Dyna-Hex 2

Drug Facts

Active ingredient
chlorhexidine gluconate 2% solution

Purpose
Antiseptic

Uses
• surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
• healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
• skin wound and general skin cleansing

Warnings
For external use only

Allergy alert:
This product may cause a severe allergic reaction. Symptoms may include: wheezing/difficulty breathing
shock
facial swelling
hives
rash
If an allergic reaction occurs, stop use and seek medical help right away.

Do not use
• if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
• in contact with meninges
• in the genital area

When using this product
• keep out of eyes, ears and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
• if solution should contact these areas, rinse out promptly and thoroughly with water
• wounds that involve more than the superficial layers of the skin should not be routinely treated
• repeated general skin cleansing of large body areas should not be done except when advised by a health care provider

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs
Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Directions
- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical hand scrub:
- wet hands and forearms under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds
- dry thoroughly

Healthcare personnel handwash:
- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

Skin wound and general skin cleaning:
- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

Other information
- store at 20-25° C (68-77° F)
- avoid excessive heat above 40° C (104° F)

Inactive ingredients
citric add. cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments?
call 1-800-587-3721
Monday through Friday 8:00 AM to 4:30 PM CST
NDC 0116-1021-08
Chlorhexidine Gluconate 2% Solution
Antiseptic Foam Handwash
Distributed by:
Xttrium Laboratories, Inc.
Mount Prospect, IL 60056
2BLDY08BTLMLBLB
Dyna-Hex ®
Net Wt 8 fl oz (237 mL)
# Drug Facts

<table>
<thead>
<tr>
<th>Active ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine gluconate</td>
<td>Antiseptic</td>
</tr>
<tr>
<td>2% solution</td>
<td></td>
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</tbody>
</table>

## Uses
- **surgical hand scrub**: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash**: helps reduce bacteria that potentially can cause disease
- **skin wound and general skin cleansing**

## Warnings

For external use only

**Allergy alert:**
This product may cause a severe allergic reaction. Symptoms may include:
- wheezing/difficulty breathing

Lift Here
Drug Facts (continued)

- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use
- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area

When using this product
- keep out of eyes, ears and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when advised by a health care provider

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

Directions
- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical hand scrub:
- wet hands and forearms under running water for 30 seconds.
  Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds
- dry thoroughly

Healthcare personnel handwash:
- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly
**Drug Facts** (continued)

### Skin wound and general skin cleaning:
- Thoroughly rinse the area to be cleaned with water.
- Apply the minimum amount of product necessary to cover the skin or wound area and wash gently.
- Rinse again thoroughly.

### Other information
- Store at 20-25°C (68-77°F).
- Avoid excessive heat above 40°C (104°F).

### Inactive ingredients
- Citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water.

### Questions or comments?
Call 1-800-587-3721
Monday through Friday 8:00 AM to 4:30 PM CST

Laundering/Cleaning Instructions:
Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

NDC 0116-1021-85

DYNA-HEX 2®

ANTIMICROBIAL HAND SOAP

Chlorhexidine Gluconate 2% Solution

Antiseptic

Contains: 2% Chlorhexidine Gluconate

FOR EXTERNAL USE ONLY

FDA approved formula

Helps Reduce Bacteria

Fragrance-Free

Used by Healthcare personnel in hospitals

Net Contents: 8.5 fl oz (251 mL)

2DYN85FLBL
Dynasole Laboratories, Inc., Mount Prospect, IL 60056

**Drug Facts**

**Active ingredient**

Chlorhexidine gluconate 2% solution ................................ Antiseptic

**Uses**

- Surgical hand scrub significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- Healthcare personnel handwash helps reduce bacteria that potentially can cause disease

**Warnings**

- **For external use only**
- **Allergy alert:**

  This product may cause a severe allergic reaction. Symptoms may include:
  - Swelling/difficulty breathing
  - Shock
  - Facial swelling
  - Hives
  - Rash

  If an allergic reaction occurs, stop use and seek medical help right away.
- **Do not use**

  - If you are allergic to chlorhexidine gluconate or any other ingredient in this product

  When using this product:
  - Keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause dizziness when instilled in the middle ear through perforated eardrum.

Lilith cure for more Drug Facts
Drug Facts (continued)

- If solution should contact these areas, rinse out promptly and thoroughly with water.
- Do not use routinely if you have wounds which involve more than the superficial layers of the skin.
- Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- Surgical hand scrubs:
  - Wet hands with water.
  - Dispense about 5 mL of product (5 full pumps) into cupped hands and wash in a vigorous manner for 15 seconds.
  - Rinse and dry thoroughly.
- Handwashing:
  - Scrub for 1.5 minutes with about 8 mL of product (5 full pumps) with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers.
  - Rinse thoroughly under running water for 30 seconds.
  - Wash for an additional 1.5 minutes with 8 mL of product (5 full pumps) and rinse under running water for 30 seconds.

