

DURASHIELD- benzalkonium chloride lotion

Advanced Biomedical Incorporated

Active ingredient

Benzalkonium chloride, 0.13%

Purpose

Antimicrobial

Uses

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

Warnings

For external use only: hands

When using this product

- keep out of eyes. In case of contact with eyes, flush thoroughly with water.
- avoid contact with broken skin
- do not ingest

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children

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

Directions

- Apply a small amount of lotion into palm of hand
- Rub hands together thoroughly until dry
- No towels or wiping required
- for children under 6, use only under adult supervision

Other information

- Store between 35°-100°F

Inactive ingredients

purified water (aqua), zea mays (corn) starch, perseae gratissima (avocado) oil, pectin,

petrolatum, phenoxyethanol, xanthan gum, potassium sorbate, tributyl phosphate, citrus paradisi (grapefruit) seed extract, ethylhexylglycerin, tocopherol, glycerin, ascorbic acid, bht, sodium hydroxide

Questions or comments?

www.DuraShieldProtects.com

Tel: 1-855-NOT-ALCO or 1-855-668-2520

Durashield Hand Sanitizing Lotion 0.011 Fl Oz - NDC 85131-013-00

Puts The Power To Fight Germs In Your Hands™

Drug Facts	
Active ingredient Benzalkonium chloride, 0.13%	Purpose Antimicrobial
Uses ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use	
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Inactive ingredients purified water (aqua), zea mays (corn) starch, persea gratissima (avocado) oil, pectin, petrolatum, phenoxyethanol, xanthan gum, potassium sorbate, tributyl phosphate, citrus paradisi (grapefruit) seed extract, ethylhexylglycerin, tocopherol, glycerin, ascorbic acid, bht, sodium hydroxide	

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ALCOHOL - FREE HAND SANITIZING LOTION NDC: 85131-013-00

DuraShield®

Advanced Hand Sanitizing Lotion

Moisturizing Vitamin E & Avocado Oil Formula

Dermatologically Tested

Safe on Skin

Prolonged Protection

Kills 99.99% of Germs*

Made in the USA

0.011 FL OZ (0.33mL)

100% Fragrance Free

100% Alcohol-Free

100% Paraben-Free

Clinically Tested

Safe for all glove types

- Latex
- Vinyl

- Nitrile

*Kills 99.99% of most common germs that may cause illness.

Puts The Power To Fight Germs In Your Hands™

Alcohol-Free Hand Sanitizing Lotion

NDC: 85131-013-00

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Durashield Hand Sanitizing Lotion 2 Fl Oz - NDC 85131-013-02

Puts The Power To Fight Germs In Your Hands™

Drug Facts

Active ingredient	Purpose
Benzalkonium chloride, 0.13%	Antimicrobial

Uses ■ To decrease bacteria on the skin that could cause disease
■ recommended for repeated use

Warnings
For external use only: hands
When using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water ■ avoid contact with broken skin ■ do not ingest
Stop use and ask a doctor if ■ irritation and redness develop ■ condition persists for more than 72 hours
Keep out of reach of children ■ if swallowed, get medical help or contact a Poison Control Center right away

Directions ■ Apply a small amount of lotion into palm of hand ■ Rub hands together thoroughly until dry ■ No towels or wiping required ■ for children under 6, use only under adult supervision

Other information ■ Store between 35°- 100°F

Inactive ingredients purified water (aqua), zea mays (corn) starch, persea gratissima (avocado) oil, pectin, petrolatum, phenoxyethanol, xanthan gum, potassium sorbate, tributyl phosphate, citrus paradisi (grapefruit) seed extract, ethylhexylglycerin, tocopherol, glycerin, ascorbic acid, bht, sodium hydroxide

ALCOHOL - FREE HAND SANITIZING LOTION NDC: 85131-013-02

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DuraShield®

Advanced Hand Sanitizing Lotion

Moisturizing Vitamin E & Avocado Oil Formula

Dermatologically Tested

Safe on Skin

Prolonged Protection

Kills 99.99% of Germs*

Made in the USA

2 FL OZ (59mL)

100% Fragrance Free

100% Alcohol-Free

100% Paraben-Free

Clinically Tested

Safe for all glove types

- Latex
- Vinyl
- Nitrile

*Kills 99.99% of most common germs that may cause illness.

