# SUNFISHER - THE FISHERMANS SUNSCREEN BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene cream TBSC LLC

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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#### SUNFISHER - BROAD SPECTRUM SPF 50 - THE FISHERMAN'S SUNSCREEN

#### **ACTIVE INGREDIENTS**

AVOBENZONE 2.4% HOMOSALATE 12.0% OCTISALATE 4.0% OCTOCRYLENE 4.8%

#### **PURPOSE**

**SUNSCREEN** 

#### USES

- HELPS PREVENT SUNBURN
- IF USED AS DIRECTED WITH OTHER SUN PROTECTION MEASURES (SEE DIRECTIONS), DECREASES THE RISK OF SKIN CANCER AND EARLY SKIN AGING CAUSED BY THE SUN.

# **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 SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

### **DIRECTIONS**

- APPLY LIBERALLY 15 MINUTES BEFORE SUN EXPOSURE
- REAPPLY: AFTER 80 MINUTES OF SWIMMING OR SWEATING
- IMMEDIATELY AFTER TOWEL DRYING
- AT LEAST EVERY 2 HOURS
- 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 THE SUN, ESPECIALLY FROM 10 A.M. 2 P.M.
- WEAR LONG-SLEEVED SHIRTS, PANTS, HATS AND SUNGLASSES
- CHILDREN UNDER 6 MONTHS: ASK A DOCTOR.

## **OTHER INFORMATION**

- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN
- MAY STAIN SOME FABRICS

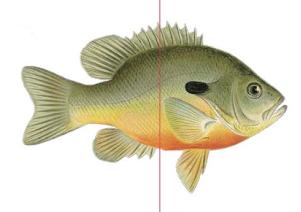
# **INACTIVE INGREDIENTS**

WATER, PROPYLENE GLYCOL, CETYL PEG/PPG-10/1 DIMETHICONE, PHENOXYETHANOL, BENZOIC ACID, ETHYLHEXYLGLYCERIN, GLYCERETH-2 COCOATE, OCTYLDODECYL STEARYL CITRATE CROSSPOLYMER, DISODIUM EDTA, SODIUM CHLORIDE, FRAGRANCE.

# **Sunfisher**

**Broad Spectrum SPF 50** 

# THE FISHERMAN'S SUNSCREEN



# FISH FRIENDLY SCENT

Mild anise aroma masks human and chemical scents

> PROTECTS AGAINST **UVA & UVB**

WATER-RESISTANT

(80 Minutes)

4.5 fl oz (133 mL)

Specially formulated for people who love to fish. If inadvertently transferred from hands to baits or lures. Sunfisher™ sunscreen is designed to not scare away fish like bass, steelhead, salmon, trout, catfish, kokanee, carp and other popular sportfishing species. Provides broad spectrum protection against both long (UVA) and short (UVB) rays. Water resistant with a light, non-greasy protection that absorbs quickly. Contains anise and other fish-friendly fragrances. Paraben and Oxybenzone free.

| Drug Facts   |                   |
|--|-------------------|
| Active ingredients Avobenzone 2.4% Homosalate 12.0% Octisalate 4.0% Octocrylene 4.8% | Purpose Sunscreen |

**Uses** • Helps prevent sunburn • If used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun.

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

**Directions** • Apply liberally 15 minutes before sun exposure Reapply: after 80 minutes of swimming or sweating

- immediately after towel drying at least every 2 hours
- 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 the sun, especially from 10 a.m. 2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: ask a doctor.

Other Information • Protect this product from excessive heat and direct sun . May stain some fabrics.

Inactive Ingredients • Water, Propylene Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Phenoxyethanol, Benzoic Adid, Ethylhexylglycerin, Glycereth-2 Cocoate, Octyldodecyl Stearyl Citrate Crosspolymer, Disodium EDTA, Sodium Chloride, Fragrance,



Dist. by TSBC LLC, Beaverton, OR 97007 • Patent pending Learn more and tell us about your fishing experience at www.sunfisher.fish

### SUNFISHER - THE FISHERMANS SUNSCREEN BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene cream

| Prod | luct | Info | rmati | ion |
|------|------|------|-------|-----|
|      |      |      |       |     |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72227-101

Route of Administration TOPICAL

| Active Ingredient/Active Moiety                                |                   |                 |  |  |
|--|-------------------|-----------------|--|--|
| Ingredient Name  | Basis of Strength | Strength        |  |  |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 2.4 g in 100 mL |  |  |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 12 g in 100 mL  |  |  |
| OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | OCTISALATE        | 4 g in 100 mL   |  |  |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 4.8 g in 100 mL |  |  |

| Inactive Ingredients   |          |
|--|----------|
| Ingredient Name  | Strength |
| WATER (UNII: 059QF0KO0R)                                     |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                          |          |
| CETYL PEG/PPG-10/1 DIMETHICO NE (HLB 1.5) (UNII: V2W71V8T0X) |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                            |          |
| BENZOIC ACID (UNII: 8 SKN0 B0 MIM)                           |          |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)                        |          |
| GLYCERETH-2 CO CO ATE (UNII: JWM00VS7HC)                     |          |
| OCTYLDODECYL STEARATE (UNII: K6F16QGO28)                     |          |
| EDETATE DISO DIUM (UNII: 7FLD91C86K)                         |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                           |          |

| Packaging                       |                    |   |                           |  |
|---------------------------------|--------------------|---|---------------------------|--|
| # Item Code Package Description |                    | <b>Marketing Start Date</b>                         | <b>Marketing End Date</b> |  |
| ı                               | 1 NDC:72227-101-11 | 133 mL in 1 TUBE; Type 0: Not a Combination Product | 04/12/2018                |  |

| Marketing Information                                       |         |                      |                    |  |
|---|---------|----------------------|--------------------|--|
| Marketing Category Application Number or Monograph Citation |         | Marketing Start Date | Marketing End Date |  |
| OTC monograph final   | part352 | 04/12/2018           |                    |  |
|   |         |                      |                    |  |

# Labeler - TBSC LLC (060954860)

| Establishment    |         |           |                         |
|------------------|---------|-----------|-------------------------|
| Name             | Address | ID/FEI    | Business Operations     |
| Health Specialty |         | 794053863 | manufacture (72227-101) |

Revised: 4/2018 TBSC LLC