Other Information
- Store at 20-25°C (68-77°F).
- Avoid excessive heat above 40°C (104°F).

Inactive Ingredients
- Citric acid, cocamidopropyl betaine, isopropl alcohol, lauramine oxide, purified water.

Questions or comments? Call 1-800-587-3721
- Monday through Friday 8:00 AM to 4:30 PM CST

Laundry/Cleaning Instructions:
- Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

NDC 0116-1021-16
Chlorhexidine Gluconate 2% Solution
Antiseptic Foam Handwash
Distributed by:
Xttrium Laboratories, Inc.
Mount Prospect, IL 60056
2DYN16BTLLBLCL
Dyna-Hex ®
Net Wt 16 fl oz (473 mL)
DYNA-HEX 2®
Chlorhexidine Gluconate 2% Solution
Antiseptic

Contains: 2% Chlorhexidine Gluconate
Distributed By: Xttrium Laboratories, Inc.
Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY

Net Contents: 16 fl oz (473 mL)
**Drug Facts**

**Active ingredient**
Chlorhexidine gluconate 2% solution .................................................. Antiseptic

**Uses**
- Surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- Healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- Skin wound and general skin cleansing

**Warnings**
**For external use only**

**Allergy alert:**
This product may cause a severe allergic reaction. Symptoms may include:
- Wheezing/difficulty breathing
- Shock
- Facial swelling
- Hives
- Rash

If an allergic reaction occurs, stop use and seek medical help right away.

**Drug Facts (continued)**

**Do not use**
- If you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- In contact with meninges
- In the genital area

**When using this product**
- Keep out of eyes, ears and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- If solution should contact these areas, rinse out promptly and thoroughly with water
- Wounds which involve more than the superficial layers of the skin should not be routinely treated
repeated general skin cleansing of large body areas should not be done except when
dvised by a health care provider

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may
be signs of a serious condition.

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

Directions
- use with care in premature infants or infants under 2 months of age. These products
  may cause irritation or chemical burns.

Surgical hand scrub:
- wet hands and forearms under running water for 30 seconds. Clean fingernails using a
  nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying
  close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water
  for 30 seconds
- dry thoroughly

Healthcare personnel handwash:
- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for
  15 seconds
- rinse and dry thoroughly

Skin wound and general skin cleansing:
- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and
  wash gently
- rinse again thoroughly

Other information
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients citric acid, cocamide DEA, hydroxyethylcellulose,
  isopropyl alcohol, lauramine oxide, purified water

Drug Facts (continued)

Questions or comments?
call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST

Laundering/Cleaning Instructions:
Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing
products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.
NDC 0116-1021-17
Chlorhexidine Gluconate 2% Solution
Antiseptic Foam Handwash
Distributed by:
Xttrium Laboratories, Inc.
Mount Prospect, IL 60056
2BLDYNATLBDL
Dyna-Hex ®
Net Wt 16 fl oz (473 mL)

DYNA-HEX ®
Chlorhexidine Gluconate 2% Solution
Antiseptic

Contains: 2% Chlorhexidine Gluconate
Distributed By: Xttrium Laboratories, Inc.
Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY

Net Contents: 16 fl oz (473 mL)
Drug Facts

Active ingredient
Chlorhexidine gluconate 2% solution

Purpose
Antiseptic

Uses
- Surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- Healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- Skin wound and general skin cleansing

Warnings
For external use only

Allergy alert:
This product may cause a severe allergic reaction. Symptoms may include:
- Wheezing/difficulty breathing
- Shock
- Facial swelling
- Hives
- Rash

If an allergic reaction occurs, stop use and seek medical help right away.

Lift Here
**Drug Facts (continued)**

**Do not use**
- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area

**When using this product**
- keep out of eyes, ears and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when advised by a health care provider

**Stop use and ask a doctor** if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

**Directions**
- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

**Surgical hand scrub:**
- wet hands and forearms under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds
- dry thoroughly

**Healthcare personnel handwash:**
- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

**Skin wound and general skin cleansing:**
- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

**Other information**
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

**Inactive ingredients** citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water
Drugs Facts (continued)

Questions or comments?
call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST

Laundering/Cleaning Instructions:
Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing
products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

NDC 0116-1021-32
Chlorhexidine Gluconate 2% Solution
Antiseptic Foam Handwash
Distributed by:
Xttrium Laboratories, Inc.
Mount Prospect, IL 60056
2DYN32BTLLBLA
Dyna-Hex ®
Net Wt 32 fl oz (946 mL)
# Drug Facts

### Active ingredient
Chlorhexidine gluconate 2% solution

### Purpose
Antiseptic

## Uses
- **surgical hand scrub**: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash**: helps reduce bacteria that potentially can cause disease
- **skin wound and general skin cleansing**

## Warnings
For external use only

### Allergy alert:
This product may cause a severe allergic reaction. Symptoms may include:
- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

### Do not use:
- if you or the patient are allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area

### When using this product:
- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when advised by a health care provider

**Stop use and ask a doctor** if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

### Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.
Drug Facts (continued)

Directions
- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical hand scrub:
- Wet hands and forearms under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- Scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers.
- Rinse thoroughly under running water for 30 seconds.
- Wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds.
- Dry thoroughly.

