

**TOPICAL ANESTHETIC- benzocaine gel
NDC, Inc.**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

**Topical Anesthetic Gel -
20% Benzocaine**

Gel – 1oz/34g

2731001 Cherry

2731002 Mint

2731004 Pina Colada

2731005 Bubble Gum

2731006 Strawberry

2731007 Raspberry

For dental use only

Rx only

1. INDICATIONS AND USAGE

Indicated as a topical anesthetic for use on oral mucosa prior to local anesthetic injections, scaling and prophylaxis. Also useful to relieve discomfort associated with taking impressions and intra- oral radiographs.

2. DOSAGE AND ADMINISTRATION

- Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the bottle.
- Tightly re-cap the jar after each use.

3. DOSAGE FORMS AND STRENGTH

Each gram of 20% Benzocaine Gel contains between 180-220 mg benzocaine in a flavored base.

4. CONTRAINDICATIONS

Should not be used with individuals with a known sensitivity to benzocaine or PABA.

5. WARNINGS AND PRECAUTIONS

METHEMOGLOBINEMIA WARNING

Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient in your care develops:

- pale, gray or blue colored skin (cyanosis)
- headache
- rapid heart rate

- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

- ☐ Not for use in children under 2 years of age
- ☐ Keep out of reach of children
- ☐ For professional dental use only
- ☐ Take care not to contaminate the bottle by reintroducing a used cotton applicator into the bottle

6. OVERDOSAGE

In case of overdose, get medical help or contact a Poison Control Center right away.

7. DESCRIPTION

Flavored 20% benzocaine gel for topical mucosa anesthesia

8. HOW SUPPLIED/STORAGE AND HANDLING

20% benzocaine gel is supplied in multiple use containers

Store between 59°-86°F (15°-30°C). Protect from freezing.

For more information call NDC at 1-800-929-4232

Manufactured for NDC Nashville, TN 37217

Made in the USA

2731001DF, R1-120116

PRINCIPAL DISPLAY PANEL - 34g Jar Label - Cherry

Topical Anesthetic Gel

20% Benzocaine

Cherry

REF: 2731001

CHERRY

Quala®

DENTAL PRODUCTS

NET CONTENTS:

1 oz (34g)

Rx Only

NDC 43128-021-30

Topical Anesthetic Gel
 20% Benzocaine
 Cherry
 REF: 2731001




NET CONTENTS:
 1 oz (34g)

Rx Only
 NDC 43128-021-30

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.
Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use.
Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.
Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.
Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient in your care develops: pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy. Not for use in children under 2 years of age.
Keep out of reach of children.
Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.
Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Artificial Cherry Flavor, Sodium Saccharin USP, Purified Water, Licorice Essence, FD&C Red #40
Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.

Made in USA for:
 NDC, Inc., 402 BNA Drive, Suite 500 | Nashville, TN 37217 | www.quala.com

1X1 2D Barcode
 Area
 UNVARNISHED

PRINCIPAL DISPLAY PANEL - 34g Jar Label - Mint

Topical Anesthetic Gel
 20% Benzocaine
 Mint

REF: 2731002

MINT

Quala®
 DENTAL PRODUCTS

NET CONTENTS:
 1 oz (34g)

Rx Only
 NDC 43128-023-30

Topical Anesthetic Gel
 20% Benzocaine
 Mint
 REF: 2731002




NET CONTENTS:
 1 oz (34g)

Rx Only
 NDC 43128-023-30

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.
Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use.
Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.
Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.
Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient in your care develops: pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy. Not for use in children under 2 years of age.
Keep out of reach of children.
Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.
Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Sodium Saccharin USP, Natural Peppermint Flavor, Purified Water, Licorice Essence, D&C Green #5
Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.

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1X1 2D Barcode
 Area
 UNVARNISHED

PRINCIPAL DISPLAY PANEL - 34g Jar Label - Piña Colada

Topical Anesthetic Gel
 20% Benzocaine
 Piña Colada

REF: 2731004

PIÑA COLADA

Quala®
 DENTAL PRODUCTS

NET CONTENTS:
 1 oz (34g)

Rx Only

NDC 43128-024-30

Topical Anesthetic Gel
20% Benzocaine
Piña Colada
REF: 2731004

NET CONTENTS:
1 oz (34g)

Quala
DENTAL PRODUCTS

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.
Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use.
Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.
Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.
Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient in your care develops: pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy. Not for use in children under 2 years of age.
Keep out of reach of children.
Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.
Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Artificial Piña Colada Flavor, Sodium Saccharin USP
Storage: Store between 59°-36°F (15°-30°C). Protect from freezing.

