

**DELTA SKY CLUB- sodium monofluorophosphate
Buzz Export Services Pty Ltd**

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.

Delta Sky Club Dental Kit

Drug Fact

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, aqua(water), sorbitol, sodium lauryl sulfate, aroma(flavour,) cellulose gum, tetrasodium pyrophosphate, sodium saccharinm limonene

Questions or comments?

Call to-free 1-800-468-6502

Package Labeling:

| | | | |
|---|------------------------------|---|--|
| Drug Facts | | Drug Facts (continued) | |
| Active ingredient Sodium monofluorophosphate 0,76% (0,15% w/v fluoride ion)..... | Purpose Anticavity | Directions | |
| Use helps protect against cavities | | 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 |
| 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. | | children 2 to 6 years | use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing) |
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| | | ☒ Questions or comments? Call toll-free 1-800-468-6502 | |

DENTAL KIT CONTENTS:

TOOTHBRUSH
Made in China

COLGATE TOOTHPASTE 10g
Made in Thailand

delta.com



▲ DELTA
SKY CLUB™

MANUFACTURED FOR BUZZ EXPORT SERVICES PTY., LTD

DENTAL KIT

▲ DELTA
SKY CLUB™



DELTA SKY CLUB

sodium monofluorophosphate kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69491-101 |
|---------------------|----------------|---------------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:69491-101-00 | 1 in 1 KIT | 01/01/2015 | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 1 TUBE | 10 g |

Part 1 of 1

COLGATE

sodium fluoride paste

Product Information

| | |
|---------------------------|---------------|
| Item Code (Source) | NDC:69491-060 |
|---------------------------|---------------|

| | |
|--------------------------------|--------|
| Route of Administration | DENTAL |
|--------------------------------|--------|

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|--|--------------|---------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 1.5 mg in 1 g |
|--|--------------|---------------|

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | |
| SODIUM PYROPHOSPHATE (UNII: O352864B8Z) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69491-060-94 | 1 in 1 CARTON | | |
| 1 | | 10 g in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355 | 01/01/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355B | 01/01/2015 | |

Labeler - Buzz Export Services Pty Ltd (747317902)