Puts The Power To Fight Germs In Your Hands™

Alcohol-Free Hand Sanitizing Lotion

NDC: 85131-013-02

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Durashield Hand Sanitizing Lotion 4 Fl Oz - NDC 85131-013-04

Put The Power To Fight Germs In Your Hands™

Drug Facts

Active ingredient	Purpose
Benzalkonium chloride, 0.13%	Antimicrobial

Uses ■ to decrease bacteria on the skin that could cause disease
 ■ recommended for repeated use

Warnings
 For external use only: hands
When using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water ■ avoid contact with broken skin ■ do not ingest

Stop use and ask a doctor if ■ irritation and redness develop ■ condition persists for more than 72 hours

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

Directions ■ Apply a small amount of lotion into palm of hand ■ Rub hands together thoroughly until dry ■ No towels or wiping required ■ for children under 6, use only under adult supervision

Other information ■ Store between 35°- 100°F

Inactive ingredients purified water (aqua), zea mays (corn) starch, persea gratissima (avocado) oil, pectin, petrolatum, phenoxyethanol, xanthan gum, potassium sorbate, tributyl phosphate, citrus paradisi (grapefruit) seed extract, ethylhexylglycerin, tocopherol, glycerin, ascorbic acid, bht, sodium hydroxide

ALCOHOL - FREE HAND SANITIZING LOTION NDC: 85131-013-04

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DuraShield®

Advanced Hand Sanitizing Lotion

Moisturizing Vitamin E & Avocado Oil Formula

Dermatologically Tested

Safe on Skin

Prolonged Protection

Kills 99.99% of Germs*

Made in the USA

4 FL OZ (118mL)

100% Fragrance Free

100% Alcohol-Free

100% Paraben-Free

Clinically Tested

Safe for all glove types

- Latex
- Vinyl
- Nitrile

*Kills 99.99% of most common germs that may cause illness.

Puts The Power To Fight Germs In Your Hands™

Alcohol-Free Hand Sanitizing Lotion

NDC: 85131-013-04

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Durashield Hand Sanitizing Lotion 8 Fl Oz - NDC 85131-013-08

DURASHIELD®
ADVANCED
HAND SANITIZING LOTION
MOISTURIZING VITAMIN E
& AVOCADO OIL FORMULA

DERMATOLOGICALLY TESTED
SAFE ON SKIN

PROLONGED PROTECTION
KILLS 99.99% OF GERMS*

Made in the USA ■ 8 FL OZ (237mL)

100% FRAGRANCE FREE
100% ALCOHOL-FREE
100% PARABEN-FREE

CLINICALLY TESTED SAFE FOR ALL GLOVE TYPES
■ Latex
■ Vinyl
■ Nitrile

*Kills 99.99% of most common germs that may cause illness.

Puts The Power To Fight Germs In Your Hands™

Drug Facts	
Active ingredient Benzalkonium chloride, 0.13%	Purpose Antimicrobial
Uses ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use	
Warnings For external use only: hands When using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water ■ avoid contact with broken skin ■ do not ingest	
Stop use and ask a doctor if ■ irritation and redness develop ■ condition persists for more than 72 hours	
Keep out of reach of children ■ If swallowed, get medical help or contact a Poison Control Center right away	
Directions ■ Apply a small amount of lotion into palm of hand ■ Rub hands together thoroughly until dry ■ No towels or wiping required ■ for children under 6, use only under adult supervision	
Other information ■ Store between 35°- 100°F	
Inactive ingredients purified water (aqua), zea mays (corn) starch, persea gratissima (avocado) oil, pectin, petrolatum, phenoxethanol, xanthan gum, potassium sorbate, tributyl phosphate, citrus paradisi (grapefruit) seed extract, ethylhexylglycerin, tocopherol, glycerin, ascorbic acid, bht, sodium hydroxide	

ALCOHOL - FREE HAND SANITIZING LOTION NDC: 85131-013-08

Questions or comments?
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DuraShield®

Advanced Hand Sanitizing Lotion

Moisturizing Vitamin E & Avocado Oil Formula

Dermatologically Tested

Safe on Skin

Prolonged Protection

Kills 99.99% of Germs*

Made in the USA

8 FL OZ (237mL)

100% Fragrance Free

100% Alcohol-Free

100% Paraben-Free

Clinically Tested

Safe for all glove types

- Latex
- Vinyl
- Nitrile

*Kills 99.99% of most common germs that may cause illness.

