

KOLORZ TOPICAL ANESTHETIC TRIPLE MINT- benzocaine gel
KOLORZ TOPICAL ANESTHETIC CHERRY BURST- benzocaine gel
KOLORZ TOPICAL ANESTHETIC COTTON CANDY- benzocaine gel
KOLORZ TOPICAL ANESTHETIC BLUE RASBERRY- benzocaine gel
KOLORZ TOPICAL ANESTHETIC PINA COLADA- benzocaine gel
DMG AMERICA, LLC

KOLORZ[®] TOPICAL ANESTHETIC

Drug Facts

Active ingredients (in each gram)

Benzocaine 200 mg

Purpose

Oral Anesthetic

Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

Warnings

Methemoglobinemia warning

Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heartrate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert

Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore

mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, see your dentist or doctor promptly.

Do not use

- for teething
- in children under 2 years of age

When using this product

Avoid contact with eyes. If contact occurs, flush with water.

If pregnant or breast feeding, consult a doctor before use.

KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older: apply only amount needed to the oral mucosa to prevent or relieve pain
- children under 2 years of age: do not use

Other information

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

Inactive ingredients

flavoring, PEG 3350, PEG 400, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

Questions or comments?

800-6626383 • www.dmg-america.com

Distributed by DMG America LLC
242 South Dean St., Englewood, NJ 07631

PRINCIPAL DISPLAY PANEL - 29.6 grams Bottle Label - Triple Mint

Best Taste...
Guaranteed!

kolorz®

Topical Anesthetic Gel
(Benzocaine 20%)
Triple Mint

1 FL OZ (29.6 grams)

D0337551010



INGREDIENTS: Each gram of Kolorz® Topical Anesthetic Gel contains 200mg of Benzocaine U.S.P., in a water soluble base. D&C Green #5. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

NDC 25047-751-01
RE-ORDER # 755101

EMERGENCY RESPONSE:
Call Infotrac 1-800-535-5053
For professional use only.

Best Taste...
Guaranteed!



Topical Anesthetic Gel
(Benzocaine 20%)
Triple Mint

1 FL OZ (29.6 grams)

Distributed by DMG America LLC
242 South Dean St., Englewood, NJ 07631
800-662-6383 • www.dmg-america.com
Made in USA

XXXXXX

Rev 03/19

Drug Facts

Active ingredients (in each gram)

Benzocaine 200 mg

Purpose

Oral Anesthetic

Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

Warnings

Methemoglobinemia

warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heartrate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert: Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, see your dentist or doctor promptly.

Do not use

- for teething
- in children under 2 years of age

When using this product

Avoid contact with eyes. If contact occurs, flush with water.

If pregnant or breast feeding, consult a doctor before use.

KEEP OUT OF REACH OF

CHILDREN. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older: apply only amount needed to the oral mucosa to prevent or relieve pain
- children under 2 years of age: do not use

Other information

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

Inactive ingredients

flavoring, PEG 3350, PEG 400, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

Questions or comments?

800-6626383 •
www.dmg-america.com

PRINCIPAL DISPLAY PANEL - 29.6 grams Bottle Label - Cherry Burst

Best Taste...

Guaranteed!

kolorz[®]

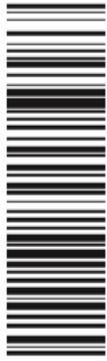
Topical Anesthetic Gel

(Benzocaine 20%)

Cherry Burst

1 FL OZ (29.6 grams)

D0337551020.



INGREDIENTS: Each gram of Kolorz® Topical Anesthetic Gel contains 200mg of Benzocaine U.S.P., in a water soluble base. FD&C Red #40. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

NDC 25047-752-01
RE-ORDER # 755102

EMERGENCY RESPONSE:
Call Infotrac 1-800-535-5053
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Rev 03/19

**Best Taste...
Guaranteed!**



Topical Anesthetic Gel
(Benzocaine 20%)

Cherry Burst

1 FL OZ (29.6 grams)

Drug Facts

**Active ingredients
(in each gram)**

Benzocaine 200 mg

Purpose

Oral Anesthetic

Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heartrate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert: Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, see your dentist or doctor promptly.

Do not use

- for teething
- in children under 2 years of age

When using this product

Avoid contact with eyes. If contact occurs, flush with water.

If pregnant or breast feeding, consult a doctor before use.

KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older: apply only amount needed to the oral mucosa to prevent or relieve pain
- children under 2 years of age: do not use

Other information

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

Inactive ingredients

flavoring, PEG 3350, PEG 400, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

Questions or comments?

800-6626383 •
www.dmg-america.com

PRINCIPAL DISPLAY PANEL - 29.6 grams Bottle Label - Cotton Candy

Best Taste...
Guaranteed!

kolorz®

Topical Anesthetic Gel
(Benzocaine 20%)
Cotton Candy

1 FL OZ (29.6 grams)

D0337551030_



INGREDIENTS: Each gram of Kolorz® Topical Anesthetic Gel contains 200mg of Benzocaine U.S.P., in a water soluble base. D&C Red #33. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

NDC 25047-753-01
RE-ORDER # 755103

EMERGENCY RESPONSE:
Call Infotrac 1-800-535-5053
For professional use only.

