINFECTANT- sunbeam wash-free hand sanitizer/disinfectant gel**

**Xiamen Sunbeam Industries 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.*

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**hand sanitizer gel**

**Active Ingredient(s)**

Compound quaternary ammonium salt, Alcohol 60%v/v

**Purpose**

Antibacterial & Disinfectant

**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

Storage sealed, stored in ventilated and dry place at normal temperature.  
Avoiding freezing and excessive heat above 40C(104F)

## Inactive ingredients

vitamin E, aloe extract, flavor, carbomer, purified water, USP

## Package Label - Principal Display Panel

**SUNBEAM**

**Wash - free hand sanitizer gel**  
Compound quaternary ammonium salt (containing vitamin E)

**Killing 99.9 % Viruses & Bacteria**

7440Floz / 220000ml

Tender skin  
Virus killing  
Wash hands without water

**Active Ingredient(s)** Compound quaternary ammonium salt, Alcohol 60% v/v  
**Purpose** Antibacterial & Disinfectant  
**Use** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use with soap and water; see next available.  
**Warnings** [WARNING SECTION] 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 SECTION** 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.  
**OTC - STOP USE SECTION** Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.  
**OTC - KEEP OUT OF REACH OF CHILDREN** 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.  
**Storage** Sealed, stored in ventilated and dry place at normal temperature.  
Avoid freezing and excessive heat above 40C (104F)  
**Inactive ingredients** vitamin E, aloe extract, flavor, carbomer, purified water, USP  
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:  
**Shelf life:** 24 months    **Executive standards:** Q/SLDFJ008-2020  
\*SUNBEAM\* authorized production  
Client: Xiamen Sunbeam Industries Ltd.  
**The date of production and the deadline for use are shown in the mark**  
**MADE IN CHINA**

6 973164 880006



# Wash - free hand sanitizer gel

Compound quaternary ammonium salt  
(containing vitamin E)

**Killing 99.9 %  
Viruses & Bacteria**

5072.7Fl oz / 150000ml

Tender skin  
Virus killing  
Wash hands without water



**Active Ingredient(s)** Compound quaternary ammonium salt, Alkylol 60% v/v

**Purpose** Antibacterial & Disinfectant

**Use** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings [WARNINGS SECTION]** 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.

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"SUNBEAM" authorized production

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MADE IN CHINA



# Wash - free hand sanitizer gel

Compound quaternary ammonium salt  
(containing vitamin E)

**Killing 99.9 %  
Viruses & Bacteria**

3381.8Fl oz / 100000ml

Tender skin  
Virus killing  
Wash hands without water



**Active Ingredient(s)** Compound quaternary ammonium salt, Alkylol 60% v/v

**Purpose** Antibacterial & Disinfectant

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# Wash - free hand sanitizer gel

Compound quaternary ammonium salt  
(containing vitamin E)

**Killing 99.9 %  
Viruses & Bacteria**

169.1Fl oz / 5000ml

Tender skin  
Virus killing  
Wash hands without water



**Active Ingredient(s)** Compound quaternary ammonium salt, Alkylol 60% v/v

**Purpose** Antibacterial & Disinfectant

**Use** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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# Wash - free hand sanitizer gel

Compound quaternary ammonium salt  
(containing vitamin E)

**Killing 99.9 %  
Viruses & Bacteria**

101.5Floz / 3000ml

Tender skin  
Virus killing  
Wash hands without water



**Active Ingredient(s)** Compound quaternary ammonium salt, Alkylol 60% v/v

**Purpose** Antibacterial & Disinfectant

**Use** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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**Supervise children** under 6 years of age when using this product to avoid swallowing.

