

SEAWEED OIL-CONTROL SPF 15- octisalate, avobenzone, octinoxate, and octocrylene lotion
Buth-Na-Bodhaige, 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.

Seaweed Oil-Control Lotion SPF 15

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Avobenzone (3.0% w/w)	Sunscreen
Octinoxate (2.9% w/w)	Sunscreen
Octisalate (5.0% w/w)	Sunscreen
Octocrylene (2.2% w/w)	Sunscreen

Uses

- helps prevent sunburn.

Warnings

- ***For external use only.***

Do not use

- on damaged or broken skin.

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash occurs.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in sun especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses.
 - reapply this product at least every 2 hours.
 - use a water resistant sunscreen if swimming or sweating.
- children under 6 months of age: ask a doctor.

Other information

- protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Water, C12-15 Alkyl Benzoate, Glyceryl Stearate, Glycerin, Butylene Glycol, Caprylic/Capric Triglyceride, Sorbitol, Cetearyl Alcohol, Potassium Cetyl Phosphate, Dimethicone, Phenoxyethanol, Bertholletia Excelsa Seed Oil, Caprylyl Glycol, Fragrance, Xanthan Gum, Carbomer, Potassium Sorbate, Tetrasodium EDTA, Pentylene Glycol, Propylene Glycol, Sodium Hydroxide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fucus Vesiculosus Extract, Linalool, Zinc Gluconate, Benzyl Salicylate, Acacia Senegal Gum, Hydrolyzed Wheat Protein, Propylene Glycol Alginate, BHT, Hydrolyzed Algin, Serine, Sodium Stearate, Zinc Sulfate.

PRINCIPAL DISPLAY PANEL - 50 ml Tube Label

THE
BODY
SHOP

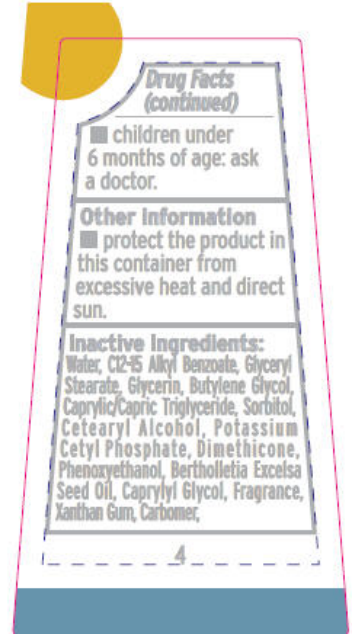
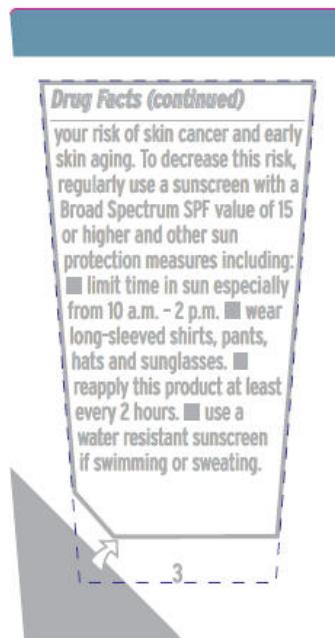
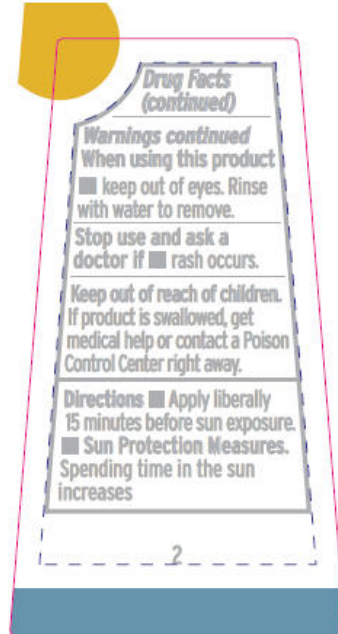
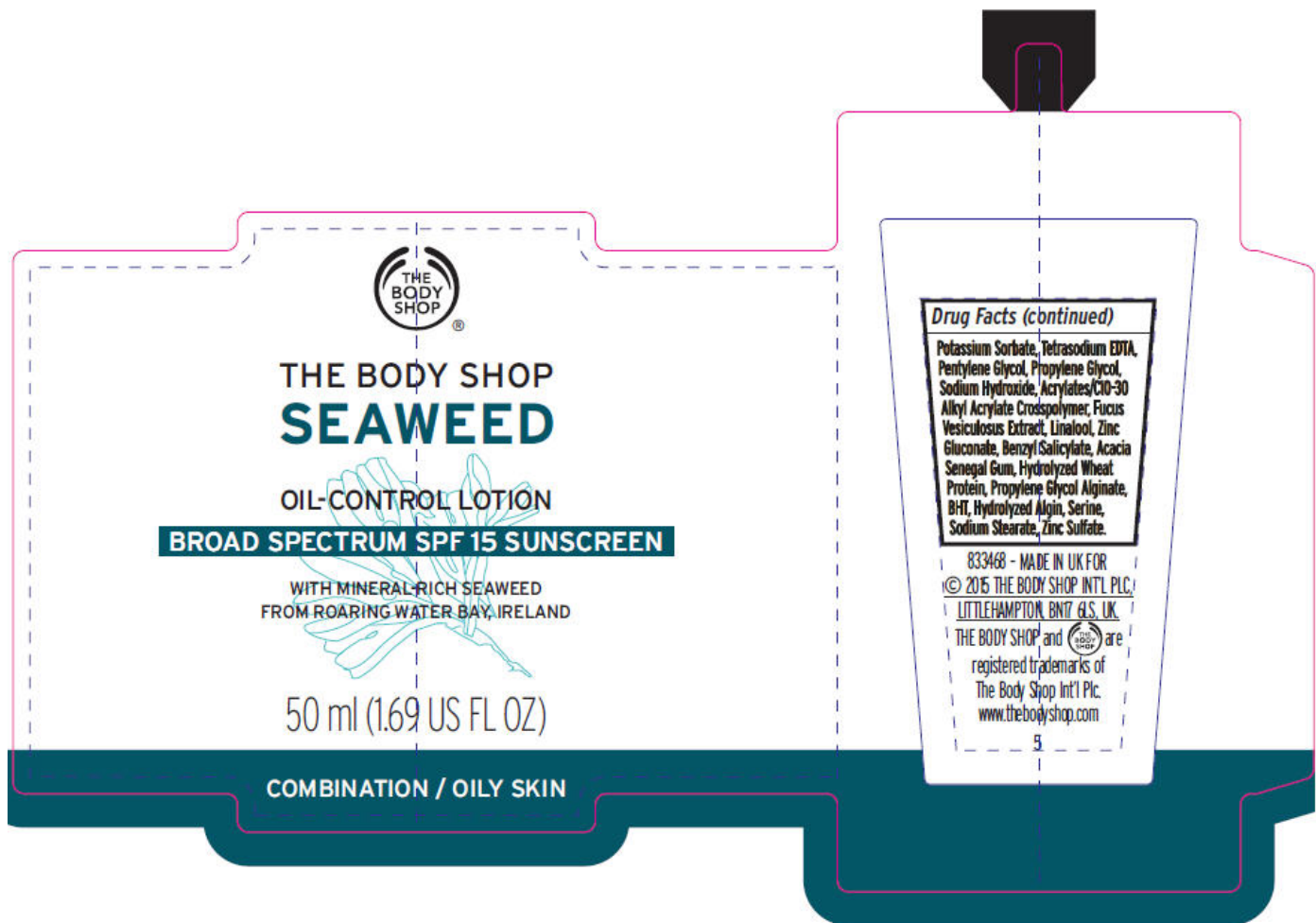
THE BODY SHOP
SEAWEED

