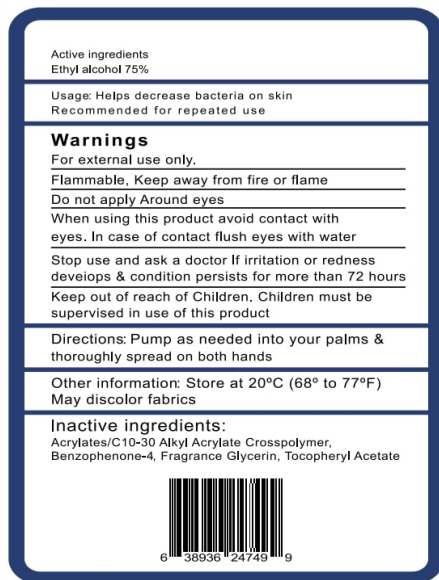


HAND SANITIZER- alcohol gel Design Element Group INC

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.

Ethyl Alcohol 75%

240_{ML}



Stop use and ask a doctor if irritation or redness develops & condition persists for more than 72 hours.

Do no apply around eyes.

When using this product avoid contact with eyes. In case of contact flush eyes with water.

Keep out of reach of children.

Children must be supervised in use of this product.

Helps decrease bacteria on skin.

Recommended for repeated use.

Stop use and ask a doctor if irritation or redness develops & condition persists for more than 72 hours.

When using this product avoid contact with eyes. In case of contact flush eyes with water.

Store at 20 C (68-77 F)

May discolor fabrics

Store at 20 C (68-77F)

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Benzophenone-4, Fragrance Glycerin, Tocopheryl Acetate

For external use only.

Flammable. Keep away from fire or flame.

Do not apply around eyes.

Pump as needed into your palms & thoroughly spread on both hands.

Active 75% ethyl alcohol

Help decrease bacteria on skin.

Pump as needed into your palms & thoroughly spread on both hands.

hand sanitizer gel

75% active ethyl alcohol

inactive ingredients

acrylate crosspolymer

benzophenone-4

fragrance glycerin

tocopheryl acetate



75% Alcohol

Hand sanitizer with added moisturiser

Feeling clean and smooth

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:8 10 11-128
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
WATER (UNII: 059QF0K00R)	
FRAGRANCE FRESHWATER CUCUMBER ORC2000871 (UNII: NL1QX9C6TG)	
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPAS NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	
SULISOBENZONE (UNII: 1W6L629B4K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81011-128-01	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/05/2020	
2	NDC:81011-128-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/05/2020	
3	NDC:81011-128-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/05/2020	
4	NDC:81011-128-04	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/05/2020	
5	NDC:81011-128-05	1000 mL in 1 POUCH; Type 0: Not a Combination Product	11/05/2020	

240_{ML}

Active ingredients
Ethyl alcohol 75%


Usage: Helps decrease bacteria on skin
Recommended for repeated use

Warnings
For external use only.
Flammable. Keep away from fire or flame
Do not apply Around eyes
When using this product avoid contact with eyes. In case of contact flush eyes with water
Stop use and ask a doctor If irritation or redness develops & condition persists for more than 72 hours
Keep out of reach of Children. Children must be supervised in use of this product

Directions: Pump as needed into your palms & thoroughly spread on both hands

Other information: Store at 20°C (68° to 77°F)
May discolor fabrics

Inactive ingredients:
Acrylates/C10-30 Alkyl Acrylate Crosspolymer,
Benzophenone-4, Fragrance Glycerin, Tocopheryl Acetate



75%
Alcohol

**HAND
SANITIZER**

with added moisturiser



Feeling clean and smooth

240ML

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/02/2020	

Labeler - Design Element Group INC (023273678)

Registrant - Design Element Group INC (023273678)

Establishment

Name	Address	ID/FEI	Business Operations
Design Element Group INC		023273678	manufacture(81011-128)

Revised: 10/2020

Design Element Group INC