

CAL-SHINE ANTISEPTIC HAND SANITIZER- isopropyl alcohol liquid
California Shine Construction

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.

CAL-SHINE ANTISEPTIC HAND SANITIZER

Drug Facts

Active ingredient

Isopropyl alcohol 75% v/v

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping

- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

aloe vera leaf extract, glycerin, hydrogen peroxide, lavender oil, water

Questions? +1-559-412-7402

You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 4:00 PM

With Lavender Essential Oils and Aloe vera

Manufactured by:

California Shine Construction & Sanitizing,
3251 N Marks Ave, Fresno, CA 93722

MADE IN THE U.S.A.

Packaging

Package 60 mL

NDC # 78604-646-60

CAL-SHINE
**ANTISEPTIC
HAND SANITIZER**



*With
Lavender Essential Oils
and Aloe vera*



Drug Facts	
Active ingredient	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Uses	
<ul style="list-style-type: none"> • hand sanitizer to decrease bacteria on the skin • recommended for repeated use • for use when soap and water are not available 	
Warnings	
Flammable, keep away from fire/flame	
For external use only	
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 • do not get into eyes. In case of contact, rinse eyes thoroughly with water	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • irritation and redness develop • condition persists for more than 72 hours 	
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"> • wet hands thoroughly with product and allow to dry without wiping • supervise children under 6 years of age when using this product to avoid swallowing 	
Other information	
<ul style="list-style-type: none"> • store between 15-30°C (59-86°F) 	

MADE IN THE U.S.A.

 d by:
 e Construction & Sanitizing
 Ave., Fresno, CA 93722



2 fl oz (60 mL)

- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients aloe vera leaf extract, glycerin, hydrogen peroxide, lavender oil, water

Questions? +1-559-412-7402
You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 4:00 PM

Manufacture
California Shin
3251 N. Marks /

Package 118 mL

NDC # 78604-646-11

CAL-SHINE

ANTISEPTIC HAND SANITIZER



*With
Lavender Essential Oils
and Aloe vera*



4 fl oz (118 mL)

Drug Facts

Active ingredient	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flare
For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients aloe vera leaf extract, glycerin, hydrogen peroxide, lavender oil, water

Questions? +1-559-412-7402
You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 4:00 PM

MADE IN THE U.S.A.

Manufactured by:
California Shine Construction & Sanitizing
3251 N. Marks Ave., Fresno, CA 93722

Package 237 mL

NDC # 78604-646-23

CAL-SHINE

ANTISEPTIC HAND SANITIZER



Drug Facts

Active ingredient	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flare
For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

MADE IN THE U.S.A.


*With
 Lavender Essential Oils
 and Aloe vera*



8 fl oz (237 mL)

Package 474 mL

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients aloe vera leaf extract, glycerin, hydrogen peroxide, lavender oil, water

Questions? +1-559-412-7402
 You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 4:00 PM

Manufactured by:
 California Shine Construction & Sanitizing
 3251 N. Marks Ave., Fresno, CA 93722

NDC # 78604-646-47

**CAL-SHINE
 ANTISEPTIC
 HAND SANITIZER**


*With
 Lavender Essential Oils
 and Aloe vera*



16 fl oz (474 mL)

Package 3785 mL

Drug Facts

Active ingredient	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame
 For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients aloe vera leaf extract, glycerin, hydrogen peroxide, lavender oil, water

Questions? +1-559-412-7402
 You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 4:00 PM

MADE IN THE U.S.A.

Manufactured by:
 California Shine Construction & Sanitizing
 3251 N. Marks Ave., Fresno, CA 93722

NDC # 78604-646-37

CAL-SHINE ANTISEPTIC HAND SANITIZER



*With
Lavender Essential Oils
and Aloe vera*



1 Gallon (3.78L)

Drug Facts	
Active ingredient Isopropyl alcohol 75% v/v.....	Purpose Antiseptic
Uses	
<ul style="list-style-type: none"> • hand sanitizer to decrease bacteria on the skin • recommended for repeated use • for use when soap and water are not available 	
Warnings	
Flammable, keep away from fire/flame For external use only	
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 • do not get into eyes. In case of contact, rinse eyes thoroughly with water	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • irritation and redness develop • condition persists for more than 72 hours 	
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"> • wet hands thoroughly with product and allow to dry without wiping • supervise children under 6 years of age when using this product to avoid swallowing 	
Other information	
<ul style="list-style-type: none"> • store between 15-30 °C (59-86 °F) • avoid freezing and excessive heat above 40 °C (104 °F) 	
Inactive ingredients aloe vera leaf extract, glycerin, hydrogen peroxide, lavender oil, water	
Questions? +1-559-412-7402 You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 4:00 PM	

MADE IN THE U.S.A.

Manufactured by:
California Shine Construction & Sanitizing
3251 N. Marks Ave., Fresno, CA 93722

CAL-SHINE ANTISEPTIC HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78604-646
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78604-646-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	
2	NDC:78604-646-11	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	
3	NDC:78604-646-23	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	
4	NDC:78604-646-47	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	
5	NDC:78604-646-37	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/10/2020	

Labeler - California Shine Construction (030762135)

Establishment			
Name	Address	ID/FEI	Business Operations
California Shine Construction		030762135	manufacture(78604-646)

Revised: 1/2023

California Shine Construction