

## **MYBODY PROTECT AND SERVE SPF-30- zinc oxide lotion**

**mybody**

*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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ACTIVE INGREDIENT

ZINCE OXIDE 13.5%

PURPOSE

SUNSCREEN

USE

HELPS PROTECT AGAINST SUNBURN

WARNINGS

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT

- AVOID CONTACT WITH EYES. IF PRODUCT GETS INTO EYES, RINSE THOROUGHLY WITH WATER.

STOP USE AND ASK A DOCTOR IF RASH OR IRRITATION DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN.

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

STORE AT ROOM TEMPERATURE.

AVOID HIGH TEMPERATURES AND PROTECT FROM FREEZING.

DO NOT USE IF INNER SEAL IS BROKEN.

DO NOT USE

- ON INFLAMED OR BROKEN SKIN.

Directions

- Use AM. Apply as needed to face and neck area. Can also be applied to the ears, hands and décolletage. Apply evenly 15-30 minutes before sun exposure and as needed. Reapply as needed or after swimming or perspiring. For best results
- Cleanse skin thoroughly before applying.
- Apply liberally to face and neck before sun exposure.
- Use alone or under make-up.
- Children under

6 months of age: ask a doctor.

SUN ALERT

LIMITING SUN EXPOSURE, WEARING PROTECTIVE CLOTHING, AND USING SUNSCREENS MAY REDUCE THE RISKS OF SKIN AGING, SKIN CANCER AND OTHER HARMFUL EFFECTS OF THE SUN.

Inactive Ingredients Water/Aqua/Eau, C12-15 Alkyl Benzoate, Carthamus Tinctorius (Safflower) Seed Oil, Polysorbate 60, Cetyl Alcohol,

Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Cetearyl Alcohol, Coco-Glucoside, Caprylic/Capric Triglyceride, Leuconostoc/Radish Root Ferment Filtrate, Isostearic Acid, Polyhydroxystearic Acid, Caprylyl Glycol, Sclerotium Gum, Hamamelis Virginiana (Witch Hazel) Water, Alcohol, Xanthan Gum, Phytic Acid, Citric Acid.

QUESTIONS OR COMMENTS?

CALL 877.423.1314 \* WWW.MYBODYSKINCARE.COM

 <p><b>PROTECT &amp; SERVE®</b></p> <p>Sun Shield UVA/UVB Broad Spectrum Protection SPF 30</p> <p>Crème Solaire Large Spectre UVA/UVB SPF 30</p> <p>A high-performance, non-whitening, physical sunscreen protects the skin with broad spectrum UVA/UVB SPF 30 and serves the skin with a dose of light hydration free of chemicals and fragrances.</p> <p>Key Ingredients:</p> <ul style="list-style-type: none"> <li>• <b>Zinc Oxide</b> – helps naturally protect the skin against long wave UVA rays.</li> </ul> <p><small>Distributed by: mybody, LLC • Phoenix, AZ 85018 Made in the USA • 877-423-1314 Kikivice &amp; body • Hengedicht 232, 1016 BX Amsterdam, The Netherlands • ©2014 mybody LLC • All rights reserved. www.mybodyskincare.com • 104PST3 • R0815</small></p>	<p><i>Drug Facts</i></p> <p><b>Active Ingredient</b> Zinc Oxide 13.5%</p> <p><b>Purpose</b> Sunscreen</p> <p><b>USE</b> helps protect against sunburn</p> <p><b>Warnings</b> <b>For external use only</b></p> <p><b>When using this product</b> • Avoid contact with eyes. If product gets into eyes, rinse thoroughly with water. • <b>Stop use and ask a doctor if</b> • Rash or irritation develops and lasts. • <b>Keep out of reach of children.</b> • If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p><b>Do not use</b> • On inflamed or broken skin.</p> <p><b>Directions</b> • Use AM. Apply as needed to face and neck area. Can also be applied to the ears, hands and décolletage. Apply evenly 15-30 minutes before sun exposure and as needed. Reapply as needed or after swimming or perspiring. For best results • Cleanse skin thoroughly before applying. • Apply liberally to face and neck before sun exposure. • Use alone or under make-up. • Children under 8 months of age: ask a doctor.</p> <p><b>Application</b> Appliquez le matin. Suivant myhydrator drapé 3, appliquer au visage et au cou selon besoin. Peut s'appliquer aux mains et au décolleté. Appliquez uniformément de 15 à 30 minutes avant toute exposition au soleil. Réappliquez selon besoin, en sortant de l'eau et en cas de transpiration. Demandez conseil à votre médecin pour les enfants de moins de 8 mois.</p> <p><b>Other Information</b> • Store at room temperature. • Avoid high temperatures and protect from freezing. Do not use if inner seal is broken.</p> <p><b>Sun Alert</b> Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer and other harmful effects of the sun.</p>	 <p><b>PROTECT &amp; SERVE®</b></p> <p>Sun Shield UVA/UVB Broad Spectrum Protection SPF 30</p> <p>Crème Solaire Large Spectre UVA/UVB SPF 30</p> <p>mySPF STEP 4 • AM FACE &amp; NECK</p> <p>ADVANCED <b>PROBIOTIC</b> SKINCARE</p> <p>2 FL OZ / 60 mL</p>	<p><i>Drug Facts (continued)</i></p> <p><b>Inactive Ingredients</b> Water/Aqua/Eau, C12-15 Alkyl Benzoate, Carthamus Tinctorius (Safflower) Seed Oil, Polyorbate 60, Cetyl Alcohol, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Cetearyl Alcohol, Coco-Glucoside, Caprylic/Capric Triglyceride, Leuconostoc/Radish Root Ferment Filtrate, Isostearic Acid, Polyhydroxystearic Acid, Caprylyl Glycol, Sclerotium Gum, Hamamelis Virginiana (Witch Hazel) Water, Alcohol, Xanthan Gum, Phytic Acid, Citric Acid.</p> <p><b>Questions or Comments?</b> Call 877.423.1314 • www.mybodyskincare.com</p> <p>mybody products are:</p> <ul style="list-style-type: none"> <li>• phthalate-free</li> <li>• sulfate-free</li> <li>• FD&amp;C dye-free</li> <li>• cruelty-free</li> </ul>
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## MYBODY PROTECT AND SERVE SPF-30

zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49520-302
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	11 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0TH5PCI0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
CALCIUM BEHENATE (UNII: J5VFA9V6YG)	
MELANIN SYNTHETIC (TYROSINE, PEROXIDE) (UNII: O0CV1RMR44)	
DIMETHICONOL (41 MPA.S) (UNII: 343C7U75XW)	
ALUMINUM OXIDE (UNII: LM26O6933)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
LYCOPENE (UNII: SB0N2N0WV6)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUCROSE PALMITATE (UNII: 3OSQ643ZK5)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49520-302-52	1 in 1 BOX		
1	NDC:49520-302-32	60 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/03/2015	

**Labeler** - mybody (004460532)

**Registrant** - mybody (004460532)

Revised: 9/2015

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