

**KINDFILL- mint toothpaste tablets tablet, chewable**  
**Make USA LLC**

*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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**MAKE USA- BYHUMANKIND: Kindfill Dental Tabs**

**Active Ingredient(s)**

Sodium Fluoride .62mg (28 mg flouride ion)

**Purpose**

Anti-cavity

**Use**

aids in the prevention of dental cavities

**Warnings**

- When using this product, if irritation or sensitivity occurs discontinue use.
- Keep out of the reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

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**Directions**

- Adults and children 6 years of age and older; chew one tablet until crushed, wet toothbrush, brush for 2 minutes. Spit out.
- Do not swallow the tablet.
- Children under 6 years of age should be supervised when using this product.

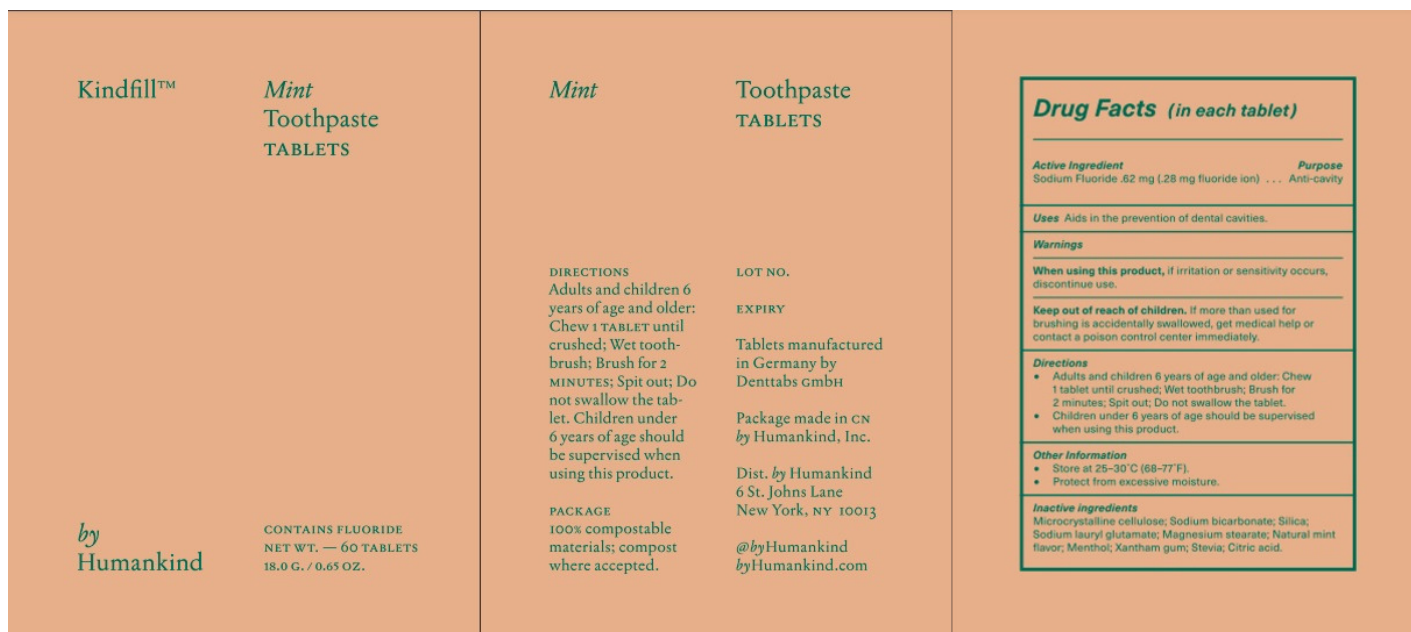
**Other information**

Store at 25-30°C (68-77°F). Protect from excessive moisture.

**Inactive ingredients**

Microcrystalline Cellulose, Sodium bicarbonate (Baking Soda), Silica, Sodium Lauryl Glutamate, Magnesium Stearate, Natural Mint Flavor, Menthol, Xanthan Gum, Stevia (Stevioside), Citric Acid

**Package Label - Principal Display Panel**



60 in Each Box NDC: 80486-112-11

<b>KINDFILL</b>			
mint toothpaste tablets tablet, chewable			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80486-112
<b>Route of Administration</b>	DENTAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.62 mg in 312 mg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	STEVIA LEAF (UNII: 6TC6NN0876)		
	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
	SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
	MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
	MINT (UNII: FV98Z8GTPP)		
	MENTHOL, (+)- (UNII: C6B1OE8P3W)		
	XANTHAN GUM (UNII: TTV12P4NEE)		
	SODIUM LAUROYL GLUTAMATE (UNII: NCX1UU2D33)		
	MAGNESIUM STEARATE (UNII: 70097M6I30)		
<b>Product Characteristics</b>			
<b>Color</b>	white	<b>Score</b>	no score

<b>Shape</b>	ROUND	<b>Size</b>	10 mm
<b>Flavor</b>	PEPPERMINT	<b>Imprint Code</b>	NONE
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80486-112-11	60 in 1 BOX	02/09/2021	
1		312 mg in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/22/2020	

**Labeler** - Make USA LLC (110142615)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Make USA LLC		110 1426 15	repack(80486-112)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Denttabs GmbH		340 1096 25	manufacture(80486-112)

Revised: 2/2021

Make USA LLC