ECODENT ULTIMATE ESSENTIAL MOUTHCARE SPARKLING CLEAN MINTsodium 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[®] Sparkling Clean Mint

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, Stevia Rebaudiana (Stevia) Extract, Anethole, 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, Pelargonium Graveolens (Geranium) Oil, Rosmarinus Officinalis (Rosemary) Oil, Hamamelis Virginiana (Witch Hazel) Water, Citrus Aurantium Bergamia (Bergamot) Peel Oil, Citrus Paradisi (Grapefruit) Seed Extract, Foeniculum Vulgare (Fennel) Oil, Eugenia Caryophyllus (Clove) Flower Oil, Ocimum Basilicum (Basil) Oil, Rosewater Concentrate, Ubiquinone (CoQ10)

Questions 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®

Sparkling Clean Mint

DAILYRINSE™ AND ORAL WOUND CLEANSER/ ORAL DEBRIDING AGENT

A Blend of 12 Essential Oils with CoQ10, Echinacea, Goldenseal, & Baking Soda For Sparkling Fresh Breath

Used and recommended by Dentists, Oral Surgeons and Periodontists $\text{Mer} \hspace{-0.5mm} \bullet \hspace{-0.5mm} \text{flu} \hspace{-0.5mm} \bullet \hspace{-0.5mm} \text{an}_{\hspace{-0.5mm} \hspace{-0.5mm} \hspace{-0.5mm} \mathbb{R}}$

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

ECODENT ULTIMATE ESSENTIAL MOUTHCARE SPARKLING CLEAN MINT

sodium bicarbonate liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76328-223

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:HN1Z RA3Q20)	SODIUM BICARBONATE	25 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)				
ANETHOLE (UNII: Q3JEK5DO4K)				
ECHINACEA PURPUREA WHOLE (UNII: QI7G114Y98)				
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)				
CITRUS X LIMON SEED OIL (UNII: T78Z8273XO)				
LAVENDER OIL (UNII: ZBP1YXW0H8)				
SULFATED CASTOR OIL (UNII: 75T1HFY189)				
GOLDENSEAL (UNII: ZW3Z11D0JV)				
STAR ANISE OIL (UNII: 6RXP35EIRE)				
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)				
ROSEMARY OIL (UNII: 8LGU7VM393)				
WITCH HAZEL (UNII: 10114J0U34)				
BERGAMOT OIL (UNII: 39W1PKE3JI)				
CITRUS PARADISI SEED (UNII: 12F08874Y7)				
FENNEL OIL (UNII: 59AAO5F6HT)				
Clove Oil (UNII: 578389D6D0)				
BASIL OIL (UNII: Z129UMU8LE)				
ROSA X DAMASCENA FLOWER OIL (UNII: 18920M3T13)				
UBIDECARENONE (UNII: EJ27X76M46)				

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:76328- 223-01	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(76328-223)	

Revised: 1/2022 Lotus Brands, Inc.