**FOUNDATION- octinoxate emulsion**
**Oxygen Development 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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**PUR 4-IN-1 LIQUID 14-HOUR WEAR FOUNDATION BROAD SPECTRUM SPF 15**

## Medicinal Ingredient / Active Ingredient

Octinoxate 5.0% w/w

## Purpose

Sunscreen

## Uses

Helps prevent sunburn.

## Warnings

For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove.

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. Use a water resistant sunscreen if swimming or sweating.
Reapply at least every 2 hours. Children under 6 months: ask a doctor.
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 10am to 2 pm
Wear long-sleeved shirts, pants, hats, and sunglasses

## Other

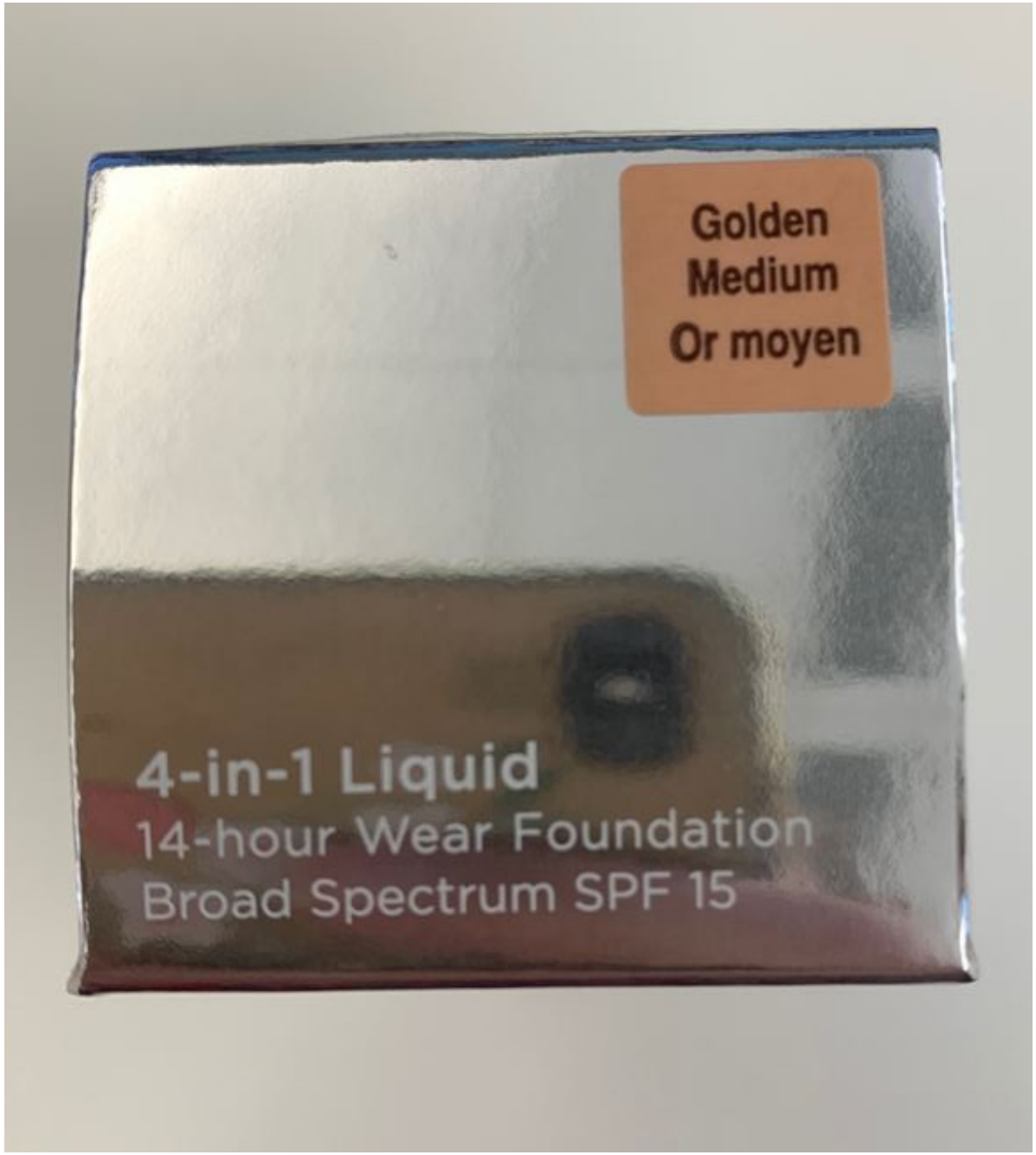
Protect this product from excessive heat and direct sun.
In the unlikely event of an adverse reaction, please contact 1.866.PUR.0022.

**Non-medicinal Ingredients / Inactive Ingredients**

Aqua, Cyclopentasiloxane, Propanediol, Sodium PCA, Cetyl PEG/PPG-10/1 Dimethicone,Trimethylsiloxysilicate, Boron Nitride, Dimethicone/Vinyl Dimethicone Crosspolymer, C12-15 Alkyl Ethylhexanoate, Magnesium Sulfate, Silica Silylate, Zinc Stearate, Phenoxyethanol, Mannitol, Bis-PEG/PPG-14/14 Dimethicone, Laureth-7, Amodimethicone, Lecithin, Tribehenin, Butyrospermum Parkii (Shea) Butter Extract, Sodium Starch Octenylsuccinate, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Disteardimonium Hectorite, Glucosamine HCl, Trihydroxystearin, Dimethiconol, Triethoxycaprylylsilane, Pisum Sativum (Pea) Extract, Xanthan Gum, Bambusa Vulgaris Leaf/Stem Extract, Hydroxyethylcellulose, Tocopheryl Acetate, Ethylhexylglycerin, Propylene Carbonate, Sodium Gluconate, Pentylene Glycol, Lactic Acid, Citric Acid, Sodium Citrate, Dextrin, Retinol, Waltheria Indica Leaf Extract, Ferulic Acid, EDTA, Ceramide AP, May Contain: Mica, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499).