Healthcare personnel handwash:
- Wet hands with water.
- Dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds.
- Rinse and dry thoroughly.

Skin wound and general skin cleaning:
- Thoroughly rinse the area to be cleaned with water.
- Apply the minimum amount of product necessary to cover the skin or wound area and wash gently.
- Rinse again thoroughly.

Other information
- Store at 20-25°C (68-77°F).
- Avoid excessive heat above 40°C (104°F).

Inactive ingredients: citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water.

Questions or comments?
Call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST

Laundering/Cleaning Instructions:
Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

NDC 0116-1021-01
Chlorhexidine Gluconate 2% Solution
Antiseptic Foam Handwash
Distributed by:
Xttrium Laboratories, Inc.
Mount Prospect, IL 60056
2DYN1GBTLLBLA
Dyna-Hex ®
Net Wt 128 fl oz (1 gal)
DYNAX-HEX 2®
Chlorhexidine Gluconate 2% Solution
Antiseptic

Contains: 2% Chlorhexidine Gluconate
Distributed By: Xtttrim Laboratories, Inc.
Mount Prospect, IL 60056

Net Contents: 128 fl oz (1 gal) (3.785 L)

Drug Facts

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine gluconate 2% solution</td>
<td>Antiseptic</td>
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</tbody>
</table>

Drug Facts (continued)

Uses
- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease
- **skin wound and general skin cleansing**

Warnings
For external use only

Allergy alert:
This product may cause a severe allergic reaction. Symptoms may include:
- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use:
- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area

When using this product
keep out of eyes, ears and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.

if solution should contact these areas, rinse out promptly and thoroughly with water

wounds which involve more than the superficial layers of the skin should not be routinely treated

repeated general skin cleansing of large body areas should not be done except when advised by a health care provider

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

Directions
use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical hand scrub:
- wet hands and forearms under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds
- dry thoroughly

Healthcare personnel handwash:
- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

Skin wound and general skin cleansing:
- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

Drug Facts (continued)

Other information
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients: citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments?
call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST

Cleaning instructions:
Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.
## Product Information

<table>
<thead>
<tr>
<th><strong>Product Type</strong></th>
<th><strong>Item Code (Source)</strong></th>
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<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td>NDC:0116-1021</td>
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<table>
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<th><strong>Route of Administration</strong></th>
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### Active Ingredient/Active Moiety

#### Ingredient Name

<table>
<thead>
<tr>
<th><strong>Basis of Strength</strong></th>
<th><strong>Strength</strong></th>
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<tbody>
<tr>
<td>CHLORHEXIDINE GLUCONATE</td>
<td>2 g in 100 mL</td>
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### Inactive Ingredients

#### Ingredient Name

<table>
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<tr>
<th><strong>Strength</strong></th>
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<tr>
<td>CITRIC ACID MONOHYDRATE</td>
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<tr>
<td>COCO DIETHANOLAMIDE</td>
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<tr>
<td>HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%)</td>
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<tr>
<td>ISOPROPYL ALCOHOL</td>
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<tr>
<td>LAURAMINE OXIDE</td>
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<td>WATER</td>
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### Packaging

<table>
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<tr>
<th><strong>#</strong></th>
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<th><strong>Package Description</strong></th>
<th><strong>Marketing Start Date</strong></th>
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<tbody>
<tr>
<td>1</td>
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<td>237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
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<td>250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product</td>
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### Marketing Information

#### Marketing Category

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<th><strong>Application Number or Monograph Citation</strong></th>
<th><strong>Marketing Start Date</strong></th>
<th><strong>Marketing End Date</strong></th>
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<tbody>
<tr>
<td>NDA</td>
<td>NDA019422</td>
<td>01/01/2014</td>
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#### Labeler

- Xttrium Laboratories, Inc. (007470579)

#### Registrant

- Xttrium Laboratories, Inc. (007470579)

### Establishment

#### Name

<table>
<thead>
<tr>
<th><strong>Address</strong></th>
<th><strong>ID/FEI</strong></th>
<th><strong>Business Operations</strong></th>
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<tr>
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