

COLOR ELEMENT ADVANCED HAND SANITIZER WITH MOISTURIZERS AND VITAMIN E- alcohol gel

Zhejiang iColor Biotech Co., Ltd

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.

Color Element Advanced Hand Sanitizer with Moisturizers and Vitamin E

Drug Facts

Active ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Uses

- For hand washing to help reduce bacteria that potentially can cause disease. Recommended for repeated use. For use when soap and water are not available.

Warnings

For external use only.

Flammable. Keep away from heat or flame.

When using this product

do not use in or near 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 appears on the skin.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Children under 6 years of age should be supervised by adult when applying this product.
- Do not use on children less than 2 months of age or on open skin wounds.

Other information

- Store below 110 °F (43 °C)
- May discolor certain fabrics or surfaces

Inactive Ingredients

Water, Glycerin, Squalane, Panthenol, Inulin, Sodium Hyaluronate, Fructose, Tocopheryl Acetate, Acrylates/C10-30 Alkyl Acrylate Cross Polymer, Aminomethyl Propanol.

Package Labeling: 60 mL 74934-002-60

COLOR ELEMENT

ADVANCED HAND SANITIZER

with

Moisturizers & Vitamin E



2FL.OZ/60mL

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
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Manufactured by
 Zhejiang iColor Biotech Co., Ltd
 Add: 188 Punan Avenue,
 Shengzhou Economic Development Zone,
 Shaoxing city, Zhejiang Province, 312473, China
 US Add: 380 Lexington Ave, 17 Floor,
 New York, NY 10168
 Tel: +1 212-551-2657
 Made in China


Package Labeling: 100 mL 74934-002-10

COLOR ELEMENT

ADVANCED HAND SANITIZER

with

Moisturizers & Vitamin E



3.4FL.OZ/100mL

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
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Package Labeling: 300 mL 74934-002-30

COLOR ELEMENT

ADVANCED HAND SANITIZER with

Moisturizers & Vitamin E



10.2FL.OZ/300mL

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
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Warnings For external use only Flammable. Keep away from heat or flame When using this product do not use in or near 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 appears on the skin. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
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Other information •Store below 110°F(43°C). •May discolor certain fabrics or surfaces.	
Inactive ingredients Water, Glycerin, Squalene, Panthenol, Inulin, Sodium Hyaluronate, Fructose, Tocopheryl Acetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol.	



6 972973 040175

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Package Labeling: 500 mL 74934-002-50

COLOR ELEMENT

ADVANCED HAND SANITIZER with

Moisturizers & Vitamin E

17FL.OZ/500mL



6 972973 040168

Drug Facts	
Active Ingredient	Purpose
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Package Labeling 1L 74934-002-01

COLOR ELEMENT

ADVANCED HAND SANITIZER

with

Moisturizers & Vitamin E



Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
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Warnings	
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•May discolor certain fabrics or surfaces.	
Inactive ingredients	
Water, Glycerin, Squalane, Panthenol, Inulin, Sodium Hyaluronate, Fructose, Tocopherol Acetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol.	



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Made in China

34FL.OZ/1L

COLOR ELEMENT ADVANCED HAND SANITIZER WITH MOISTURIZERS AND VITAMIN E

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74934-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SQUALANE (UNII: GW89575KF9)	
PANTHENOL (UNII: WV9CM0O67Z)	
INULIN (UNII: JOS53KRJ01)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
FRUCTOSE (UNII: 6YSS42VSEV)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74934-002-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2020	
2	NDC:74934-002-10	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2020	
3	NDC:74934-002-30	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2020	
4	NDC:74934-002-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2020	
5	NDC:74934-002-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333E	04/25/2020	

Labeler - Zhejiang iColor Biotech Co., Ltd (554528308)

Establishment			
Name	Address	ID/FEI	Business Operations
Zhejiang iColor Biotech Co., Ltd		554528308	manufacture(74934-002)