**Best Taste...
Guaranteed!**



Topical Anesthetic Gel
(Benzocaine 20%)

Cotton Candy 1 FL OZ (29.6 grams)

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Made in USA

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Rev 03/19

Drug Facts

**Active ingredients
(in each gram)**

Benzocaine 200 mg

Purpose

Oral Anesthetic

Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heartrate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert: Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, see your dentist or doctor promptly.

Do not use

- for teething
- in children under 2 years of age

When using this product

Avoid contact with eyes. If contact occurs, flush with water.

If pregnant or breast feeding, consult a doctor before use.

KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older: apply only amount needed to the oral mucosa to prevent or relieve pain
- children under 2 years of age: do not use

Other information

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

Inactive ingredients

flavoring, PEG 3350, PEG 400, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

Questions or comments?

800-6626383 •
www.dmg-america.com

PRINCIPAL DISPLAY PANEL - 29.6 grams Bottle Label - Blue Raspberry

Best Taste...

Guaranteed!

kolorz[®]

Topical Anesthetic Gel
(Benzocaine 20%)
Blue Raspberry

1 FL OZ (29.6 grams)

D0337551040\$



INGREDIENTS: Each gram of Kolorz® Topical Anesthetic Gel contains 200mg of Benzocaine U.S.P., in a water soluble base. FD&C Blue #1. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

NDC 25047-754-01
RE-ORDER # 755104

EMERGENCY RESPONSE:
Call Infotrac 1-800-535-5053
For professional use only.

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Made in USA

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Rev 03/19

Best Taste...
Guaranteed!



Topical Anesthetic Gel
(Benzocaine 20%)

Blue Raspberry 1 FL OZ (29.6 grams)

Drug Facts

**Active ingredients
(in each gram)**

Benzocaine 200 mg

Purpose

Oral Anesthetic

Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heartrate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert: Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, see your dentist or doctor promptly.

Do not use

- for teething
- in children under 2 years of age

When using this product

Avoid contact with eyes. If contact occurs, flush with water.

If pregnant or breast feeding, consult a doctor before use.

KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older: apply only amount needed to the oral mucosa to prevent or relieve pain
- children under 2 years of age: do not use

Other information

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

Inactive ingredients

flavoring, PEG 3350, PEG 400, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

Questions or comments?

800-6626383 •
www.dmg-america.com

PRINCIPAL DISPLAY PANEL - 29.6 grams Bottle Label - Piña Colada

Best Taste...

Guaranteed!

kolorz[®]

Topical Anesthetic Gel
(Benzocaine 20%)
Piña Colada

1 FL OZ (29.6 grams)

+D0337551050/



INGREDIENTS: Each gram of Kolorz® Topical Anesthetic Gel contains 200mg of Benzocaine U.S.P., in a water soluble base. FD&C Yellow #5. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

NDC 25047-755-01
RE-ORDER # 755105

EMERGENCY RESPONSE:
Call Infotrac 1-800-535-5053
For professional use only.

Distributed by DMG America LLC
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Made in USA

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Rev 03/19

Best Taste...
Guaranteed!



Topical Anesthetic Gel
(Benzocaine 20%)

Piña Colada

1 FL OZ (29.6 grams)

Drug Facts

**Active ingredients
(in each gram)**

Benzocaine 200 mg

Purpose

Oral Anesthetic

Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

Warnings

Methemoglobinemia

warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heartrate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert: Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, see your dentist or doctor promptly.

Do not use

- for teething
- in children under 2 years of age

When using this product

Avoid contact with eyes. If contact occurs, flush with water.

If pregnant or breast feeding, consult a doctor before use.

KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older: apply only amount needed to the oral mucosa to prevent or relieve pain
- children under 2 years of age: do not use

Other information

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

Inactive ingredients

flavoring, PEG 3350, PEG 400, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

Questions or comments?

800-6626383 •
www.dmg-america.com

KOLORZ TOPICAL ANESTHETIC TRIPLE MINT

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25047-751
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-751-01	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M022	09/06/2019	

KOLORZ TOPICAL ANESTHETIC CHERRY BURST

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25047-752
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-752-01	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M022	09/06/2019	

KOLORZ TOPICAL ANESTHETIC COTTON CANDY

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25047-753
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)

SUCRALOSE (UNII: 96K6UQ3ZD4)

D&C RED NO. 33 (UNII: 9DBA0SBB0L)

FD&C RED NO. 40 (UNII: WZB9127XOA)

D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-753-01	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M022	09/06/2019	

KOLORZ TOPICAL ANESTHETIC BLUE RASBERRY

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25047-754
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-754-01	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M022	09/06/2019	

KOLORZ TOPICAL ANESTHETIC PINA COLADA

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25047-755
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-755-01	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M022	09/06/2019	

Labeler - DMG AMERICA, LLC (106792427)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	MANUFACTURE(25047-751, 25047-752, 25047-753, 25047-754, 25047-755) , PACK(25047-751, 25047-752, 25047-753, 25047-754, 25047-755) , LABEL(25047-751, 25047-752, 25047-753, 25047-754, 25047-755)

Revised: 10/2021

DMG AMERICA, LLC