KIDS ORAL CARE STRAWBERRY FLAVOR- xylitol, calcium lactate spray
TOOTHFILM INC.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Kids Oral Care Strawberry Flavor

Active ingredients: Xylitol 2.0mL/20mL; Calcium Lactate 0.02mL/20mL

Inactive ingredients: Water, Glycerin, Sodium Levulinate, Sodium Anisate, Trehalose, Sodium Chloride, Dicalcium Phosphate, Silica, Calcium Oxide

Purpose: Anticavity

keep out of reach of children: For external use only. Keep out of reach of children. Avoidcontact with eyes. Discontinue use if signs of irritation or rash occur.

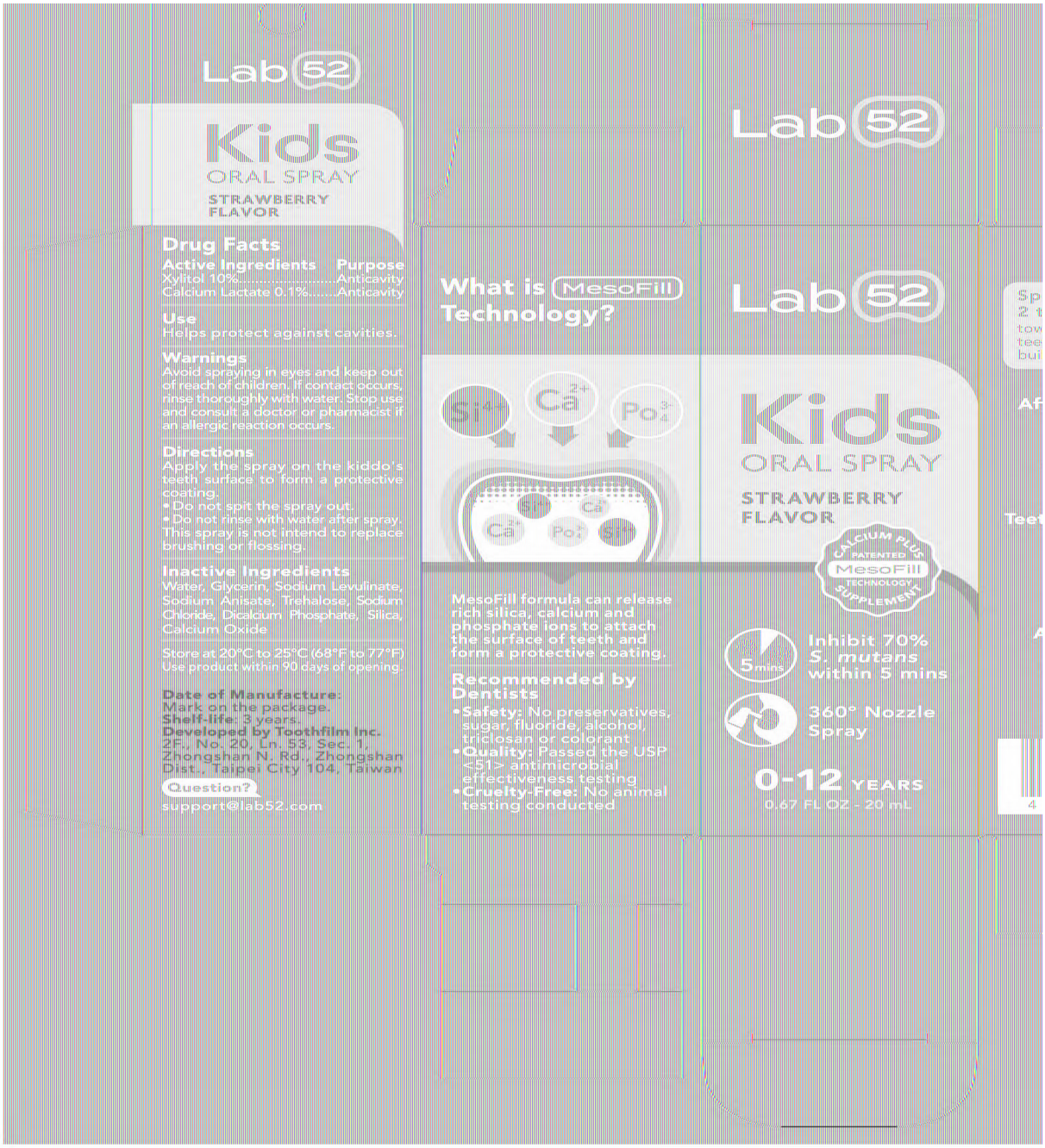
Helps protect against cavities. Spray 2 to 3 times towards children's teeth to prevent plaque build up and cavities.

Warnings: Avoid spraying in eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor or pharmacist if you have an allergic reaction to this product or any of its ingredients.

Directions: Apply the spray on the kiddo's teeth surface to form a protective coating.Do not spit the spray out.Do not rinse with water after spray. This spray is not intend to replace brushing or flossing.

Question: support@lab52.com

Other: Store at 20°C to 25°C (68°F to 77°F) Use product within 90 days of opening.



See Label

KIDS ORAL CARE STRAWBERRY FLAVOR

xylitol, calcium lactate spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82711-101
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

CALCIUM LACTATE (UNII: 2URQ2N32W3) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM LACTATE	0.02 mg in 20 mg
XYLITOL (UNII: VCQ006KQ1E) (XYLITOL - UNII:VCQ006KQ1E)	XYLITOL	2 mg in 20 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM ANISATE (UNII: F9WFJ28MV9)	
SODIUM LEVULINATE (UNII: VK44E1MQU8)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CALCIUM OXIDE (UNII: C7X2M0VVNH)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SILICA (UNII: ETJ7Z6XBU4)	
DICALCIUM PHOSPHATE (UNII: L11K75P92J)	
TREHALOSE (UNII: B8WCK70T7I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82711-101-02	1 in 1 BOX	03/13/2025	
1	NDC:82711-101-01	20 mg in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/13/2025	

Labeler - TOOTHFILM INC. (656036549)

Establishment

Name	Address	ID/FEI	Business Operations
JUN DA BEAUTY-TEC CO., LTD.		658442561	manufacture(82711-101) , label(82711-101)

Revised: 3/2025 TOOTHFILM INC.