Puts The Power To Fight Germs In Your Hands™

Alcohol-Free Hand Sanitizing Lotion

NDC: 85131-013-08

Distributed by: Advanced Biomedical, Inc. Frisco, TX 75035

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Durashield Hand Sanitizing Lotion 12 Fl Oz - NDC 85131-013-12

Puts The Power To Fight Germs In Your Hands™

Drug Facts

Active ingredient	Purpose
Benzalkonium chloride, 0.13%	Antimicrobial

Uses ■ to decrease bacteria on the skin that could cause disease
■ recommended for repeated use

Warnings
For external use only; hands
When using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin
■ do not ingest

Stop use and ask a doctor if ■ irritation and redness develop
■ condition persists for more than 72 hours

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

Directions ■ Apply a small amount of lotion into palm of hand
■ Rub hands together thoroughly until dry ■ No towels or wiping required
■ for children under 6, use only under adult supervision

Other information ■ Store between 35°- 100°F

Inactive ingredients purified water (aqua), zea mays (corn) starch, persea gratissima (avocado) oil, pectin, petrolatum, phenoxyethanol, xanthan gum, potassium sorbate, tributyl phosphate, citrus paradisi (grapefruit) seed extract, ethylhexylglycerin, tocopherol, glycerin, ascorbic acid, bht, sodium hydroxide

Questions or comments?
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ALCOHOL - FREE HAND SANITIZING LOTION NDC: 85131-013-12

DuraShield®

Advanced Hand Sanitizing Lotion

Moisturizing Vitamin E & Avocado Oil Formula

Dermatologically Tested

Safe on Skin

Prolonged Protection

Kills 99.99% of Germs*

Made in the USA

12 FL OZ (355mL)

100% Fragrance Free

100% Alcohol-Free

100% Paraben-Free

Clinically Tested

Safe for all glove types

- Latex
- Vinyl
- Nitrile

*Kills 99.99% of most common germs that may cause illness.

Puts The Power To Fight Germs In Your Hands™

Alcohol-Free Hand Sanitizing Lotion

NDC: 85131-013-12

Distributed by: Advanced Biomedical, Inc. Frisco, TX 75035

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Durashield Hand Sanitizing Lotion 16 Fl Oz - NDC 85131-013-16

Puts The Power To Fight Germs In Your Hands™	
Drug Facts	
Active ingredient	Purpose
Benzalkonium chloride, 0.13%	Antimicrobial
Uses ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use	
Warnings	
For external use only: hands	
When using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin ■ do not ingest	
Stop use and ask a doctor if ■ irritation and redness develop ■ condition persists for more than 72 hours	
Keep out of reach of children ■ If swallowed, get medical help or contact a Poison Control Center right away	
Directions ■ Apply a small amount of lotion into palm of hand ■ Rub hands together thoroughly until dry ■ No towels or wiping required ■ for children under 6, use only under adult supervision	
Other information ■ Store between 35°- 100°F	
Inactive ingredients purified water (aqua), zea mays (corn) starch, persea gratissima (avocado) oil, pectin, petrolatum, phenoxyethanol, xanthan gum, potassium sorbate, tributyl phosphate, citrus paradisi (grapefruit) seed extract, ethylhexylglycerin, tocopherol, glycerin, ascorbic acid, bht, sodium hydroxide	

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DuraShield®

Advanced Hand Sanitizing Lotion

Moisturizing Vitamin E & Avocado Oil Formula

Dermatologically Tested

Safe on Skin

Prolonged Protection

Kills 99.99% of Germs*

Made in the USA

16 FL OZ (473mL)

100% Fragrance Free

100% Alcohol-Free

100% Paraben-Free

Clinically Tested

Safe for all glove types

- Latex
- Vinyl
- Nitrile

*Kills 99.99% of most common germs that may cause illness.

Puts The Power To Fight Germs In Your Hands™

Alcohol-Free Hand Sanitizing Lotion

NDC: 85131-013-16

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DURASHIELD

benzalkonium chloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85131-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STARCH, CORN (UNII: O8232NY3SJ)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
PECTIN (UNII: 89NA02M4RX)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
TRI-N-BUTYL PHOSPHATE (UNII: 95UAS8YAF5)	
CITRUS PARADISI SEED (UNII: 12F08874Y7)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERIN (UNII: PDC6A3C0OX)	

ASCORBIC ACID (UNII: PQ6CK8PD0R)

BHT (UNII: 1P9D0Z171K)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85131-013-00	0.33 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2024	
2	NDC:85131-013-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2024	
3	NDC:85131-013-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2024	
4	NDC:85131-013-08	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/18/2024	
5	NDC:85131-013-12	355 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/18/2024	
6	NDC:85131-013-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/18/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	12/18/2024	

Labeler - Advanced Biomedical Incorporated (029084777)

Establishment

Name	Address	ID/FEI	Business Operations
PhytogenX, Inc.		624386772	manufacture(85131-013)

Revised: 12/2024

Advanced Biomedical Incorporated