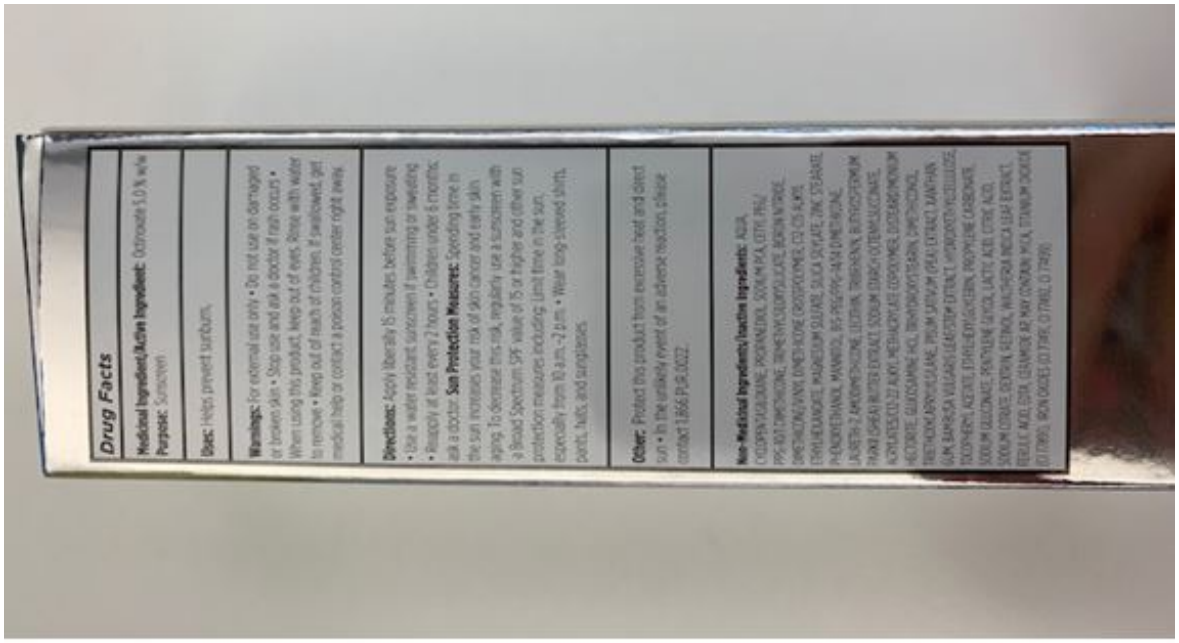
**Primary packaging**

**Secondary Packaging**


Golden
Medium
Or moyen
4-in-1 Liquid
14-hour Wear Foundation
Broad Spectrum SPF 15


Application: Smooth
clean, moisturized
the Liquid Chisel
fingertips. For best
apply over the
Primer of your


4-in-1
Liquid
14-hour Wear
Foundation Broad
Spectrum SPF 15
0.9 FL OZ/27 mL





# FOUNDATION

octinoxate emulsion

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:61354-040 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 4.9965 mg in 100 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **SILICA DIMETHYL SILYLATE** (UNII: EU2PSP0G0W) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **C12-15 ALKYL ETHYLHEXANOATE** (UNII: GQJ580CH83) | |
| **MAGNESIUM SULFATE, UNSPECIFIED FORM** (UNII: DE08037SAB) | |
| **TRIBEHENIN** (UNII: 8OC9U7TQZ0) | |
| **LECITHIN, SOYBEAN** (UNII: 1DI56QDM62) | |
| **CYCLOMETHICONE 5** (UNII: 0THT5PCI0R) | |
| **PROPANEDIOL** (UNII: 5965N8W85T) | |
| **SODIUM PYRROLIDONE CARBOXYLATE** (UNII: 469OTG57A2) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0)** (UNII: 25LXE464L2) | |
| **DIMETHICONE/DIVINYLDIMETHICONE/SILSESQUIOXANE CROSSPOLYMER** (UNII: T3064TZ75A) | |
| **MANNITOL** (UNII: 3OWL53L36A) | |
| **BIS-PEG/PPG-14/14 DIMETHICONE** (UNII: X2I70H0QJE) | |
| **CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)** (UNII: V2W71V8T0X) | |
| **MICA** (UNII: V8A1AW0880) | |
| **BORON NITRIDE** (UNII: 2U4T60A6YD) | |
| **ZINC STEARATE** (UNII: H92E6QA4FV) | |
| **LAURETH-7** (UNII: Z95S6G8201) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:61354-040-01 | 1 in 1 CARTON | 02/23/2021 | 02/10/2023 |
| **1** | | 27 mg in 1 BOTTLE, GLASS; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part352 | 02/23/2021 | |

## Labeler - Oxygen Development LLC (137098492)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Oxygen Development LLC | | 137098492 | manufacture(61354-040) |