ECODENT ULTIMATE ESSENTIAL MOUTHCARE SPICY-COOL CINNAMONsodium bicarbonate liquid Lotus Brands, Inc.

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.

EcoDent_® Ultimate Essential Mouthcare[®] Spicy-Cool Cinnamon

Drug Facts

Active ingredient

Sodium Bicarbonate 2.5%

Purpose

Oral Wound Cleanser/Oral Debriding Agent

Uses

For temporary use in cleansing minor wounds or minor gum inflammation resulting from

- minor dental procedures
- dentures
- orthodontic appliances
- accidental injury
- or other irritations of the mouth and gums

Warnings

Do not use this product as an oral wound cleanser for more than 7 days unless directed by a dentist or doctor

Stop use and ask a doctor or dentist if

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops

Keep out of reach of children

If more than used for oral wound cleansing is accidentally swallowed, get medical help or contact a Poison Control Center right away

Directions

• Adults and children 2 years of age and older: Swish 2-3 capfuls around in mouth over

affected area for at least 1 minute and then spit it out. Use up to 4 times daily or as directed by a dentist or doctor

- Children under 12 should be supervised in the use of the product
- Children under 2 years of age: Consult a dentist or doctor

Other Information

store at 59° - 86°F (15°-30° C)

Inactive ingredients

Aqua (Purified Water), Glycerin (Vegetable), Polysorbate 20, Aloe Barbadensis (Aloe Vera) Leaf Juice (Decolorized), Menthol, Mentha Piperita (Peppermint) Oil, Cinnamomum Cassia (Cassia) Oil, Stevia Rebaudiana (Stevia) Extract, Cinnamomum Zeylanicum (Cinnamon) Leaf Oil, Echinacea Purpurea (Echinacea) Extract, Citrus Aurantium Dulcis (Orange) Oil, Citrus Limon (Lemon) Peel Oil, Lavandula Angustifolia (Lavender) Oil, Ricinus Communis (Castor) Seed Oil, Hydrastis Canadensis (Goldenseal) Leaf Extract, Pimpinella Anisum (Anise) Fruit Oil, Rosmarinus Officinalis (Rosemary) Leaf/Stem Oil, Hamamelis Virginiana (Witch Hazel) Water, Pelargonium Graveolens (Geranium) Oil, Citrus Paradisi (Grapefruit) Seed Extract, Anethole, Eugenia Caryophyllus (Clove) Flower Oil, Ocimum Basilicum (Basil) Oil, Foeniculum Vulgare (Fennel) Oil, Citrus Aurantium Bergamia (Bergamot) Peel Oil, Ubiquinone (CoQ10), Rosewater Concentrate

Ouestions and Comments?

Call toll free 1-888-326-3368, Monday - Friday, 9:00 - 5:00, CST

Dist. by ECO-DENT P.O. Box 325 Twin Lakes, WI 53181 USA

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

ECO • DENT_®
PREMIUM ORAL CARE PRODUCTS

ULTIMATE Essential MouthCare®

Spicy-Cool Cinnamon

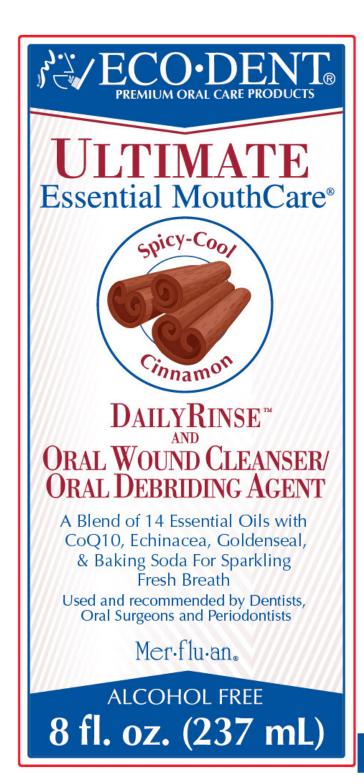
DAILYRINSE™ AND ORAL WOUND CLEANSER/ ORAL DEBRIDING AGENT

A Blend of 14 Essential Oils with CoQ10, Echinacea, Goldenseal, & Baking Soda For Sparkling Fresh Breath

Used and recommended by Dentists, Oral Surgeons and Periodontists

Mer • flu • an ®

ALCOHOL FREE 8 fl. oz. (237 mL)



Daily Rinse Use: To improve daily oral hygiene, rinse mouth for 30 seconds, with 1 capful, after eating or brushing. Do not swallow.

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Do Not Use if printed safety seal under cap is tampered with or is missing

sodium bicarbonate liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76328-221

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	25 mg in 1 mL		

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	3
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CHINESE CINNAMON OIL (UNII: A4WO0626T5)	
CINNAMON LEAF OIL (UNII: S92U8SQ71V)	
WITCH HAZEL (UNII: 10114J0U34)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRUS PARADISI SEED (UNII: 12F08874Y7)	
UBIDECARENONE (UNII: EJ27X76M46)	
ECHINACEA PURPUREA WHOLE (UNII: QI7G114Y98)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
CLOVE OIL (UNII: 578389D6D0)	
ANETHOLE (UNII: Q3JEK5DO4K)	
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
CITRUS X LIMON SEED OIL (UNII: T78Z8273XO)	
STAR ANISE OIL (UNII: 6RXP35EIRE)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
BASIL OIL (UNII: Z129UMU8LE)	
FENNEL OIL (UNII: 59AAO5F6HT)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
SULFATED CASTOR OIL (UNII: 75T1HFY189)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

Product Characteristics Color Score Shape Size

Flavor	CINNAMON (Spicy-Cool)	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:76328- 221-01	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/01/2013	

Labeler - Lotus Brands, Inc. (879022713)

Registrant - Sun Deep Inc. (189788201)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sun Deep Inc.		189788201	MANUFACTURE(76328-221)	

Revised: 1/2022 Lotus Brands, Inc.