Made in USA for:
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1X1 2D Barcode
Area
UNVARNISHED

PRINCIPAL DISPLAY PANEL - 34g Jar Label - Bubble Gum

Topical Anesthetic Gel
20% Benzocaine
Bubble Gum

REF: 2731005

BUBBLE GUM

Quala®
DENTAL PRODUCTS

NET CONTENTS:
1 oz (34g)

Rx Only
NDC 43128-022-30

Topical Anesthetic Gel
20% Benzocaine
Bubble Gum
REF: 2731005

NET CONTENTS:
1 oz (34g)

Quala
DENTAL PRODUCTS

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.
Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use.
Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.
Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.
Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient in your care develops: pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy. Not for use in children under 2 years of age.
Keep out of reach of children.
Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.
Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Artificial Bubble Gum Flavor, Sodium Saccharin USP, Purified Water, D&C Red #28
Storage: Store between 59°-36°F (15°-30°C). Protect from freezing.

Made in USA for:
NDC, Inc., 402 BNA Drive, Suite 500 | Nashville, TN 37217 | www.quala.com

1X1 2D Barcode
Area
UNVARNISHED

PRINCIPAL DISPLAY PANEL - 34g Jar Label - Strawberry

Topical Anesthetic Gel
20% Benzocaine
Strawberry

REF: 2731006

STRAWBERRY

Quala®
DENTAL PRODUCTS

NET CONTENTS:
1 oz (34g)

Rx Only
NDC 43128-020-30



Topical Anesthetic Gel
20% Benzocaine
Strawberry
REF: 2731006
NET CONTENTS:
1 oz (34g)

Quala
DENTAL PRODUCTS
Rx Only
NDC 43128-020-30

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.
Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use.
Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.
Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.
Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient in your care develops: pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy. Not for use in children under 2 years of age.
Keep out of reach of children.
Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.
Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Sodium Saccharin USP, Artificial Strawberry Flavor, Purified Water, FD&C Red #40
Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.
Made in USA for:
NDC, Inc., 402 BNA Drive, Suite 500 | Nashville, TN 37217 | www.quala.com

1X1 2D Barcode
Area
UNVARNISHED

PRINCIPAL DISPLAY PANEL - 34g Jar Label - Raspberry

Topical Anesthetic Gel
20% Benzocaine
Raspberry

REF: 2731007

RASPBERRY

Quala®
DENTAL PRODUCTS

NET CONTENTS:
1 oz (34g)

Rx Only
NDC 43128-026-30



Topical Anesthetic Gel
20% Benzocaine
Raspberry
REF: 2731007
NET CONTENTS:
1 oz (34g)

Quala
DENTAL PRODUCTS
Rx Only
NDC 43128-026-30

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.
Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use.
Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.
Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.
Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient in your care develops: pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy. Not for use in children under 2 years of age.
Keep out of reach of children.
Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.
Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Sodium Saccharin USP, Artificial Raspberry Flavor, Purified Water, FD&C Red #40, D&C Red #28, FD&C Blue #1
Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.
Made in USA for:
NDC, Inc., 402 BNA Drive, Suite 500 | Nashville, TN 37217 | www.quala.com

1X1 2D Barcode
Area
UNVARNISHED

TOPICAL ANESTHETIC

benzocaine gel

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:43128-021 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5) | Benzocaine | 220 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Polyethylene Glycol 3350 (UNII: G2M7P15E5P) | |
| Polyethylene Glycol 400 (UNII: B697894SGQ) | |
| Saccharin Sodium (UNII: SB8ZUX40TY) | |
| Water (UNII: 059QF0K00R) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | RED | Score | |
| Shape | | Size | |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:43128-021-30 | 34 g in 1 JAR; Type 0: Not a Combination Product | 02/19/1963 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| UNAPPROVED DRUG OTHER | | 02/19/1963 | |

TOPICAL ANESTHETIC

benzocaine gel

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:43128-023 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5) | Benzocaine | 220 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Polyethylene Glycol 3350 (UNII: G2M7P15E5P) | |

| | |
|---|--|
| Polyethylene Glycol 400 (UNII: B697894SGQ) | |
| Saccharin Sodium (UNII: SB8ZUX40TY) | |
| Water (UNII: 059QF0KO0R) | |
| D&C GREEN NO. 5 (UNII: 8J6RDU8L9X) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | GREEN | Score | |
| Shape | | Size | |
| Flavor | MINT | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:43128-023-30 | 34 g in 1 JAR; Type 0: Not a Combination Product | 02/19/1963 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| UNAPPROVED DRUG OTHER | | 02/19/1963 | |

