

ACQUA AROMA HAND SANITIZER GEL- alcohol gel
Smell It Industria e Comercio Ltda

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.

Drug Facts

Active Ingredient: Ethyl Alcohol 70% v/v

Purpose:

Purpose: Antiseptic

Use

Acqua Aroma Hand Sanitizer Gel
1.0 FL OZ (30mL)

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic

Use: Decreases bacteria on hands.

Warnings

- **Flammable. Keep away from flame or high heat.**
- **For external use only.**
- **When using this product avoid contact with eyes.**
- **Stop use and ask a doctor if irritation and redness develop or increase.**
- **Keep out reach of Children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Rub into hands until dry.

Other information:

- Store below 104°F (40°C).
- May discolor certain fabrics or surfaces.

Inactive ingredients: Water (Aqua), Methyl Gluceth-20, Acrylates C10-30 Alkyl Acrylate Crosspolymer, Fragrance (Parfum), Aminomethyl Propanol, Mannitol, Cellulose, Citronellol, Linalool, Alpha-isomethyl Ionone, Coumarin, CI 77492, D-limonene, Geraniol, Tocopheryl Acetate, Hydroxypropyl Methylcellulose.

Manufactured by Smell It Ind. e Com. Ltda
Distributed by Acqua Aroma US, LLC.
3648 Silver Star Rd, Orlando, FL 32808.
Made in Brazil | www.acquaaroma.com
Questions?: 1-844-636-7504 | CustomerService@acquaaroma.com

Decreases hands.

bacteria on

Warnings

Flammable. Keep away from flame or high heat.☐

For external use only.[]

(For 1.0 FL OZ) Warnings:

When using this product avoid contact with eyes.

(For 12.9 FL OZ) Warnings:

When using this product avoid contact with eyes. If contact occurs, rinse with water.[]

Warnings

Stop use and ask a doctor if irritation and redness develop or increase.[]

(For 1.0 FL OZ) Warnings

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

(For 12.9 FL OZ) Warnings:

Keep out reach of Children. Children under 6 year old should be supervised when using it. If swallowed, get medical help or contact a Poison Control Center right away.

Other Information:

Store below 104°F (40°C). May discolor certain fabrics or surfaces.

Directions

Rub into hands until dry.

(For 1.0 FL OZ) Inactive Ingredients:

Inactive ingredients: Water (Aqua), Methyl Gluceth-20, Acrylates C10-30 Alkyl Acrylate Crosspolymer, Fragrance (Parfum), Aminomethyl Propanol, Mannitol, Cellulose, Citronellol, Linalool, Alpha-isomethyl Ionone, Coumarin, CI 77492, D-limonene, Geraniol, Tocopheryl Acetate, Hydroxypropyl Methylcellulose.

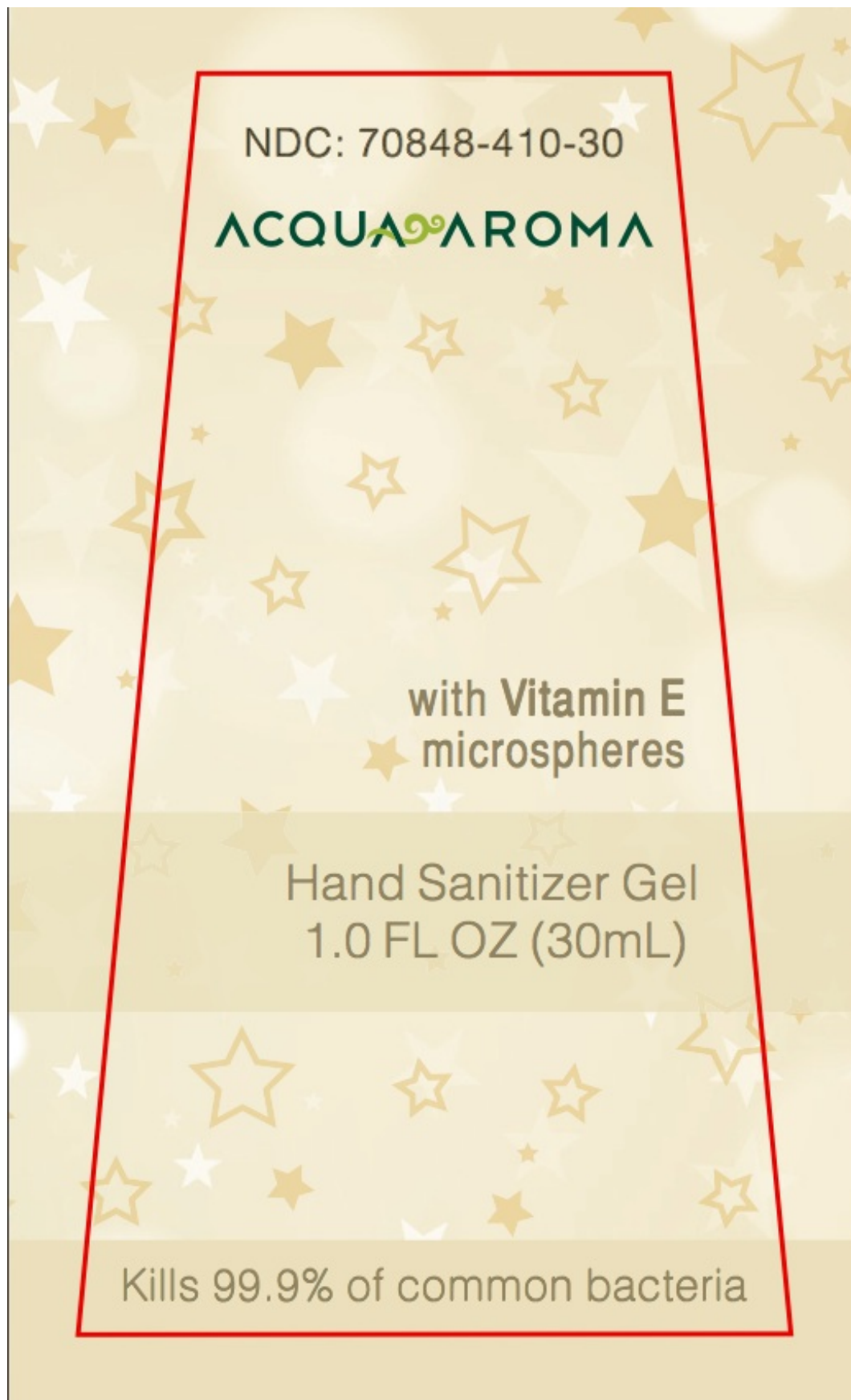
(For 12.9 FL OZ) Inactive Ingredients:

