

ACORE LAVENDER HAND SANITIZER GIRLS- alcohol denat. gel
Gold Orient International Limited

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.

ACORE Lavender(Girls)Hand Sanitizer

Active ingredient

Alcohol Denat. 62%

Purpose

Antiseptic

Use

Use for hand-washing to decrease bacteria on the skin, only when water is not available.

Warnings

For external use only. Flammable, keep away from fire and flames.

When using this product

Do not get into eyes.

If contact occurs, rinse eyes thoroughly with water.

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

If irritation and redness develop.

Directions

Wet hands thoroughly with product and allow to dry without wiping.

Other information

Store at 68 to 77F (20-25C)

Do not store above 110F (43C)

You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536

Inactive ingredient

Water,

Glycerin,

Acrylates/C10-30 Alkyl Acrylate Crosspolymer,
Fragrance,
Polysorbate 20,
Sodium Hydroxide,
Red 33,
Blue 1

Label

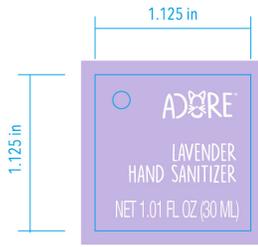


PANTONE
2635
WITH GLITTER

HAND SANI COLOR:

PANTONE
2635C @ 70%

PANTONE 7506 @ 50%	PANTONE 196	PANTONE 1205
PANTONE 358	PANTONE 290	PANTONE 2635
	BLACK	WHITE



FRONT



BACK

PANTONE
2635



FIRST SPREAD

Drug Facts	
Active ingredient	Purpose
Alcohol Denat. 62% Antiseptic	
Use for hand-washing to decrease bacteria on the skin, only when water is not available	
Warnings	
For external use only	
Flammable, keep away from fire and flames	
GLUE AREA	

GLUE AREA	
Drug Facts (continued)	
When using this product	
do not get into eyes.	
If contact occurs, rinse eyes thoroughly with water.	
Stop use and ask a doctor if	
irritation and redness develop	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
GLUE AREA	

SECOND SPREAD

Drug Facts (continued)	
Directions	
wet hands thoroughly with product and allow to dry without wiping	
Other information	
Store at 68° to 77°F (20°-25°C)	
Do not store above 110°F (43°C)	
You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536	
GLUE AREA	

GLUE AREA	
Drug Facts (continued)	
Inactive ingredients	
Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Polysorbate 20, Sodium Hydroxide, Red 33, Blue 1.	

ACORE LAVENDER HAND SANITIZER GIRLS

alcohol denat. gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51522-047
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51522-047-01	1 in 1 CASE	08/03/2020	
1		30 mL in 1 BOTTLE, PLASTIC; 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	08/03/2020	

Labeler - Gold Orient International Limited (679905914)

Establishment

Name	Address	ID/FEI	Business Operations
Gold Orient International Limited		679905914	manufacture(51522-047)