TOPICAL ANESTHETIC

benzocaine gel

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:43128-024 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5) | Benzocaine | 220 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Polyethylene Glycol 3350 (UNII: G2M7P15E5P) | |
| Polyethylene Glycol 400 (UNII: B697894SGQ) | |
| Saccharin Sodium (UNII: SB8ZUX40TY) | |
| Water (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|--------------|-------|--------------|--|
| Color | WHITE | Score | |
|--------------|-------|--------------|--|

| | | | |
|------------------------------|---|--|-----------------------------|
| Shape | | Size | |
| Flavor | COCONUT (Pina Colada) | Imprint Code | |
| Contains | | | |
| Packaging | | | |
| # | Item Code | Package Description | Marketing Start Date |
| 1 | NDC:43128-024-30 | 34 g in 1 JAR; Type 0: Not a Combination Product | 02/19/1963 |
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| UNAPPROVED DRUG OTHER | | 02/19/1963 | |

TOPICAL ANESTHETIC

benzocaine gel

| | | | |
|--|--|----------------------------|-----------------------------|
| Product Information | | | |
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:43128-022 |
| Route of Administration | DENTAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5) | Benzocaine | 220 mg in 1 g |
| Inactive Ingredients | | | |
| | Ingredient Name | | Strength |
| | Polyethylene Glycol 3350 (UNII: G2M7P15E5P) | | |
| | Polyethylene Glycol 400 (UNII: B697894SGQ) | | |
| | Saccharin Sodium (UNII: SB8ZUX40TY) | | |
| | Water (UNII: 059QF0KO0R) | | |
| | D&C RED NO. 28 (UNII: 767IP0Y5NH) | | |
| Product Characteristics | | | |
| Color | PINK | Score | |
| Shape | | Size | |
| Flavor | BUBBLE GUM | Imprint Code | |
| Contains | | | |
| Packaging | | | |
| # | Item Code | Package Description | Marketing Start Date |
| | | | |

| | | | |
|---|------------------|--|------------|
| 1 | NDC:43128-022-30 | 34 g in 1 JAR; Type 0: Not a Combination Product | 02/19/1963 |
|---|------------------|--|------------|

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| UNAPPROVED DRUG OTHER | | 02/19/1963 | |

TOPICAL ANESTHETIC
benzocaine gel

| Product Information | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:43128-020 |
| Route of Administration | DENTAL | | |

| Active Ingredient/Active Moiety | | |
|--|-------------------|---------------|
| Ingredient Name | Basis of Strength | Strength |
| Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5) | Benzocaine | 220 mg in 1 g |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| Polyethylene Glycol 3350 (UNII: G2M7P15E5P) | |
| Polyethylene Glycol 400 (UNII: B697894SGQ) | |
| Saccharin Sodium (UNII: SB8ZUX40TY) | |
| Water (UNII: 059QF0KO0R) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

| Product Characteristics | | | |
|-------------------------|------------|--------------|--|
| Color | RED | Score | |
| Shape | | Size | |
| Flavor | STRAWBERRY | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:43128-020-30 | 34 g in 1 JAR; Type 0: Not a Combination Product | 02/19/1963 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| UNAPPROVED DRUG OTHER | | 02/19/1963 | |

TOPICAL ANESTHETIC

benzocaine gel

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:43128-026 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5) | Benzocaine | 220 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Polyethylene Glycol 3350 (UNII: G2M7P15E5P) | |
| Polyethylene Glycol 400 (UNII: B697894SGQ) | |
| Saccharin Sodium (UNII: SB8ZUX40TY) | |
| Water (UNII: 059QF0KO0R) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

Product Characteristics

| | | | |
|-----------------|-----------|---------------------|--|
| Color | RED | Score | |
| Shape | | Size | |
| Flavor | RASPBERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:43128-026-30 | 34 g in 1 JAR; Type 0: Not a Combination Product | 02/19/1963 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| UNAPPROVED DRUG OTHER | | 02/19/1963 | |

Labeler - NDC, Inc. (009831413)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------|---------|-----------|---|
| Caulk | | 083235549 | MANUFACTURE(43128-021, 43128-023, 43128-024, 43128-022, 43128-020, 43128-026) |

