# UNITED AIRLINES TRANSCON KIT- sodium monofluorophosphate, alcohol Buzz Export Services Pty Ltd (Buzz Products)

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.

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#### **United Airlines Transcon Kit**

### **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?

### **Drug Facts**

### **Active Ingredient**

Ethyl Alcohol 75% (v/v)

### **Purpose**

Antiseptic

#### Uses

• To help reduce bacteria on the skin.

### Warnings

- For external use only.
- Do not dispose of wipes in flush toilets.

#### **Flammable**

• Keep away from fire or flame.

### When using this product

- avoid contact with eyes.
- If contact occurs, rinse thoroughly with water.

### Stop using and ask a doctor if

irritation or redness develops and lasts.

### Keep out of reach of children

• In case of accidental ingestion, get medical help or contact a poison control center immediately.

### **Directions**

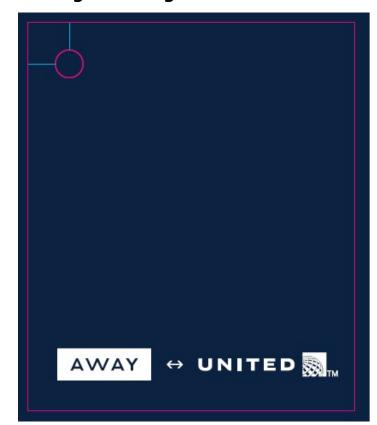
- Appyl to hands or surface.
- No rinsing required.
- Discard after use.

#### Other Information

- Store below 110°F (43°C).
- May discolor certain fabrics or surfaces.

### Inactive ingredients

### **Package Labeling:69491-038-01**







Package Labeling:42555-060-94



Drug Facts	Drug Facts (continued)	
Active ingredient Purpose Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)Anticavity	<b>Directions</b> adults and children 2 years of age and older	brush teeth thoroughly, preferably after each meal or a least twice a day, or as directed by a dentist or physician
Use helps protect against cavities	children 2 to 6 years	use only a pea sized amount and supervise child brushing and rinsing (to minimize swallowing)
OSE 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.	<b>Inactive ingredients</b> dicalcium phosphate dihydrate, water, sorbitol, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin	
If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	C Questions or comments? Call toll-free 1-800-468-6502	

Read this full drug facts information before use.

### **Package Labeling:69491-035-01**





FRONT BACK

#### **UNITED AIRLINES TRANSCON KIT**

sodium monofluorophosphate, alcohol kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69491-038

### **Packaging**

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:69491-038-01	1 in 1 KIT	02/15/2022	

### **Quantity of Parts**

4 00	quantity of the control of the contr		
Part #	Package Quantity	Total Product Quantity	
Part 1	1 TUBE	5 g	
Part 2	1 PATCH	5 mL	

### Part 1 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	
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	7.6 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
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
<b>1</b> NDC:42555-060-	5 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	02/15/2022	

### Part 2 of 2

### **SANITIZER WIPE IN SACHET**

alcohol cloth

Product Information		
Item Code (Source)	NDC:69491-035	
Route of Administration	TOPICAL	

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
TEA TREE OIL (UNII: VIF565UC2G)			

Packaging			
" Item	Parkana Parawintian	Marketing	Marketing

#	Code	Раскаде резсприон	Start Date	End Date
1	NDC:69491- 035-01	1 in 1 PACKAGE		
1		5 mL in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	02/15/2022		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part355	02/15/2022		

## **Labeler -** Buzz Export Services Pty Ltd (Buzz Products) (747317902)

Revised: 1/2023 Buzz Export Services Pty Ltd (Buzz Products)