

**SAFE AND SILKY NATURAL 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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**Safe & Silky Natural Hand Sanitizer**

**Safe & Silky Fragrance Hand Sanitizer**

**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 - Safe & Silky Fragrance Hand Sanitizer - Label**

Original Label:



## Front Panel

[Safe & Silky Fragrance HS]

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</b> if 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)<br>• 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, white linen fragrance |                |
| <b>Questions?</b> 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).

Revised 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><br><b>For external use only.</b><br><b>Do not use</b> • in children less than 2 months of age • on open skin wounds<br><b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.<br><b>Stop use and ask a doctor if</b> irritation or rash occurs. These may be signs of a serious condition.<br><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)<br>• 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   |                |

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**330 Gallon Tote - Safe & Silky Fragrance Hand Sanitizer - Label**



## Front Panel

[Safe & Silky Fragrance HS]

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</b> if 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)<br>• 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, white linen fragrance |                |
| <b>Questions?</b> call 1-855-668-2520  |                |

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## 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)<br>• 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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**1 Gallon Jug - Safe & Silky Fragrance Hand Sanitizer - Label**



## Front Panel

[Safe & Silky Fragrance HS]

Hand Sanitizer

1 Gallon Jug

## 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</b> if 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)<br>• 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, white linen fragrance |                |
| <b>Questions? call 1-855-668-2520</b>  |                |

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## 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)<br>• 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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## Front Panel

[Safe & Silky Fragrance HS]

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  |                |
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| <b>Other Information</b> • store between 15-30°C (59-86°F)<br>• 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, white linen fragrance |                |
| <b>Questions?</b> call 1-855-668-2520  |                |

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## Front Panel

[Safe & Silky Fragrance HS]

Hand Sanitizer

5 Gallons Pail

## 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.  |                |
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| <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)<br>• 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, white linen fragrance |                |
| <b>Questions? call 1-855-668-2520</b>  |                |

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## Front Panel

[Safe & Silky Fragrance HS]

Hand Sanitizer

5 Gallons Pail

## 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.  |                |
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| <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)<br>• 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, white linen fragrance |                |
| <b>Questions? call 1-855-668-2520</b>  |                |

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# 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**

| <b>Active ingredient</b>         | <b>Purpose</b> |
|----------------------------------|----------------|
| 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), 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 - Safe & Silky Fragrance 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**

| <b>Active ingredient</b>         | <b>Purpose</b> |
|----------------------------------|----------------|
| 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), 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 - Safe & Silky Fragrance 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                | Purpose       |
|----------------------------------|---------------|
| 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), fragrance

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

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

## SAFE AND SILKY NATURAL HAND SANITIZER

safe and silky fragrance hs lotion

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:78235-009 |
| 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)                            |
| METHYL PARABEN (UNII: A2I8C7HI9T)                                |
| PROPYL PARABEN (UNII: Z8IX2SC1OH)                                |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                      |
| BENZYL BENZOATE (UNII: N863NB338G)                               |
| HEXAMETHYLINDANOPYRAN (UNII: 14170060AT)                         |
| TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES (UNII: 2JU6ZH6GRE)       |
| .ALPHA.-ISOBUTYLPHENETHYL ALCOHOL (UNII: 2SBL0E110N)             |
| BENZYL ACETATE (UNII: 0ECG3V79ZJ)                                |
| METHYL-.ALPHA.-IONONE (UNII: QMK5X3FBG7)                         |
| BENZYL SALICYLATE (UNII: WAO5MKN9TU)                             |
| ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)                      |
| BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)                   |
| NEROL (UNII: 38G5P53250)   |
| GERANIOL (UNII: L837108USY)                                      |
| ISOAMYL SALICYLATE (UNII: M25E4ZMR0N)                            |
| HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q) |
| CINNAMON LEAF OIL (UNII: S92U8SQ71V)                             |

| Packaging |                  |  |                      |                    |
|-----------|------------------|--|----------------------|--------------------|
| #         | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
| 1         | NDC:78235-009-01 | 3780 mL in 1 JUG; Type 0: Not a Combination Product          | 10/08/2020           |                    |
| 2         | NDC:78235-009-02 | 208190 mL in 1 DRUM; Type 0: Not a Combination Product       | 10/08/2020           |                    |
| 3         | NDC:78235-009-03 | 18927.1 mL in 1 CONTAINER; Type 0: Not a Combination Product | 10/08/2020           |                    |
| 4         | NDC:78235-009-04 | 1249190 mL in 1 CONTAINER; Type 0: Not a Combination Product | 10/08/2020           |                    |
| 5         | NDC:78235-009-05 | 1040990 mL in 1 CONTAINER; 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           |                    |

**Labeler** - CK Polymers LLC (079790285)

| Establishment   |         |           |                        |
|-----------------|---------|-----------|------------------------|
| Name            | Address | ID/FEI    | Business Operations    |
| CK Polymers LLC |         | 079790285 | manufacture(78235-009) |