BON SCENT SPARKLING TOOTH WASH- sodium fluoride tablet
Lucella 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.

ACTIVE INGREDIENT

Active ingredients: Sodium Fluoride 1.1%

INACTIVE INGREDIENT

Inactive ingredients:

DL-Malic acid, DL-Camphor, Glyceryl Monostearate, Glycyrrhizinic acid, Sodium Lauroyl Sarcosinate, Mannitol, Menthol, peppermint oil, Sodium Saccharin dihydrate, Magnesium stearate, Xylitol, Tricalcium phosphate, Calcium Carbonate, Colloid Silica, Sodium bicarbonate, PEG-150, Enzymatically Modified Stevia, Hydroxypropylmethylcellulose

PURPOSE

Purpose: Anticaries & Anticavity

WARNINGS

Warnings:

- Keep in a cool and dry place.
- Do not swallow.
- The fluorine content is 583.21ppm. (Total content should be less than 1,000ppm)
- If a child under 6 years of age swallowed large quantities, consult a physician or dentist immediately.
- Keep out of the reach of children under 6 years.

KEEP OUT OF REACH OF CHILDREN

Keep out of the reach of children under 6 years.

Uses

Uses:
Helps protect against cavities

Directions

Directions:
- Put 1 tablet into your mouth and wash your gums, teeth, and tongue using your tongue and lips.
-Lastly rinse several times with water.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

BON SCENT SPARKLING TOOTH WASH

sodium fluoride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72869-010
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	9.38 mg in 853 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Mannitol (UNII: 3OWL53L36A)	
Menthol (UNII: L7T10EIP3A)	

Product Characteristics			
Color	white	**Score**	no score

Shape	ROUND	**Size**	12mm
Flavor	PEPPERMINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72869-010-02	30 in 1 POUCH	01/02/2019	
1	NDC:72869-010-01	853 mg in 1 BLISTER PACK; 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	01/02/2019	

Labeler - Lucella Co.,ltd (694733285)

Registrant - Lucella Co.,ltd (694733285)

Establishment

Name	Address	ID/FEI	Business Operations
EQMAXON Corp.		557821534	manufacture(72869-010)

Revised: 4/2019 Lucella Co.,ltd