

**DURASHIELD FRAGRANCE FREE HAND SANITIZER- benzalkonium chloride
lotion lotion
CK Polymers LLC**

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.

DuraShield® Fragrance Free

DuraShield® Fragrance Free

Active Ingredients

Active Ingredients: Benzalkonium chloride 0.13%

Purpose

Purpose: 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.

Do not use in children less than 2 months of age or 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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store between 15-30°C (59-86°F)

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

Inactive Ingredients

water, corn starch, soybean oil, petrolatum, pectin, xanthan gum, citricidal, tributyl phosphate, methyl paraben, propyl paraben, vitamin E acetate, white linen fragrance

Questions

275 Gallon Tote - DuraShield® Fragrance Free Hand Sanitizer - Label



Front Panel

[DuraShield "Fragrance Free"]

Hand Sanitizer

275 Gallons Tote

Back Panel

Drug Facts	
Active Ingredients	Purpose
Benzalkonium chloride 0.13%.....	hand sanitizer
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Warnings	
For external use only.	
Do not use • in children less than 2 months of age • on open skin wounds	
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Inactive Ingredients water, corn starch, soybean oil, petrolatum, pectin, xanthan gum, citricidal, tributyl phosphate, methyl paraben, propyl paraben, vitamin E acetate
Questions? call 1-855-668-2520

Distributed by CK Polymers, LLC
4801 Woodway Drive, Suite 275E
Houston, TX 77056
USA

Barcode, Lot #

Expiration Date:

NDC Code not required but recommended (can appear on either front or back panel).

55 Gallon Drum - DuraShield® Fragrance Free Hand Sanitizer - Label



Front Panel

[DuraShield "Original Scent"]

Hand Sanitizer

55 Gallons Drum

Back Panel

Drug Facts	
Active Ingredients	Purpose
Benzalkonium chloride 0.13%.....	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.	
Do not use • in children less than 2 months of age • on open skin wounds	

open skin wounds

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330 Gallon Tote - DuraShield® Fragrance Free - Label



Front Panel

[DuraShield "Original Scent"]

Hand Sanitizer

330 Gallons Tote

Back Panel

DURASHIELD®



HAND SANITIZING LOTION

Fragrance Free

MOISTURIZING VITAMIN E FORMULA
PROLONGED PROTECTION

ALCOHOL FREE

MADE IN THE USA • 2 FL OZ (59 mL)

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Benzalkonium Chloride 0.13%.....	Antimicrobial

Use ■ Hand sanitizer to help decrease common bacteria, viruses, and fungi on the skin.
■ Recommended for repeated use

Warnings

For external use only.

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

Do not use ■ in children less than 2 months of age ■ on open skin wounds ■ in eyes

Stop use if irritation and redness develop. If condition persists more than 72 hours, consult a doctor.

Directions ■ Apply a small amount of lotion into palm of hand ■ Rub hands together until dry

Inactive ingredients purified water, waxy corn starch, soybean oil, petrolatum, pectin, xanthan gum, citricidal, tri-n-butyl phosphate, propyl paraben, methyl paraben, D-alpha tocopherol acetate (vitamin E)

Questions? call 1-855-668-2520

Manufactured by: Advanced Biomedical, Inc
Frisco, TX 75035. USA www.DuraShieldABI.com

4OZ Bottlel - DuraShield® Fragrance Free Hand Sanitizer - Label

DURASHIELD®



HAND SANITIZING LOTION

Fragrance Free

MOISTURIZING VITAMIN E FORMULA
PROLONGED PROTECTION

ALCOHOL FREE

MADE IN THE USA • 4 FL OZ (118 mL)

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Benzalkonium Chloride 0.13%.....	Antimicrobial

Use ■ Hand sanitizer to help decrease common bacteria, viruses, and fungi on the skin.
■ Recommended for repeated use

Warnings

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Manufactured by: Advanced Biomedical, Inc
Frisco, TX 75035. USA www.DuraShieldABI.com

8OZ Bottlel - DuraShield® Fragrance Free Hand Sanitizer - Label

DURASHIELD®



HAND SANITIZING LOTION

Fragrance Free

MOISTURIZING VITAMIN E FORMULA
PROLONGED PROTECTION

ALCOHOL FREE

MADE IN THE USA • 8 FL OZ (237 mL)

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Benzalkonium Chloride 0.13%.....	Antimicrobial

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■ Recommended for repeated use

Warnings

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Manufactured by: Advanced Biomedical, Inc
Frisco, TX 75035. USA www.DuraShieldABI.com

5 Gallon Pail - DuraShield® Fragrance Free Hand Sanitizer - Label



Front Panel

[DuraShield "Original Scent"]

Hand Sanitizer

5 Gallons Pail

Back Panel

Drug Facts

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Inactive Ingredients water, corn starch, soybean oil, petrolatum, pectin, xanthan gum, citricidal, tributyl phosphate, methyl paraben, propyl paraben, vitamin E acetate	
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DURASHIELD FRAGRANCE FREE HAND SANITIZER

benzalkonium chloride lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78235-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	.13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CORN STARCH 3-E-DODECENYL SUCCINIC ANHYDRIDE MODIFIED (UNII: QG4MW19XYX)	
SOYBEAN OIL (UNII: 241ATL177A)	
PETROLATUM (UNII: 4T6H12BN9U)	
PECTIN (UNII: 89NA02M4RX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GRAPEFRUIT SEED OIL (UNII: 598D944HOL)	
TRIBUTYL PHOSPHITE (UNII: 498030B4AD)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78235-012-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	10/06/2020	
2	NDC:78235-012-02	208175 mL in 1 DRUM; Type 0: Not a Combination Product	10/06/2020	
3	NDC:78235-012-03	18927.1 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/06/2020	
4	NDC:78235-012-04	1249050 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/06/2020	
5	NDC:78235-012-05	1040875 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/09/2020	
6	NDC:78235-012-06	60 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/09/2020	
7	NDC:78235-012-07	118 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/09/2020	
8	NDC:78235-012-08	237 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/06/2020	

Labeler - CK Polymers LLC (079790285)

Establishment

Name	Address	ID/FEI	Business Operations
CK Polymers LLC		079790285	manufacture(78235-012)

