

MOISTURIZER- zinc oxide lotion
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.

H2O+ Hydration Sensitive Sunscreen Lotion SPF 30 Broad Spectrum SPF 30 Sunscreen

Active ingredient

Zinc Oxide 17%

Purpose

Sunscreen

Uses

helps prevent sunburn protection. Higher SPF gives more sunburn protection. 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

Do not use on damage or broken skin.

When using

When using this product keep out of eyes. Rinse with water to remove.

Stop use

Stop use and ask a doctor if rash occurs.

Keep out the reach of children

Keep out the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply generously and evenly 15 minutes before sun exposure.

Children under 6 months of age: Ask a doctor.

Reapply at least every 2 hours.

use a water resistant sunscreen if swimming or sweating.

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

Other information

Protect the product in this container from excessive heat and direct sun




Inactive ingredients

Water, Caprylic/Capric Triglyceride, Coco-Caprylate/Caprates, Cetearyl Olivate, Glyceryl Stearate Citrate, Stearyl/Octyldodecyl Citrate Crosspolymer, Dimethicone, Camellia Japonica Seed Oil, Glycolipids, Trehalose, Pullulan, Agastache Mexicana Flower/Leaf/Stem Extract, Camellia Oleifera Leaf Extract, Glycine, Alanine, Serine, Threonine, Chamomilla Recutita (Matricaria) Flower Extract, Leuconostoc/Radish Root Ferment Filtrate, Polylysine, Lecithin, Isostearic Acid, Polyglyceryl-3 Polyricinoleate, Hydrogenated Lecithin, Silica, Xanthan Gum, Cetearyl Alcohol, Tocopheryl Acetate, Mica, Tocopheryl, Sclerotium Gum, Glycerin, Caprylhydroxamic Acid, Titanium Dioxide (CI 77891) (090-50132-000)



In-Mold Label Artwork Template




Tube size : D30 x 105 mm

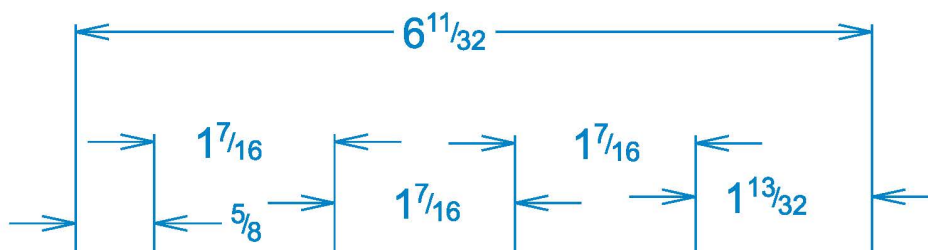
H2O+ [™]		DIMENSIONS FLAT: 95.2 mm X 105 mm	COLORS: SPOT COLOR  PMS 7693 C  EVOH Cold Foil  PMS 531 C
	RELEASE DATE: 06/30/21	PART NUMBER: 400-50132-000	
	VENDOR: Viva	JOB NAME: Hydration Sensitive Sunscreen Lotion SPF 30	
	DESIGNER: JV	LOCATION:	
		SUBSTRATE: EVOH COLD FOIL	
		ADDITIONAL FINISHES: MATTE	

