

**DURASHIELD ORIGINAL SCENT HAND SANITIZER- safe and silky fragrance  
hs 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.*

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**DuraShield® Original Scent**

**DuraShield® Original Scent**

**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 an 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

**55 Gallon Tote - DuraShield® Original Scent Hand Sanitizer - Label**



## Front Panel

[DuraShield "Original Scent"]

Hand Sanitizer

55 Gallons Drum

## Back Panel

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Benzalkonium chloride 0.13% .....	hand sanitizer
<b>Use</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only.</b> <b>Do not use</b> • in children less than 2 months of age • on open skin wounds <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor if</b> irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.	
<b>Directions</b> • 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.	
<b>Other Information</b> • store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive Ingredients</b> water, corn starch, soybean oil, petrolatum, pectin, xanthan gum, citricidal, tributyl phosphate, methyl paraben, propyl paraben, vitamin E acetate, fragrance	
<b>Questions?</b> call 1-855-668-2520	

[Distributed by/Manufactured by/Manufactured for] 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).

## 330 Gallon Tote - DuraShield® Original Scent Hand Sanitizer - Label



### Front Panel

[DuraShield "Fragrance Free"]

Hand Sanitizer

330 Gallons Tote

### Back Panel

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Benzalkonium chloride 0.13%.....	hand sanitizer
<b>Use</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only.</b> <b>Do not use</b> • in children less than 2 months of age • on open skin wounds <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor if</b> irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical	

help or contact a Poison Control Center immediately.
<b>Directions</b> • 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.
<b>Other Information</b> • store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)
<b>Inactive Ingredients</b> water, corn starch, soybean oil, petrolatum, pectin, xanthan gum, citricidal, tributyl phosphate, methyl paraben, propyl paraben, vitamin E acetate
<b>Questions?</b> call 1-855-668-2520

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USA

Barcode, Lot #

Expiration Date:

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

## 275 Gallon Tote - DuraShield® Original Scent - Label



### Front Panel

[DuraShield "Fragrance Free"]

Hand Sanitizer

275 Gallons Tote

## Back Panel

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Benzalkonium chloride 0.13%.....	hand sanitizer
<b>Use</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only.</b> <b>Do not use</b> • in children less than 2 months of age • on open skin wounds <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor if</b> irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.	
<b>Directions</b> • 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.	
<b>Other Information</b> • store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive Ingredients</b> water, corn starch, soybean oil, petrolatum, pectin, xanthan gum, citricidal, tributyl phosphate, methyl paraben, propyl paraben, vitamin E acetate	
<b>Questions?</b> call 1-855-668-2520	

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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).

**2OZ Bottle - DuraShield® Original Scent Hand Sanitizer - Label**

# DURASHIELD®



**HAND SANITIZING LOTION**

**Original Scent**

White Linen

MOISTURIZING VITAMIN E FORMULA  
PROLONGED PROTECTION

**ALCOHOL FREE**

**MADE IN THE USA • 2 FL OZ (59 mL)**

## **Drug Facts**

### **Active ingredient**

Benzalkonium Chloride 0.13%.....Antimicrobial

### **Purpose**

**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), fragrance

**Questions?** call 1-855-668-2520

**Manufactured by:** Advanced Biomedical, Inc  
Frisco, TX 75035, USA [www.DuraShieldABI.com](http://www.DuraShieldABI.com)

**4OZ Bottle - DuraShield® Original Scent Hand Sanitizer - Label**



# DURASHIELD®



**HAND SANITIZING LOTION**

***Original Scent***

White Linen

MOISTURIZING VITAMIN E FORMULA  
PROLONGED PROTECTION

**ALCOHOL FREE**

**MADE IN THE USA • 4 FL OZ (118 mL)**

## ***Drug Facts***

### ***Active ingredient***

Benzalkonium Chloride 0.13%.....Antimicrobial

### ***Purpose***

***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), fragrance

***Questions?*** call 1-855-668-2520

**Manufactured by:** Advanced Biomedical, Inc  
Frisco, TX 75035, USA [www.DuraShieldABI.com](http://www.DuraShieldABI.com)

**8OZ Bottle - DuraShield® Original Scent Hand Sanitizer - Label**



# DURASHIELD®



## HAND SANITIZING LOTION

**Original Scent**

White Linen

MOISTURIZING VITAMIN E FORMULA  
PROLONGED PROTECTION

**ALCOHOL FREE**

**MADE IN THE USA • 8 FL OZ (237 mL)**

### Drug Facts

#### Active ingredient

Benzalkonium Chloride 0.13%.....Antimicrobial

#### Purpose

**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), fragrance

**Questions?** call 1-855-668-2520

Manufactured by: Advanced Biomedical, Inc  
Frisco, TX 75035, USA [www.DuraShieldABI.com](http://www.DuraShieldABI.com)

## DURASHIELD ORIGINAL SCENT HAND SANITIZER

safe and silky fragrance hs lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78235-011
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CORN STARCH 3-E-DODECENYL SUCCINIC ANHYDRIDE MODIFIED</b> (UNII: QG4MW19XYX)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

<b>PECTIN</b> (UNII: 89NA02M4RX)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>GRAPEFRUIT SEED OIL</b> (UNII: 598D944HOL)	
<b>TRIBUTYL PHOSPHITE</b> (UNII: 498030B4AD)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>BENZYL BENZOATE</b> (UNII: N863NB338G)	
<b>HEXAMETHYLINDANOPYRAN</b> (UNII: 14170060AT)	
<b>TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES</b> (UNII: 2JU6ZH6GRE)	
<b>.ALPHA.-ISOBUTYLPHENETHYL ALCOHOL</b> (UNII: 2SBL0E1I0N)	
<b>BENZYL ACETATE</b> (UNII: 0ECG3V79ZJ)	
<b>METHYL-.ALPHA.-IONONE</b> (UNII: QMK5X3FBG7)	
<b>BENZYL SALICYLATE</b> (UNII: WAO5MNK9TU)	
<b>ISOMETHYL-.ALPHA.-IONONE</b> (UNII: 9XP4LC555B)	
<b>BUTYLPHENYL METHYLPROPIONAL</b> (UNII: T7540GJV69)	
<b>NEROL</b> (UNII: 38G5P53250)	
<b>GERANIOL</b> (UNII: L837108USY)	
<b>ISOAMYL SALICYLATE</b> (UNII: M25E4ZMR0N)	
<b>HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE</b> (UNII: QUE43B9Z2Q)	
<b>CINNAMON LEAF OIL</b> (UNII: S92U8SQ71V)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78235-011-01	3780 mL in 1 JUG; Type 0: Not a Combination Product	10/08/2020	
2	NDC:78235-011-02	208190 mL in 1 DRUM; Type 0: Not a Combination Product	10/08/2020	
3	NDC:78235-011-03	18927.1 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/08/2020	
4	NDC:78235-011-04	1249190 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/08/2020	
5	NDC:78235-011-05	1040990 mL in 1 CONTAINER; Type 0: Not a Combination Product	10/08/2020	
6	NDC:78235-011-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2020	
7	NDC:78235-011-07	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2020	
8	NDC:78235-011-08	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/08/2020	

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## Establishment

Name	Address	ID/FEI	Business Operations
CK Polymers LLC		079790285	manufacture(78235-011)

Revised: 4/2022

CK Polymers LLC