

INSTANT UNSCENTED HAND SANITIZER WITH ALOE VERA ADVANCED- alcohol liquid Earths Amenities

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.

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) :

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerin
- c. Aloe Vera Extract
- d. Water
- e. Caprylyl Glycol
- f. Decylene Glycol
- g. Benzoic Acid
- h. Carbomer
- i. Triethanolamine

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)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Uses

Antiseptic

Warnings

For external use only. Flammable. Keep away from fire or flame

When using this product do not use on damaged or broken skin. Do not leave near fire. Wash with enough water, if it gets into eyes. Do not drink

Stop use and ask a doctor if skin irritation or redness develops.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Directions

Apply enough gel to wet hands and rub together until dry. Use 1 to 3 times a day.

Other information

Store below 73.4F (23C)

Inactive ingredients

Water, aloe barbadensis (aloe vera extract), triethanolamine, glycerin, caprylyl glycol, decylene glycol, benzoic acid, carbomer

To help reduce bacteria on the skin

Package Label - Principal Display Panel

60 mL NDC: 74949-002-60



250 mL NDC: 74949-002-25

EARTH'S AMENITIES

Instant Unscented **HAND SANITIZER** *with aloe vera*

ADVANCED

Kills germs

e 8.4 fl oz (250ml)



Drug Facts

Active Ingredient	Purpose
Ethyl alcohol (70% v/v)	Antiseptic

Uses ■ To help reduce bacteria on the skin.

Warnings For external use only. Flammable. Keep away from fire or flame.

When using this product do not use on damaged or broken skin. Do not leave near fire. Wash with enough water, if it gets into eyes. Do not drink.

Stop use and ask a doctor if skin irritation or redness develops.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Directions
■ Apply enough gel to wet hands and rub together until dry. Use 1 to 3 times a day.

Other Information
■ Store below 73.4°F (23 °C).

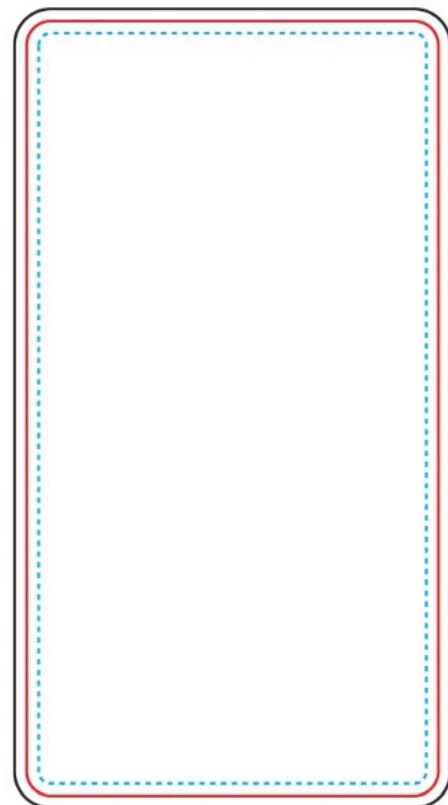
Inactive Ingredients Water, aloe barbadensis (aloe vera) extract, triethanolamine, glycerin, caprylyl glycol, decylene glycol, benzoic acid, carbomer.

Questions or comments?
■ Call 1-877-544-0311

Distributed by Earths Amenities www.earthsamenities.com
Las Vegas, NV 89169 Made in Mexico



8 60003 62861 4

495 mL NDC: 74949-002-49

EARTH'S
AMENITIES

Instant
Unscented
**HAND
SANITIZER**
with aloe vera

ADVANCED

Kills germs

e 16.73 fl oz (495ml)



Drug Facts

Active Ingredient	Purpose
Ethyl alcohol (70% v/v)	Antiseptic

Uses ■ To help reduce bacteria on the skin.

Warnings For external use only. Flammable.
Keep away from fire or flame.

When using this product do not use on damaged or broken skin. Do not leave near fire. Wash with enough water, if it gets into eyes. Do not drink.

