

AMOUAGE- sanitizer gel gel
AMOUAGE SAOC

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.

AMOUAGE Sanitizer Gel

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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

- Put enough product in your palm to cover hands and rub hands together briskly until dry

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

Other information

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

May discolor certain fabrics or surfaces

Inactive ingredients

alpha-isomethyl ionone, carbopol aqua sf-1, citronellol, eugenol, geraniol, glycerin, hydroxycitronellal, rose (as parfum), sodium hydroxide, purified water

Package Label - Principal Display Panel



DRUG FACTS	
Active Ingredient Ethyl Alcohol 70% 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.	
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 use in or near the eyes. In case of contact, 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 <ul style="list-style-type: none"> Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using products. 	
Other information <ul style="list-style-type: none"> Avoid freezing and excessive heat above 40C (104F) May discolor certain fabrics or surfaces 	
Inactive ingredients: alpha-isomethyl ionone, carbopol aqua sf-1,citronellol, eugenol, geraniol, glycerin, hydroxycitronellal, rose(parfum), sodium hydroxide, water.	

60 mL NDC:79809-111-11

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79809-111
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
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
ROSE OIL (UNII: WUB68Y35M7)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
GERANIOL (UNII: L837108USY)	
EUGENOL (UNII: 3T8H1794QW)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79809-111-11	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/17/2020	
2	NDC:79809-111-12	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/17/2020	
3	NDC:79809-111-13	120 mL in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	09/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/17/2020	

Labeler - AMOUAGE SAOC (557929992)

Establishment

Name	Address	ID/FEI	Business Operations
AMOUAGE SAOC		557929992	manufacture(79809-111)

