

AERIUM SANITIZER 75% 500ML- ethyl alcohol spray SM Global, LLC.

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.

Aerium Sanitizer Spray 75% 500ml

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 75% v/v.	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 seek 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 Spray 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°C to 30°C (59°F to 85°F). Avoid freezing and excessive heat above 40°C (104°F).

Inactive ingredients
Water, Glycerin, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Scutellaria Barbadosensis Root Extract, Portulaca Oleraceae Extract, Aloe Barbadosensis Leaf Extract.

Questions or Comments?
1-800-513-4153

Purpose

Antiseptic, Hand Sanitizer

Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 75% v/v.	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 seek 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 Spray 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°C to 30°C (59°F to 85°F). Avoid freezing and excessive heat above 40°C (104°F).

Inactive ingredients
Water, Glycerin, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Scutellaria Barbadosensis Root Extract, Portulaca Oleraceae Extract, Aloe Barbadosensis Leaf Extract.

Questions or Comments?
1-800-513-4153

Use

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

Aerium



Aerium

SANITIZER SPRAY

Helps reduce bacteria and germs

- Contains Recommended 75% Alcohol Content
- Moisturizes with Aloe Formula
- Sanitizes to Help Reduce the Spread of Germs

50ml / 1.9 fl. oz.

Distributed by SM Global, LLC.
9-461 Cherokee Blvd. #209
Beverly Hills, CA 90212



8 50422 00031 3

Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 75% v/v	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, close 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 Spray 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°C to 30°C (59°F to 85°F) Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients
Water, Glycerin, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Squalene, Betulaeulis Root Extract, Portulaca Oleraceae Extract, Aloe Barbadensis Leaf Extract

Questions or Comments?
1-800-519-4159

Warnings

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

Aerium



Aerium

SANITIZER SPRAY

Helps reduce bacteria and germs

- Contains Recommended 75% Alcohol Content
- Moisturizes with Aloe Formula
- Sanitizes to Help Reduce the Spread of Germs

50ml / 1.9 fl. oz.

Distributed by SM Global, LLC.
9-461 Cherokee Blvd. #209
Beverly Hills, CA 90212



8 50422 00031 3

Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 75% v/v	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, close 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 Spray 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°C to 30°C (59°F to 85°F) Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients
Water, Glycerin, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Squalene, Betulaeulis Root Extract, Portulaca Oleraceae Extract, Aloe Barbadensis Leaf Extract

Questions or Comments?
1-800-519-4159

Do not use

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

Aerium



Aerium

SANITIZER SPRAY

Helps reduce bacteria and germs

- Contains Recommended 75% Alcohol Content
- Moisturizes with Aloe Formula
- Sanitizes to Help Reduce the Spread of Germs

50ml / 1.9 fl. oz.

Distributed by SM Global, LLC.
9-461 Cherokee Blvd. #209
Beverly Hills, CA 90212



8 50422 00031 3

Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 75% v/v	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, close 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 Spray 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°C to 30°C (59°F to 85°F) Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients
Water, Glycerin, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Squalene, Betulaeulis Root Extract, Portulaca Oleraceae Extract, Aloe Barbadensis Leaf Extract

Questions or Comments?
1-800-519-4159

When using this product

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Aerium
SANITIZER SPRAY
 Helps reduce bacteria and germs

- Contains Recommended 75% Alcohol Content
- Moisturizes with Aloe Formula
- Sanitizes to Help Reduce the Spread of Germs

50ml / 1.9 fl. oz.

MADE IN KOREA

Distributed by SM Global, LLC.
 9401 Chelmerite Blvd. #306,
 Beverly Hills, CA 90212

Drug Facts	
Active Ingredient(s) Ethyl Alcohol 75% v/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.	
Directions Spray 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°C to 30°C (59°F to 85°F). Avoid freezing and excessive heat above 40°C (104°F).	
Inactive Ingredients Water, Glycerin, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Squalane, Biscapulea Root Extract, Portulaca Oleracea Extract, Aloe Barbadensis Leaf Extract	
Questions or Comments? 1-800-815-4159	

Stop use and ask a doctor

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Aerium
SANITIZER SPRAY
 Helps reduce bacteria and germs

- Contains Recommended 75% Alcohol Content
- Moisturizes with Aloe Formula
- Sanitizes to Help Reduce the Spread of Germs

50ml / 1.9 fl. oz.

MADE IN KOREA

Distributed by SM Global, LLC.
 9401 Chelmerite Blvd. #306,
 Beverly Hills, CA 90212

Drug Facts	
Active Ingredient(s) Ethyl Alcohol 75% v/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.	
Directions Spray 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°C to 30°C (59°F to 85°F). Avoid freezing and excessive heat above 40°C (104°F).	
Inactive Ingredients Water, Glycerin, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Squalane, Biscapulea Root Extract, Portulaca Oleracea Extract, Aloe Barbadensis Leaf Extract	
Questions or Comments? 1-800-815-4159	

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.

