# **HELLO NATURALLY WHITENING-** sodium monofluorophosphate paste, dentifrice

# **HELLO ACTIVATED CHARCOAL- sodium monofluorophosphate paste, dentifrice**

**Hello Products 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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Hello<sub>®</sub>

**Drug Facts** 

### **Active Ingredient**

Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)

#### **Purpose**

Anticavity

#### Use

helps protect against 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.

#### **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 physician
- children 2 to 6 years: use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
- children under 2 years: ask a dentist or physician

## **Inactive ingredients**

sorbitol, purified water, hydrated silica, glycerin, xylitol, charcoal powder, flavor, xanthan gum, titanium dioxide, coconut oil, cocamidopropyl betaine, sodium cocoyl glutamate and stevia rebaudiana leaf extract

# Questions?

855-HI-HELLO (1-855-444-3556)

# Distributed by Hello Products LLC Montclair, NJ 07042

# PRINCIPAL DISPLAY PANEL - 133 g Tube Label

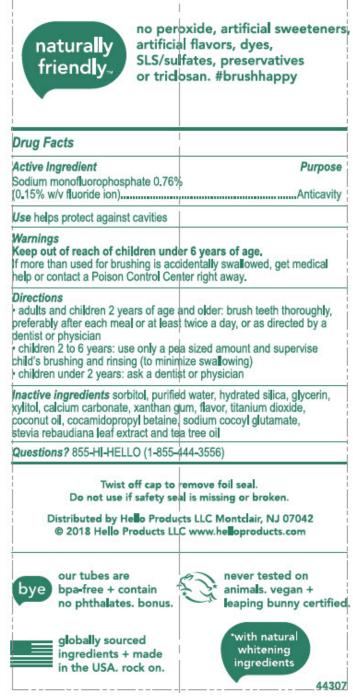
hello<sub>®</sub>

naturally whitening\* fluoride toothpaste

farm grown mint with tea tree + coconut oil

NET WT4.7 OZ (133g)





## PRINCIPAL DISPLAY PANEL - 113 g Tube Label

hello<sub>®</sub>

activated charcoal with fresh mint + coconut oil epic whitening fluoride toothpaste

NET WT 4.0 OZ (113g)



activated charcoal with fresh mint + coconut oil

> epic whitening fluoride toothpaste

NET WT 4.0 OZ (113g)



no peroxide, artificial sweeteners, artificial flavors, dyes, preservatives, SLS/sulfates, microbeads, parabens or triclosan. #brushhappy

#### Drug Facts

Active Ingredient

Purpose

Sodium monofluorophosphate 0.76%

(0.15% w/v fluoride ion)......Anticavity

Use helps protect against 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.

- 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 physician

   children 2 to 6 years: use only a pea sized amount and supervise child's brushing and ninsing (to minimize swallowing)

   children under 2 years: ask a dentist or physician

Inactive ingredients sorbitol, purified water, hydrated silica, glycerin, xylitol, charcoal powder, flavor, xanthan gum, titanium dioxide, coconut oil, cocamidopropyl betaine, sodium cocoyl glutamate and stevia rebaudiana leaf extract

Questions ? 855-HI-HELLO (1-855-444-3556)

Twist off cap to remove foil seal. Do not use if safety seal is missing or broken.

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globally sourced ingredients + made in the USA, rock on. 44309

#### HELLO **NATURALLY WHITENING**

sodium monofluorophosphate paste, dentifrice

**DENTAL** 

#### **Product Information**

**Route of Administration** 

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:55882-6100

#### **Active Ingredient/Active Moiety**

**Basis of Ingredient Name** Strength Strength

SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION -
UNII:Q80VPU4080)

FLUORIDE ION

1.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
TEA TREE OIL (UNII: VIF565UC2G)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

P	Packaging Packag			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55882- 6100-1	1 in 1 BOX	10/05/2018	10/31/2024
1		133 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:55882- 6100-2	28 g in 1 TUBE; Type 0: Not a Combination Product	10/05/2018	10/31/2024

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	10/05/2018	10/31/2024

# **HELLO ACTIVATED CHARCOAL**

sodium monofluorophosphate paste, dentifrice

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55882-6101	
Route of Administration	DENTAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	

Product Characteristics			
Color	BLACK	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55882- 6101-1	1 in 1 BOX	10/05/2018	03/10/2023	
1		113 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:55882- 6101-2	28 g in 1 TUBE; Type 0: Not a Combination Product	10/05/2018	03/10/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOCDADU				

	FINAL	part355	10/05/2018	03/10/2023
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# Labeler - Hello Products LLC (040714890)

Revised: 2/2022 Hello Products LLC