

**BEYOU ORANGE- toothpaste paste, dentifrice  
Curaden AG**

*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(s)**

Sodium monofluorophosphate 0.723%  
(0.095% W/V fluoride ion)

**Purpose**

Fluoride toothpaste

**Use**

Aids in the prevention of dental cavities.

**Warnings**

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

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**Directions**

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor

Children under 6 years of age: Instruct in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision

Children under 6 years of age: Consult dentist or doctor

**Other information**

Do not use if tamper proof seal is broken

Store at room temperature.

**Inactive ingredients**

AQUA, GLYCERIN, HYDRATED SILICA, SORBITOL, XYLITOL, PANTHENOL, AROMA, XANTHAN GUM, COCAMIDOPROPYL BETAINE, MICROCRYSTALLINE CELLULOSE, DECYL

GLUCOSIDE, HYDROXYAPATITE (NANO), GLUCOSE OXIDASE, MANNITOL, MALTODEXTRIN, MICA, SUCRALOSE, CITRIC ACID, SODIUM HYDROXIDE, ZEA MAYS STARCH, ECHINACEA PURPUREA ROOT EXTRACT, TITANIUM DIOXIDE, SODIUM CHLORIDE, D-LIMONENE, SODIUM METABISULFITE, GLUCOSE, CALCIUM CARBONATE, L-MENTHOL, CENTELLAASIATICAEXTRACT, CITRUSAURANTIUM AMARA FRUIT EXTRACT, POTASSIUM THIOCYANATE, POLYLYSINE, CETYL ALCOHOL, LINALOOL, SILICA, POTASSIUM CHLORIDE, TIN OXIDE, HARPAGOPHYTIJM PROCUMBENS ROOT EXTRACT, CI77492,CITT491

A pea-sized amount of toothpaste is enough. For the best whitening results: Do not rinse your mouth afterwards. Be gentle when brushing and use a toothbrush with soft, high-density bristles. Once a day, brush between your teeth with an interdental brush to keep your gums and teeth healthier, and your breath fresher.

Active Ingredients

Purpose

Use

Warning

OTC - Keep out of reach of children

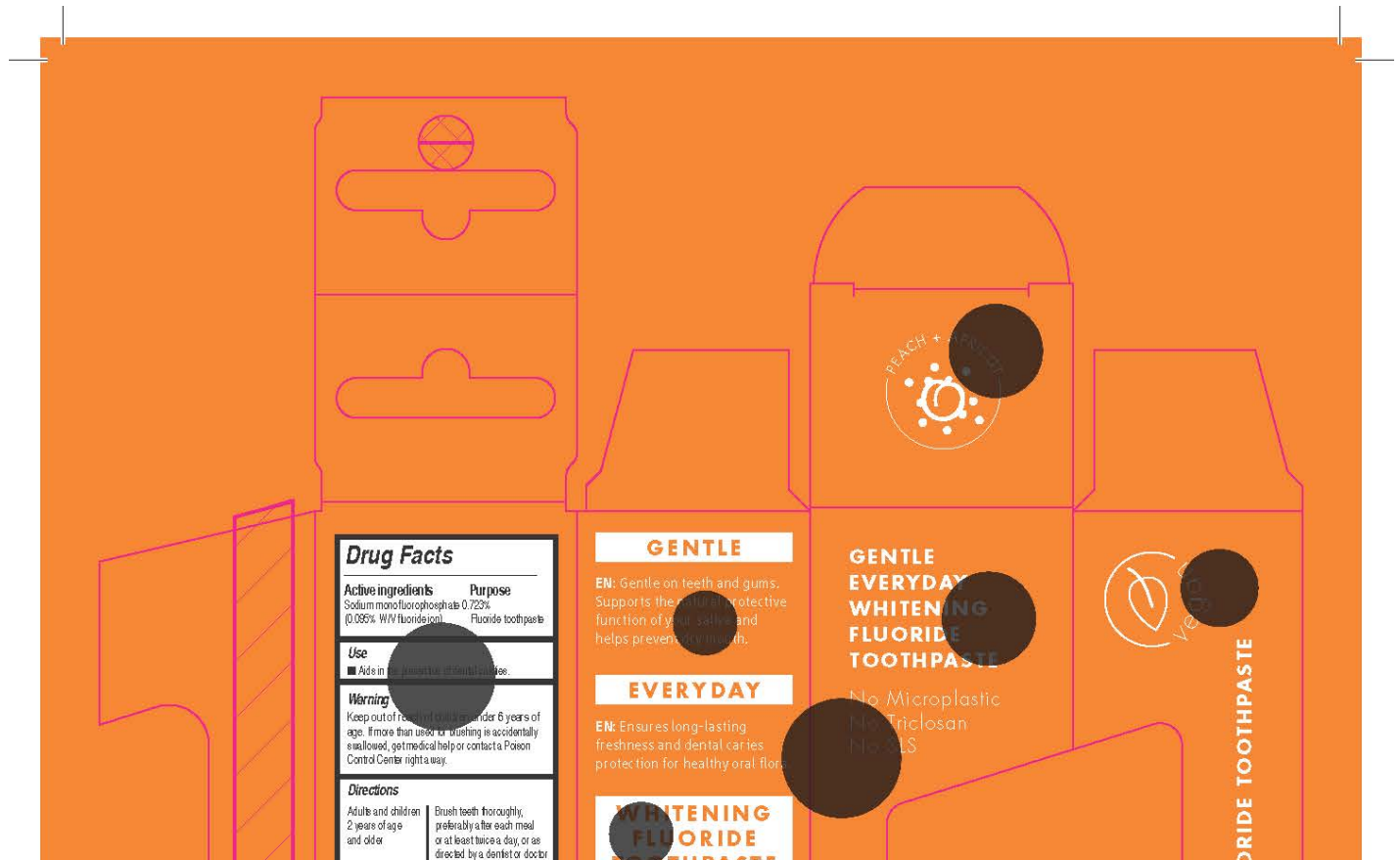
Directions

Other Information

Inactive Ingredients

Dose and administration

Curaden





## BEYOU ORANGE

toothpaste paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71112-003
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.095 g in 100 mL

### Inactive Ingredients

Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
POTASSIUM THIOCYANATE (UNII: TM7213864A)				
<b>Product Characteristics</b>				
Color		Score		
Shape		Size		
Flavor	PEACH (Peach + Apricot flavor)	Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71112-003-20	1 in 1 BOX	12/17/2021	
1		60 mL in 1 TUBE; 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	12/17/2021		

**Labeler** - Curaden AG (481145555)

**Registrant** - Curaden AG (481145555)

### Establishment

Name	Address	ID/FEI	Business Operations
Trybol AG		480305077	manufacture(71112-003)

Revised: 7/2022

Curaden AG