KOSETTE SALT TOOTH- sodium monofluorophosphate paste, dentifrice
K.Boeun Pharmaceutical Co.,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.

SODIUM MONOFLUOROPHOSPHATE

ANTI-CAVITY

Keep out of reach of children

Brush teeth thoroughly for at least one minute, preferably after each meal or at least twice a day (morning and evening) or as recommended by a dentist or physician

Storage method

1. Keep it at room temperature in a classified container.

2. Cover and store at room temperature.

3. Store in a not moisture and cool place.

4. Air may come out during use of this product, but there is no problem with its weight.

Usage Precautions

1. Be careful not to swallow. Rinse mouth thoroughly after use

2. If the use of toothpaste causes abnormalities such as gums or mouth injury, discontinue use and consult a doctor or dentist.

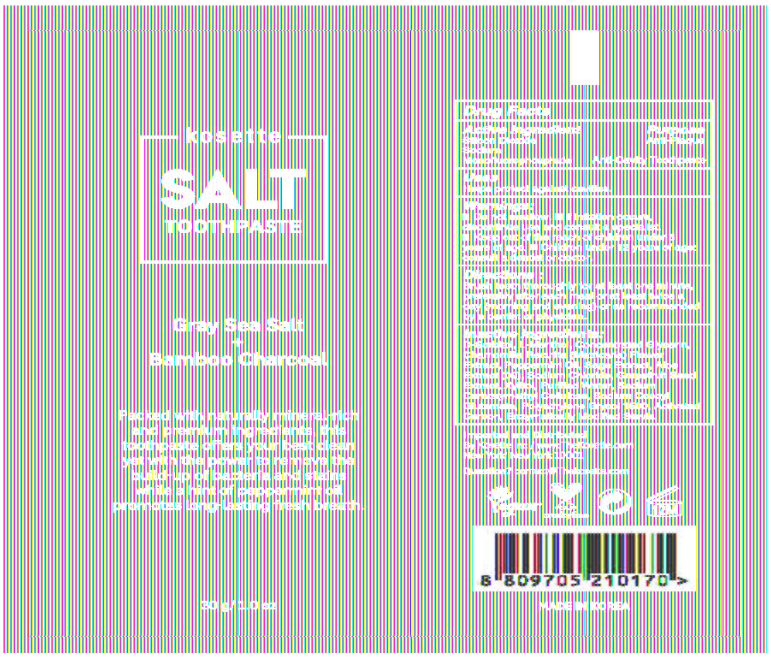
3. For children under 6 years of age, use a small amount of toothpaste as small as pea per use, and use under the guidance of a guardian to avoid sucking or swallowing.

4. If a child under 6 years old swallows large amount, consult with a doctor or dentist immediately.

5. Keep out of the reach of children under 6 years of age.

D-Sorbitol Solution, WATER, SILICON DIOXIDE, CONCENTRATED GLYCERIN, SODIUM COCOYL GLUTAMATE, POLYETHYLENE GLYCOL 1500, CARBOXYMETHYLCELLULOSE SODIUM, PEPPERMINT OIL, ACTIVE CARBON, L-MENTHOL, CITRUS PARADISI (GRAPEFRUIT) SEED EXTRACT, XYLITOL, SODIUM CHLORIDE, ENZYMATICALLY MODIFIED STEVIA, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT, ALOE EXTRACT, SAGE EXTRACT

For dental use only



KOSETTE SALT TOOTH

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74724-0011
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74724-0011-1	30 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/01/2020	

Labeler - K.Boeun Pharmaceutical Co.,Ltd. (695674074)

Registrant - K.Boeun Pharmaceutical Co.,Ltd. (695674074)

Establishment

Name	Address	ID/FEI	Business Operations
K.Boeun Pharmaceutical Co.,Ltd.		695674074	manufacture(74724-0011)

Revised: 5/2020 K.Boeun Pharmaceutical Co.,Ltd.