**Storage** Sealed, stored in ventilated and dry place at normal temperature.

**Avoid freezing and excessive heat** above 40C (104F)

**Inactive ingredients** vitamin E, aloe extract, flavor, carbomer, purified water, USP. 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:

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# Wash - free hand sanitizer gel

Compound quaternary ammonium salt  
(containing vitamin E)

**Killing 99.9 %  
Viruses & Bacteria**

1Floz / 30ml

Tender skin  
Virus killing  
Wash hands without water



**Active Ingredient(s)** Compound quaternary ammonium salt, Alkylol 60% v/v

**Purpose** Antibacterial & Disinfectant

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# Wash - free hand sanitizer gel

Compound quaternary ammonium salt  
(containing vitamin E)

**Killing 99.9 %  
Viruses & Bacteria**

1.7Floz / 50ml

Tender skin  
Virus killing  
Wash hands without water



**Active Ingredient(s)** Compound quaternary ammonium salt, Alkylol 60% v/v

**Purpose** Antibacterial & Disinfectant

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# Wash - free hand sanitizer gel

Compound quaternary ammonium salt  
(containing vitamin E)

**Killing 99.9 %  
Viruses & Bacteria**

2Floz / 60ml

Tender skin  
Virus killing  
Wash hands without water



**Active Ingredient(s)** Compound quaternary ammonium salt, Alkylol 60% v/v

**Purpose** Antibacterial & Disinfectant

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# Wash - free hand sanitizer gel

Compound quaternary ammonium salt  
(containing vitamin E)

**Killing 99.9 %  
Viruses & Bacteria**

3.4Floz / 100ml

Tender skin  
Virus killing  
Wash hands without water



**Active Ingredient(s)** Compound quaternary ammonium salt, Alkylol 60% v/v

**Purpose** Antibacterial & Disinfectant

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**MADE IN CHINA**



# Wash - free hand sanitizer gel

Compound quaternary ammonium salt  
(containing vitamin E)

**Killing 99.9 %  
Viruses & Bacteria**

8.5Floz / 250ml

Tender skin  
Virus killing  
Wash hands without water



**Active Ingredient(s)** Compound quaternary ammonium salt, Alkylol 60% v/v

**Purpose** Antibacterial & Disinfectant

**Use** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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**MADE IN CHINA**



**SUNBEAM**

**Wash - free hand sanitizer gel**  
Compound quaternary ammonium salt (containing vitamin E)

**Killing 99.9 % Viruses & Bacteria**

Tender skin  
Virus killing  
Wash hands without water

11.8Floz / 350ml

**Active Ingredient(s)** Compound quaternary ammonium salt, Alcohol 60% v/v  
**Purpose** Antibacterial & Disinfectant  
**Use** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  
**Warnings** [WARNINGS SECTION] For external use only. Flammable. Keep away from heat or flame.  
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**Directions** Place enough product on hands to cover all surfaces. Rub hands together until dry.  
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6 973164 880006

**SUNBEAM**

**Wash - free hand sanitizer gel**  
Compound quaternary ammonium salt (containing vitamin E)

**Killing 99.9 % Viruses & Bacteria**

Tender skin  
Virus killing  
Wash hands without water

16.9Floz / 500ml

**Active Ingredient(s)** Compound quaternary ammonium salt, Alcohol 60% v/v  
**Purpose** Antibacterial & Disinfectant  
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**SUNBEAM**

**Wash - free hand sanitizer gel**  
Compound quaternary ammonium salt (containing vitamin E)

**Killing 99.9 % Viruses & Bacteria**

Tender skin  
Virus killing  
Wash hands without water

33.8Floz / 1000ml

**Active Ingredient(s)** Compound quaternary ammonium salt, Alcohol 60% v/v  
**Purpose** Antibacterial & Disinfectant  
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## SUNBEAM WASH-FREE HAND SANITIZER/DISINFECTANT

sunbeam wash-free hand sanitizer/disinfectant gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78214-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	60 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE (UNII: V5VD430YW9)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:78214-001-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
2	NDC:78214-001-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
3	NDC:78214-001-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
4	NDC:78214-001-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
5	NDC:78214-001-05	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
6	NDC:78214-001-06	350 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
7	NDC:78214-001-07	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
8	NDC:78214-001-08	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
9	NDC:78214-001-09	3000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
10	NDC:78214-001-10	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
11	NDC:78214-001-11	100000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
12	NDC:78214-001-12	150000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
13	NDC:78214-001-13	220000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/19/2020	

**Labeler** - Xiamen Sunbeam Industries Ltd. (529394725)

**Registrant** - Xiamen Sunbeam Industries Ltd. (529394725)

**Establishment**

Name	Address	ID/FEI	Business Operations
Xiamen Sunbeam Industries Ltd.		529394725	manufacture(78214-001)

Revised: 5/2020

Xiamen Sunbeam Industries Ltd.