Stop use and ask a doctor if skin irritation or redness develops.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Directions
■ Apply enough gel to wet hands and rub together until dry. Use 1 to 3 times a day.

Other Information
■ Store below 73.4°F (23 °C).

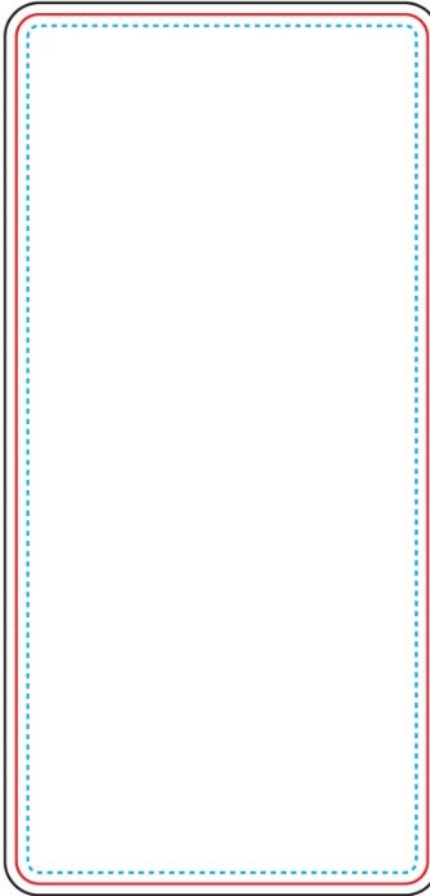
Inactive Ingredients Water, aloe barbadensis (aloe vera) extract, triethanolamine, glycerin, caprylyl glycol, decylene glycol, benzoic acid, carbomer.

Questions or comments?
■ Call 1-877-544-0311

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Las Vegas, NV 89169 Made in Mexico



8 60003 62867 6

20000 mL NDC: 74949-002-20



EARTH'S
AMENITIES

*Kills
Germs*

HAND SANITIZER
with aloe vera

ADVANCED

e 700 fl oz (20L)

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Ethyl alcohol (70% w/v).....	Antiseptic

Uses ■ For hand washing to eliminate bacteria on the skin.

Warnings For external use only. Flammable. Keep away from fire or flame.

When using this product do not use on damaged or broken skin. Do not leave near fire. Wash with enough water, if it gets into eyes. Do not drink.

Stop use and ask a doctor if skin irritation or redness develops.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Directions

■ Apply enough gel to wet hands and rub together until dry. Use 1 to 3 times a day.

Other information

■ Store below 73.4°F (23°C).

Inactive Ingredients Water, aloe barbadensis (aloe vera) extract, triethanolamine, glycerin caprylyl glycol, decylene glycol, benzoic acid, carbomer.

Questions or comments? ■ Call 1-877-644-0311

www.earthsonline.com
Manufactured by Earth's Amenities
Ly, Wisc., WI 53083
Made in Mexico



100%
100%

INSTANT UNSCENTED HAND SANITIZER WITH ALOE VERA ADVANCED
alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:749 49-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.9 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.1 mL in 100 mL
ALOE VERA FLOWER (UNII: 575DY8C1ER)	5 mL in 100 mL
WATER (UNII: 059QF0K00R)	25 mL in 100 mL
BENZOIC ACID (UNII: 8SKN0B0MIM)	0.1 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	0.1 mL in 100 mL
DECYLENE GLYCOL (UNII: S57M60MI88)	0.1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74949-002-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
2	NDC:74949-002-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
3	NDC:74949-002-49	495 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
4	NDC:74949-002-20	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/22/2020	

Labeler - Earths Amenities (117473288)**Establishment**

Name	Address	ID/FEI	Business Operations
Earths Amenities		117473288	label(74949-002)

Establishment

Name	Address	ID/FEI	Business Operations
DDI Multinacional, S.A. de C.V.		812776741	manufacture(74949-002)