THUMB THUMB NO THUMB EXTRA STRENGTH- saccharum off. gel Beautiful Day Organics, LLC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Dug Fcts

Active Ingredient Saccharum Off. (6X).....

Use-May help deter thumb and finger sucking.

Warnings:For external use only.

Allergy alert: Do not use if allergic to any of the ingredients

Do not use In or near the eyes. Do not apply To broken or sore skin.

Keep out of reach of children.

If more than intended use is swallowed, get medical help or contact a Poison Control Center right away.

Directions: Children 2 years and older: Wash thumb and fingers with warm water and soap. Apply a liberal amount and rub evenly over the entire thumb including the cuticle around the fingernail.

Re-apply as needed

Inactive Ingredients: Bitter Green Gras, Citric Acid, Potassium

Sorbate, Water (purified), Xanthan Gum.

Other Info: Store at room temperature 68-77F (20-25C). Avoid direct sunlight.



Thumb Sucking Deterrent

Homeopathic

THUMB THUMB NO THUMB!

Thumb Thumb NO THUMBI™ is a

homeopathic thumb sucking deterrent for children. Our safe and effective formula was created by caring parents. Our product may help your child stop the harmful habit of thumb sucking*.

We use natural ingredients including those derived from pure plant oils and fruit Ingredients include: salt of sorbic acid like those found in the berries of mountain ash, citric acid from fruit. Saccharum Officinale from perennial grass, Bitter Green Gras, a natural flavor, Xanthan gum, a natural and gluten-free thickener, and purified water, the source of all life.

Thumb Sucking **Deterrent Gel**

EXTRA STRENGTH



Ages 2+

Thumb Sucking Deterrent

Homeopathic

Natural Ingredients Gluten Free Dentist Approved[†] Safe & Effective

Safety sealed tube for your protection. Do not use if seal is broken or missing.

NET WT. 2 OZ (56g)

THUMB THUMB NO THUMB!

Thumb Sucking Deterrent



children from harmful thumb king habits'.

> Never tested on animals

Please recycle

†See our website for more information:

thumbthumbnothumb.com

Questions? Contact us at beautifuldayorganics.com or (888) 494-4699

Mfd, for Beautiful Day Organics, LLC P.O. Box 3048 New York, NY 10163 USA

Thumb Sucking **Deterrent Gel**

Drug Facts

Active Ingredient Purpose
Saccharum Off. (6X)......Deterrent

May help deter thumb and finger sucking.

Warnings For external use only.

Allergy alert: Do not use if allergic to any of

the ingredients.

Do not use In or near the eyes.

Do not apply To broken or sore skin.

Keep out of reach of children.

If more than intended use is swallowed, get medical help or contact a Poison Control Center right away.

Directions Children 2 years and older w Wash thumb and fingers with warm water and soap.

- Apply a liberal amount and rub evenly over the entire thumb including the cutide around the fingernail.
- Re-apply as needed.

Other Info

Store at room temperature 68-77F (20-25C). Avoid direct sunlight.

Inactive Ingredients Bitter Green Gras, Citric Acid, Potassium

Sorbate, Water (purified), Xanthan Gum.

* The use for our product is based on traditional homeopathic practice. This use has not been evaluated by the Food and Drug Administration.





NDC:72715-002

THUMB THUMB NO THUMB EXTRA STRENGTH

saccharum off. gel

Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SACCHARUM OFFICINARUM WHOLE (UNII: 3Z20C92XNB) (SACCHARUM OFFICINARUM WHOLE - UNII:3Z20C92XNB)	SACCHARUM OFFICINARUM WHOLE	6 [hp_X] in 58 g	

Inactive Ingredients		
Ingredient Name	Strength	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
WATER (UNII: 059QF0KO0R)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics		
Color	yellow (colorless to pale yellow)	Score
Shape		Size
Flavor		Imprint Code
Contains		

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:72715-002-02	1 in 1 CARTON	12/26/2019	
ı	1 NDC:72715-002-01	56 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/26/2019	

Labeler - Beautiful Day Organics, LLC (080738209)

Registrant - Beautiful Day Organics, LLC (080738209)

Establishment				
Name	Address	ID/FEI	Business Operations	
ULTRAtab Laboratories, Inc.		151051757	manufacture (72715-002)	

Revised: 12/2019 Beautiful Day Organics, LLC