GEL 1100 MINT- sodium fluoride gel, dentifrice
GEL 1100 CITRUS- sodium fluoride gel, dentifrice
GEL 1100 GRAPE- sodium fluoride gel, dentifrice
Dental Alliance Holdings LLC

Gel 1100

Active ingredients:

Sodium Fluoride 0.24%

Purpose:

Anticavity

Use:

Aids in the prevention of dental caries (cavities)

Warnings:

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Warnings:

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

Inactive ingredients:

Glycerin, Hydrated Silica, Hydrogenated Starch Hydrolysate (HSH), Hydroxyapatite, Hydroxyethyl Cellulose, Menthol (Mint only), Natural Flavors, Artificial Flavors (Citrus and Grape only) Polysorbate 20, Potassium Sorbate, Saccharin, Sodium Benzoate, Sodium Bicarbonate, Sodium Hydroxide, Sodium Lauryl Sulfate, Water, Xylitol

Gel 1100 Mint, Citrus, and Grape enclosure and carton labels


GEL 1100
ANTI-CAVITY
TOOTHPASTE
CARIFREE
CARIFREE®
CARIFREE
Drug Facts
Active Ingredients Purpose
Sodium Fluoride 0.24% ... Anticavity
Use
Aids in the prevention of dental caries (cavities)
Warnings
Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.
Directions
■ Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
■ Children under 6 years of age: Instruct in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
■ Children under 2 years of age: Consult a dentist or doctor.
Inactive Ingredients
Artificial Flavor, Glycerin, Hydrated Silica, Hydrogenated Starch Hydrolysate (HSH), Hydroxyapatite, Hydroxyethyl Cellulose, Polysorbate 20, Potassium Sorbate, Saccharin, Sodium Benzoate, Sodium Bicarbonate, Sodium Hydroxide, Sodium Lauryl Sulfate, Water, Xylitol
/CariFree
@_carifree
/carifree_
@CariFree
/carifree
GEL 1100
ANTI-CAVITY
TOOTHPASTE
grape
pH elevated
2.4 oz (68g)
pH+ HA NANO
U.S PATENTS NO. 9,427,384 and 10,143,633
Questions or comments?
800.503.0625
carifree.com
CariFree and pH+ are registered trademarks of Oral BioTech
Manufactured by Oral BioTech
Albany, Oregon 97321 USA
8 56596 00602 1
25980 15M 5.22
Die Line 12-4-19


GEL 1100
ANTI-CAVITY
TOOTHPASTE
CARIFREE
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Drug Facts
Active Ingredients Purpose
Sodium Fluoride 0.24% .... Anticavity
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■ Children under 2 years of age: Consult a dentist or doctor.
Inactive Ingredients
Glycerin, Hydrated Silica, Hydrogenated Starch Hydrolysate (HSH), Hydroxyapatite, Hydroxyethyl Cellulose, Natural and Artificial Flavors, Polysorbate 20, Potassium Sorbate, Saccharin, Sodium Benzoate, Sodium Bicarbonate, Sodium Hydroxide, Sodium Lauryl Sulfate, Water, Xylitol
/CariFree
@_carifree
/carifree_
@CariFree
/carifree
GEL 1100
ANTI-CAVITY
TOOTHPASTE
citrus
pH elevated
2.4 oz (68g)
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Manufactured by Oral BioTech Albany, Oregon 97321 USA
8 56596 00601 4
25980 15M 5.22
Die Line 12-4-19

CARIFREE®

GEL 1100

ANTI-CAVITY
TOOTHPASTE

mint

2.4 oz (68g)

Active ingredients: Sodium Fluoride 0.24%. **Purpose:** Anticavity. **Use:** Aids in the prevention of dental caries (cavities).

Warning: Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. ■ Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. ■ Children under 2 years of age: Consult a dentist or doctor.

Inactive ingredients: Glycerin, Hydrated Silica, Hydrogenated Starch Hydrolysate (HSH), Hydroxyapatite, Hydroxyethyl Cellulose, Menthol, Natural Flavors, Polysorbate 20, Potassium Sorbate, Saccharin, Sodium Benzoate, Sodium Bicarbonate, Sodium Hydroxide, Sodium Lauryl Sulfate, Water, Xylitol.

pH+® HA™ NANO

U.S. PATENTS NO. 9,427,384 and 10,143,633

Questions or comments?
800.503.0625

carifree.com

Manufactured by Oral BioTech
Albany, Oregon 97321

CARIFREE®

GEL 1100

ANTI-CAVITY
TOOTHPASTE

grape

2.4 oz (68g)

Active Ingredients: Sodium Fluoride 0.24%. **Purpose:** Anticavity. **Use:** Aids in the prevention of dental caries (cavities).

Warning: Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. ■ Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. ■ Children under 2 years of age: Consult a dentist or doctor.