Aerium
SANITIZER SPRAY
 Helps reduce bacteria and germs

- Contains Recommended 75% Alcohol Content
- Moisturizes with Aloe Formula
- Sanitizes to Help Reduce the Spread of Germs

50ml / 1.9 fl. oz.

MADE IN KOREA

Distributed by SM Global, LLC.
 9401 Chelmerite Blvd. #306,
 Beverly Hills, CA 90212

Drug Facts	
Active Ingredient(s) Ethyl Alcohol 75% v/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.	
Directions Spray 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°C to 30°C (59°F to 85°F). Avoid freezing and excessive heat above 40°C (104°F).	
Inactive Ingredients Water, Glycerin, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Squalane, Biscapulea Root Extract, Portulaca Oleracea Extract, Aloe Barbadensis Leaf Extract	
Questions or Comments? 1-800-815-4159	

Directions

- Spray 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.

The image shows the front and back of an Aerium Sanitizer Spray bottle. The front panel is white with a red vertical stripe on the left containing the brand name 'Aerium' in white. The main text on the front includes the brand name 'Aerium' in a large, bold font, followed by 'SANITIZER SPRAY' in a smaller, bold font. Below this, it says 'Helps reduce bacteria and germs'. There are three checkmarks indicating features: 'Contains Recommended 75% Alcohol Content', 'Moisturizes with Aloe Formula', and 'Sanitizes to Help Reduce the Spread of Germs'. The volume '50ml / 1.9 fl. oz.' is printed at the bottom. The back panel is white and contains a barcode, a recycling symbol, and a 'Drug Facts' panel. The 'Drug Facts' panel includes sections for 'Active Ingredient[s]', 'Use[s]', 'Warnings', 'Directions', 'Other Information', 'Inactive Ingredients', and 'Questions or Comments?'. The 'Active Ingredient[s]' section lists 'Ethyl Alcohol 75% v/v' with the purpose 'Antiseptic'. The 'Use[s]' section states 'Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.' The 'Warnings' section includes 'For external use only. Flammable. Keep away from heat or flame.' and 'Do not use in children less than 2 months of age on open skin wounds'. The 'Directions' section says 'Spray 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.' The 'Other Information' section states 'Store between 15°C to 30°C (59°F to 86°F)' and 'Avoid freezing and excessive heat above 40°C (104°F)'. The 'Inactive Ingredients' section lists 'Water, Glycerin, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Scutellaria Baicalensis Root Extract, Portulaca Oleracea Extract, Aloe Barbadensis Leaf Extract'. The 'Questions or Comments?' section provides the phone number '1-800-513-4159'. The back panel also includes the distributor information: 'Distributed by SM Global, LLC, 9401 Charleville Blvd, #306, Beverly Hills, CA 90212'.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

This is an identical copy of the Aerium Sanitizer Spray product label shown above. It features the same branding, text, and 'Drug Facts' panel. The 'Drug Facts' panel details the active ingredient (Ethyl Alcohol 75% v/v), usage instructions, warnings (flammable, avoid heat, do not use on infants), directions (spray on hands, rub until dry), storage information (15°C to 30°C), inactive ingredients (Water, Glycerin, Fragrance, PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Scutellaria Baicalensis Root Extract, Portulaca Oleracea Extract, Aloe Barbadensis Leaf Extract), and contact information (1-800-513-4159).

Inactive ingredients

Water, Glycerin, Fragrance(Parfum), PEG-40 Hydrogenated Castor Oil, PEG-60 Hydrogenated Castor Oil, Scutellaria Baicalensis Root Extract, Portulaca Oleracea Extract, Aloe Barbadensis Leaf Extract



Package Label - Principal Display Panel

Aerium
 Sanitizer Spray
 Helps reduce bacteria and germs

- Contains Recommended 70% Alcohol Content
- Moisturizes with Aloe Formula
- Sanitizes to Help Reduce the Spread of Germs

500ml/ 16.9 fl.oz.



AERIUM SANITIZER 75% 500ML

ethyl alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74924-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
PURSLANE (UNII: M6S840WYG5)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74924-110-02	24 in 1 CARTON	06/05/2020	
1	NDC:74924-110-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/05/2020	

Labeler - SM Global, LLC. (834972353)

Registrant - E.CIS COSMETIC.Co.,Ltd (689846270)

Establishment

Name	Address	ID/FEI	Business Operations
E.CIS COSMETIC.Co.,Ltd		689846270	manufacture(74924-110)

Revised: 6/2020

SM Global, LLC.