# CREST EXPRESSIONS SCOPE- sodium fluoride paste, dentifrice Teresa Cecena DBA Genesis Imports

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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#### ACTIVE INGREDIENT

Sodium Fluoride

### **PURPOSE**

Anticavity toothpaste

#### **WARNINGS**

KEEP OUT OF REACH OF CHILDREN UNDER 6 YRS OF AGE.IF MORE THAT USED FOR BRUSHING IS ACCIDENTALLY SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL VENTER RIGHT AWAY.

### **DIRECTIONS**

- Adults and children 2 yrs. & older; brush teeth thoroughly after meals or at least twice a day or use as directed a dentist
- do not swallow

to minimize swallowing use a pea-sized amount in children under 6

supervise children's brushing until good habits are established

• children under 2 yrs, ask a dentist

sorbitol, water, hydrated silica, disodium pyrophosphate, sodium lauryl sulfate, flavor, sodium hydroxide, alcohol, xanthan gum, sodium saccharin, glycerin, carbomer, cellulose gum, polysorbate 80, sodium benzoate, cethylpyridinium chloride, benzoic acid, titanium dioxide, blue 1, yellow 5

### **QUESTIONS?**

1-800-492-7378

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sodium fluoride paste, dentifrice

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69772-820
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	243 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
SACCHARIN SO DIUM DIHYDRATE (UNII: SB8ZUX40TY)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CETYLPYRIDINIUM CHLO RIDE (UNII: D9 OM4SK49 P)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM ACID PYROPHO SPHATE (UNII: H5WVD9 LZUD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics				
Color	green	Score		
Shape		Size		
Flavor	PEPPERMINT	Imprint Code		
Contains				

F	ackaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69772-820-01	100 g in 1 TUBE; Type 0: Not a Combination Product	0 1/28/20 16	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	0 1/28/20 16		

# Labeler - Teresa Cecena DBA Genesis Imports (078760958)

# Registrant - Teresa Cecena (078760958)

Establishment				
Name	Address	ID/FEI	Business Operations	
Teresa Cecena DBA Genesis		078760958	relabel(69772-820)	

Establishment				
Name	Address	ID/FEI	Business Operations	
procter & gamble manufactura s. de r.l. de cv		812807550	manufacture(69772-820)	

Revised: 1/2016 Teresa Cecena DBA Genesis Imports