Inactive ingredients: Artificial Flavor, Glycerin, Hydrated Silica, Hydrogenated Starch Hydrolysate (HSH), Hydroxyapatite, Hydroxyethyl Cellulose, Polysorbate 20, Potassium Sorbate, Saccharin, Sodium Benzoate, Sodium Bicarbonate, Sodium Hydroxide, Sodium Lauryl Sulfate, Water, Xylitol.

pH+® HA™ NANO

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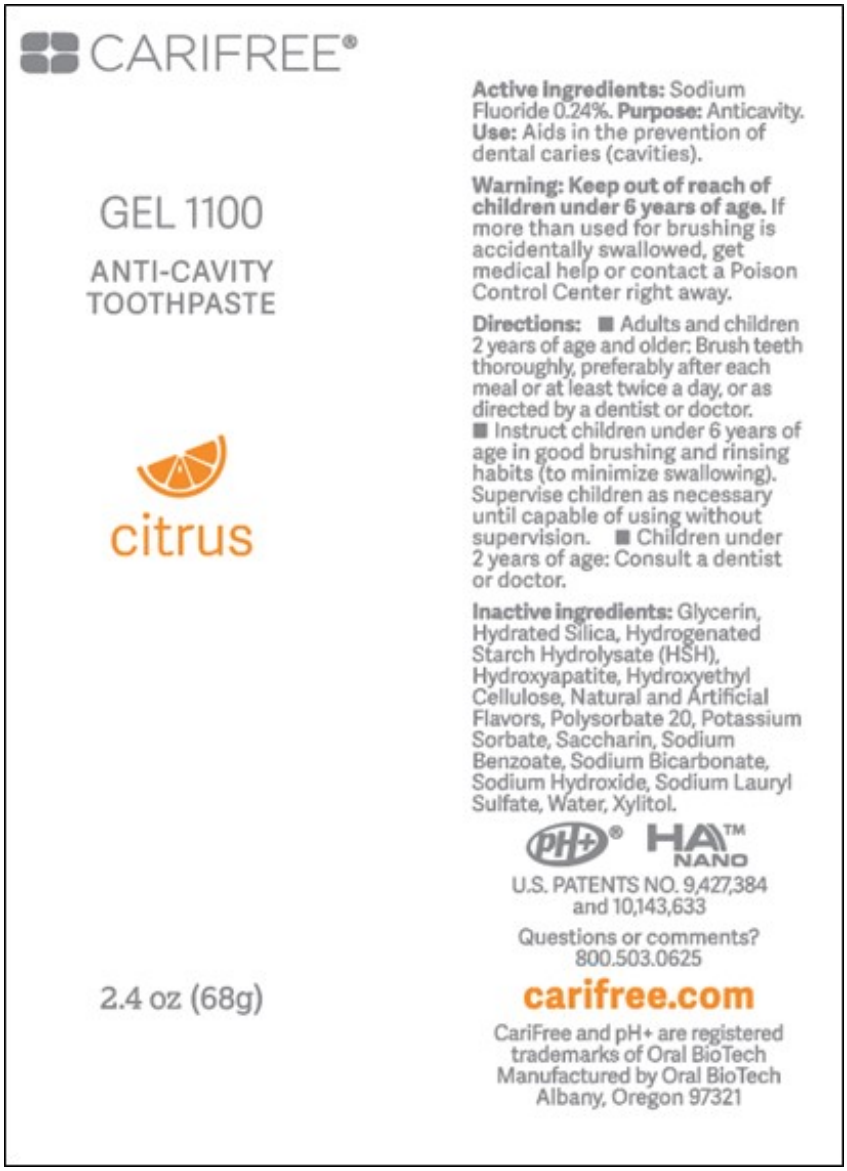
Manufactured by Oral BioTech
Albany, Oregon 97321



GEL 1100 MINT

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61578-213
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1100 ug in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	

MALTITOL (UNII: D65DG142WK)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
HYDROXYETHYL CELLULOSE (3000 CPS AT 1%) (UNII: 7Q6P4JN1QT)	
MENTHOL (UNII: L7T10EIP3A)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN (UNII: FST467XS7D)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	white (opaque)	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61578-213-01	68 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	05/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	05/10/2022	

GEL 1100 CITRUS

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61578-214
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1100 ug in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
MALTITOL (UNII: D65DG142WK)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
HYDROXYETHYL CELLULOSE (3000 CPS AT 1%) (UNII: 7Q6P4JN1QT)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN (UNII: FST467XS7D)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	white (opaque)	**Score**	
Shape		**Size**	
Flavor	CITRUS	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61578-214-01	68 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	05/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	05/10/2022	

GEL 1100 GRAPE

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61578-217
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1100 ug in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
MALTITOL (UNII: D65DG142WK)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
HYDROXYETHYL CELLULOSE (3000 CPS AT 1%) (UNII: 7Q6P4JN1QT)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN (UNII: FST467XS7D)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	white (opaque)	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61578-217-01	68 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	05/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	05/10/2022	

Labeler - Dental Alliance Holdings LLC (195544965)

Registrant - Dental Alliance Holdings LLC (195544965)

Establishment

Name	Address	ID/FEI	Business Operations

Dental Alliance Holdings LLC		195544965	manufacture(61578-214, 61578-217, 61578-213)