OIL-CONTROL LOTION
BROAD SPECTRUM SPF 15 SUNSCREEN

WITH MINERAL-RICH SEAWEED
FROM ROARING WATER BAY, IRELAND

50 ml (1.69 US FL OZ)

COMBINATION / OILY SKIN



SEAWEED OIL-CONTROL SPF 15

octisalate, avobenzone, octinoxate, and octocrylene lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:57691-904

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 1 mL
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 g in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.029 g in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.022 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
Butylene Glycol (UNII: 3XUS85K0RA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Sorbitol (UNII: 506T60A25R)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)	
Dimethicone (UNII: 92RU3N3Y1O)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
BRAZIL NUT OIL (UNII: 0G89T29HO6)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Xanthan Gum (UNII: TTV12P4NEE)	
Carboxypolymethylene (UNII: 0A5MM307FC)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Edetate Sodium (UNII: MP1J8420LU)	
Pentylene Glycol (UNII: 50C1307PZG)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Hydroxide (UNII: 55X04QC32I)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
FUCUS VESICULOSUS (UNII: 535G2ABX9M)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
Zinc Gluconate (UNII: U6WSN5SQ1Z)	
Benzyl Salicylate (UNII: WAO5MKN9TU)	
ACACIA (UNII: 5C5403N26O)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)	
Propylene Glycol Alginate (UNII: 26CD3J2R0C)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
Serine (UNII: 452VLY9402)	
Sodium Stearate (UNII: QU7E2XA9TG)	
Zinc Sulfate, Unspecified Form (UNII: 89DS0H96TB)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57691-904-50	50 mL in 1 TUBE; Type 0: Not a Combination Product	04/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	04/14/2016	

Labeler - Buth-Na-Bodhaige, Inc., (791071279)

Revised: 10/2016

Buth-Na-Bodhaige, Inc.,