Inactive Ingredients: Water (Aqua), Acrylates C10-30 Alkyl Acrylate Crosspolymer, Methyl Gluceth-20, Fragrance (Parfum), Aminomethyl Propanol, Mannitol, Cellulose, Citronellol, Linalool, Alpha-isomethyl Ionone, Acrylates Copolymer, Coumarin, CI 77492, Hydroxypropylcellulose, Mica, CI 77891, D-limonene, Geraniol, Hydroxypropyl Methylcellulose, Triethyl Citrate, Acrylate Ammonium Methacrylate Copolymer, CI 77491, Caprylyl Capryl Glucoside, Caprylic Capric Triglyceride, Lauryl Glucoside, Talc, Tocopheryl Acetate.

Questions

Questions: 1-844-636-7504 | CustomerService@acquaroma.com

(For 1.0 OZ) Primary Panel



NDC Number Acqua
Aroma With Vitamin E microspheres Hand Sanitizer Gel 1.0 FL OZ (30ML) Kills 99.9% of common
bacteria

(For 12.9 OZ) Primary Panel



Acqua Aroma The Scent of Your Home NDC Number With Vitamin E microspheres Hand Sanitizer Gel 12.9 FL OZ (380ML) Kills 99.9% of common bacteria

ACQUA AROMA HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70848-410
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	21.024 mL in 30 mL

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.0315 mL in 30 mL
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	0.009 mL in 30 mL
MANNITOL (UNII: 3OWL53L36A)	0.0138 mL in 30 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.00024 mL in 30 mL
WATER (UNII: 059QF0K00R)	8.6655 mL in 30 mL
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	0.09 mL in 30 mL
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	0.09 mL in 30 mL
HYPROMELLOSES (UNII: 3NXW29V3WO)	0.00024 mL in 30 mL
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	0.00072 mL in 30 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70848-410-30	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2016	

ACQUA AROMA HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70848-413
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	266.304 mL in 380 mL

Inactive Ingredients

Ingredient Name	Strength
METHACRYLATE/METHOXY PEG-10 MALEATE/STYRENE COPOLYMER (UNII: 39DK5WQ2PR)	0.00304 mL in 380 mL
ACRYLIC ACID/ISOPHORONE DIISOCYANATE/PEG-27 COPOLYMER (UNII: R0R8I3X29J)	0.02546 mL in 380 mL
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	0.00304 mL in 380 mL
TALC (UNII: 7SEV7J4R1U)	0.00304 mL in 380 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.399 mL in 380 mL
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	0.1824 mL in 380 mL
MANNITOL (UNII: 3OWL53L36A)	0.361 mL in 380 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.00304 mL in 380 mL
WATER (UNII: 059QF0K00R)	109.421 mL in 380 mL
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	1.14 mL in 380 mL
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	1.14 mL in 380 mL
HYPROMELLOSES (UNII: 3NXW29V3WO)	0.00608 mL in 380 mL
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	0.01216 mL in 380 mL
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	0.00304 mL in 380 mL
FERRIC OXIDE RED (UNII: 1K09F3G675)	0.00304 mL in 380 mL
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	0.01216 mL in 380 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	0.01026 mL in 380 mL
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	0.00304 mL in 380 mL
MICA (UNII: V8A1AW0880)	0.01216 mL in 380 mL
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	0.00304 mL in 380 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70848-413-80	380 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2016	

Labeler - Smell It Industria e Comercio Ltda (678349245)

Registrant - Acqua Aroma US LLC (080193028)

Establishment

Name	Address	ID/FEI	Business Operations
Smell It Industria e Comercio Ltda		678349245	manufacture(70848-410, 70848-413)

Revised: 6/2020

Smell It Industria e Comercio Ltda