SARASOTA MEMORIAL AMENITY- alcohol and sodium monofluorophosphate ASP Global, 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.

Sarasota Memorial Amenity Kit Colgate[®] Anticavity Toothpaste *Drug Facts*

Active ingredient

Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against cavities

Warnings

Keep out of the 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 physician
children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
children under 2 years	ask a dentist or physician

Inactive ingredients

dicalcium phosphate dihydrate, water, sorbitol, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin

Questions or comments?

Call toll-free 1-800-468-6502

Manufactured by:

COLGATE-PALMOLIVE (THAILAND) Limited, Chonburi 20000, Thailand.

Instant Hand Antiseptic

Drug Facts

Active Ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

For hand washing to decrease bacteria on the skin.

Recommended for repeated use.

Warnings

Flammable. Keep away from fire or flame.

For external use only.

Avoid contact with broken skin.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help.

Directions

Not recommended for infants.

Wet hands thoroughly with product and allow to dry without wiping.

Children under 6 years of age should be supervised when using this product.

Other Information

Do not store above 110°F. May discolor some fabrics.

Inactive Ingredients

Water, Aloe Barbadensis Leaf Juice, Glycerin, Propylene Glycol, Carbomer, Triethanolamine, Fragrance.

Distributed by:

ASP Global, LLC 7800 Third Flag Parkway, Austell, GA 30168, USA

PRINCIPAL DISPLAY PANEL - 53 mL Bottle Label

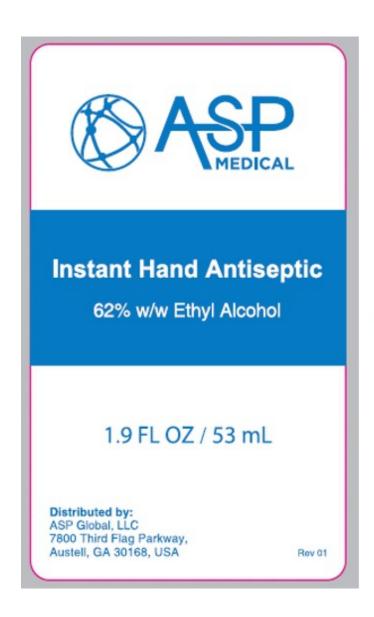
ASP MEDICAL

Instant Hand Antiseptic 62% w/w Ethyl Alcohol

1.9 FL OZ / 53 mL

Distributed by: ASP Global, LLC 7800 Third Flag Parkway, Austell, GA 30168, USA

Rev 01





PRINCIPAL DISPLAY PANEL - 10 g Tube Label

P1505037

Colgate[®] Anticavity Toothpaste

Cavity Protection

NET WT 10g 7 OTHER



Drug Facts	Drug Facts (continued)		
Active ingredient Purpose Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)Anticavity	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 physician	
Paring	children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)	
Use helps protect against cavities	children under 2 years	ask a dentist or physician	
Warnings Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed,	Inactive ingredients dicalcium phosphate dihydrate, water, sorbitol, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin		
get medical help or contact a Poison Control Center right away.	(Questions	or comments? Call toll-free 1-800-468-6502	

PRINCIPAL DISPLAY PANEL - Kit Label

SARASOTA MEMORIAL HEALTH CARE SYSTEM

Contents/Origins:

1.9 fl. oz. Hand Sanitizer Toothbrush, Sleep Mask, Ear Plugs, Facial Tissue, Patient Hand Hygiene Education Card, Paper Bag and Kit Case: Made in China

Toothpaste: Made in Thailand

Lot #: XMMDDFC Exp: YYYY-MM-DD

Distributed by: ASP Global, LLC

7800 Third Flag Parkway, Austell, GA 30168, USA

REV 02

SARASOTA MEMORIAL HEALTH CARE SYSTEM

Item #: SARASOTA01

Description: AMENITY KIT, SARASOTA

MEM WELCOME

PO #:

Lot #: XMMDDFC Exp: YYYY-MM-DD Qty: 30 KIT/CS

Carton #: XXX of XXX

Net Wt.: XX KG Gross Wt.: XX KG

Cubic Dimensions: XX x XX x XX CM

Assembled in China

Components Made in China:

- Hand Sanitizer
- Toothbrush
- Sleep Mask
- Ear Plugs
- Facial Tissue
- Paper Bag
- Kit Case

Component Made in Thailand:

• Toothpaste

SARASOTA MEMORIAL HEALTH CARE SYSTEM

FRONT OF TAG



BACK OF TAG

Contents/Origins:

1.9 fl. OZ. Hand Sanitizer

Toothbrush, Sleep Mask, Ear Plugs, Facial Tissue, Patient Hand Hygiene Education Card, Paper Bag and Kit Case: Made in China

Toothpaste: Made in Thailand

Lot #: XMMDDFC Exp: YYYY-MM-DD

Distributed by: ASP Global, LLC

7800 Third Flag Parkway, Austell, GA 30168, USA

REV 02



Item #: SARASOTA01

Description: AMENITY KIT, SARASOTA

MEM WELCOME

PO #:

Lot #: XMMDDFC

Exp: YYYY-MM-DD

Qty: 30 KIT/CS

Carton #: XXX of XXX

Net Wt.: XX KG Gross Wt.: XX KG

Cubic Dimensions: XX x XX x XX CM

Assembled in China

Components Made in China:

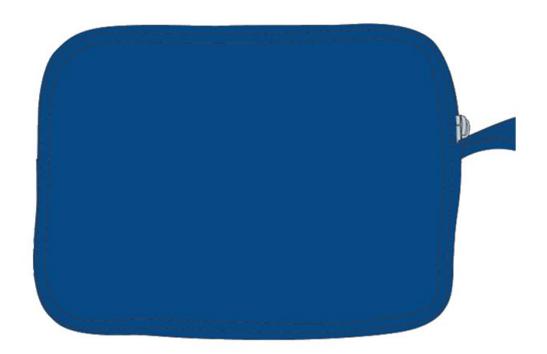
- · Hand Sanitizer
- + Toothbrush
- Sleep Mask
 Ear Plugs
- Facial Tissue
- · Paper Bag
- Kit Case

Component Made in Thailand:

Toothpaste







SARASOTA MEMORIAL AMENITY

alcohol and sodium monofluorophosphate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59448-600

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59448-600-00	30 in 1 BOX	10/08/2019		
1		1 in 1 BAG			

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	53 mL
Part 2	1 TUBE	10 g

Part 1 of 2

INSTANT HAND ANTISEPTIC

alcohol gel

Product Information

Item Code (Source)	NDC:59448-004
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Aloe Vera Leaf (UNII: ZY81Z83H0X)		
Glycerin (UNII: PDC6A3C0OX)		
Propylene Glycol (UNII: 6DC9Q167V3)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		
Trolamine (UNII: 9O3K93S3TK)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59448- 004-01	53 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Info	Marketing Information		
Marketing Category Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	11/27/2018	

Part 2 of 2

COLGATE ANTICAVITY

sodium monofluorophosphate paste, dentifrice

Product Information	
Item Code (Source)	NDC:42555-060
Route of Administration	DENTAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

Inactive Ingredients		
Ingredient Name	Strength	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
Water (UNII: 059QF0KO0R)		
Sorbitol (UNII: 506T60A25R)		
Sodium Lauryl Sulfate (UNII: 368GB5141J)		
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		

Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:42555-060- 45	10 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information					
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part355	06/04/2009			

Marketing A Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	rt333E	10/08/2019	

Labeler - ASP Global, LLc (080361159)

Establishment				
Name	Address	ID/FEI	Business Operations	
Shengzhou Kingbird Travel Products Co., Ltd.		560219293	PACK(59448-600), LABEL(59448-600)	

Establishment					
Name	Address	ID/FEI	Business Operations		
Colgate-Palmolive (Thailand) LTD		672044552	MANUFACTURE(59448-600)		

Establishment					
Name	Address	ID/FEI	Business Operations		
Nantong Health & Beyond Hygienic Products Inc.		421280161	MANUFACTURE(59448-600)		

Revised: 12/2022 ASP Global, LLc