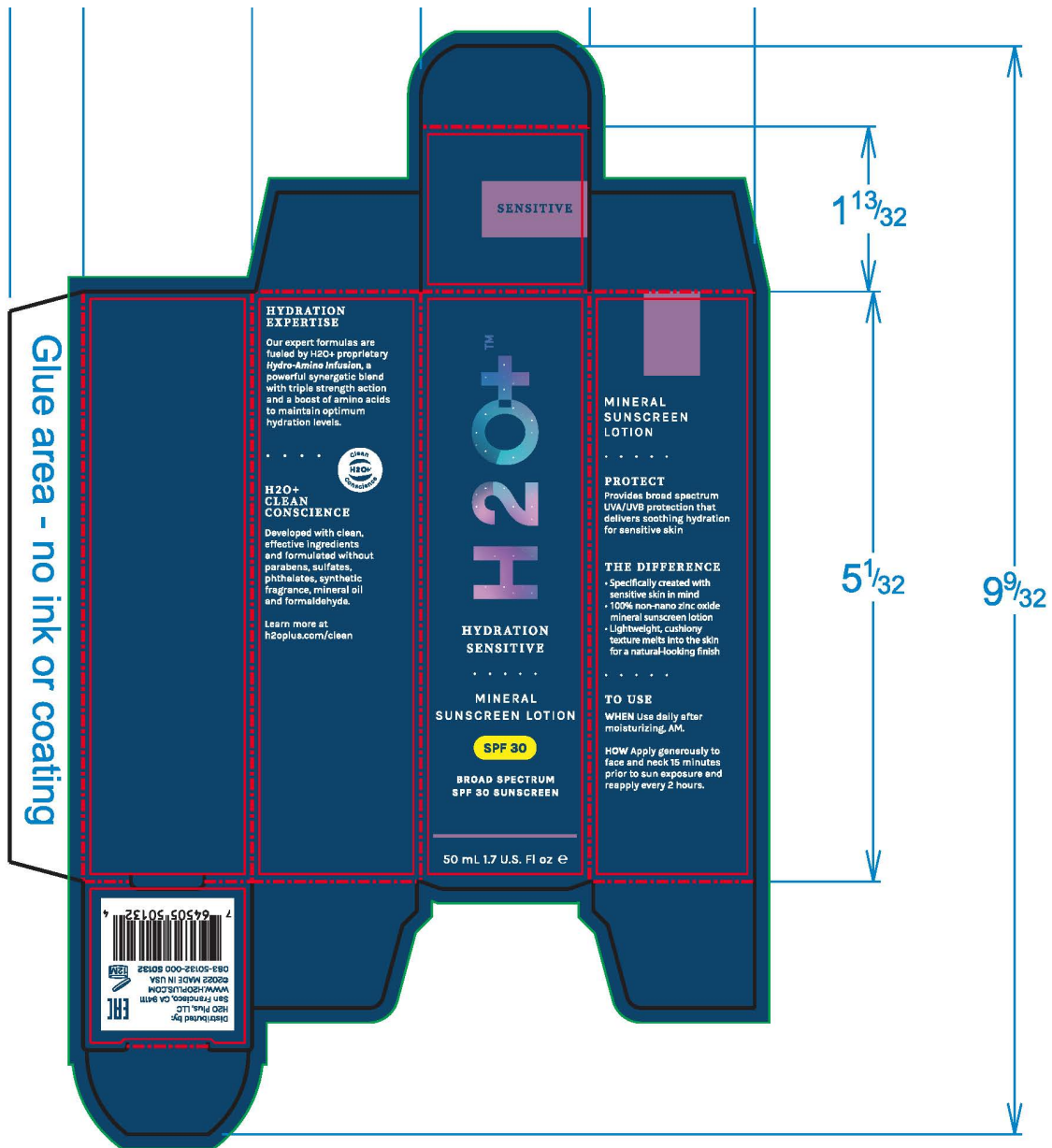
Tube Circumference
95.2 mm

Tube Body Length
105 mm



H2O+	Job Name: HYDRATION SENSITIVE SUNSCREEN LOTION SPF 30	Fonts: Source Serif Pro, Karla Reg., Karla Bold	
	Process: Carton - 50 mL / 1.7 U.S. Fl oz	NOTES: US VERSION  PMS 7693 C  Custom match Metallic PMS 10208 C  Holographic Foil	
	Part Number: 083-50132-000		
	Colors Used: CMYK + 1 Spot color		
Release Date: 08/27/21	Finishes: Matte + UV Spot Gloss		
Vendor: Westrock	Substrate:		





Customer: **H2O + Beauty**

Project: **21IN0070**

CAD File: **21IN0070.01**

Cust. Item No.:

Description: **FRT w/feet**

Blank Size: **9+9/32 x 6+11/32**

Designer: **Philip Miller**

Sales Rep: **Julie Eaton**

Board: **.018 PrintKote®**

Grain Dir: **Horizontal**

View: **Outside**


Date: **Mar 16, 2021**

Last Mod.: **Mar 16, 2021**

Size: **1+7/16 x 1+7/16 x 5+1/32**

Rule Length: **65.9 in**
Drawing is full scale.

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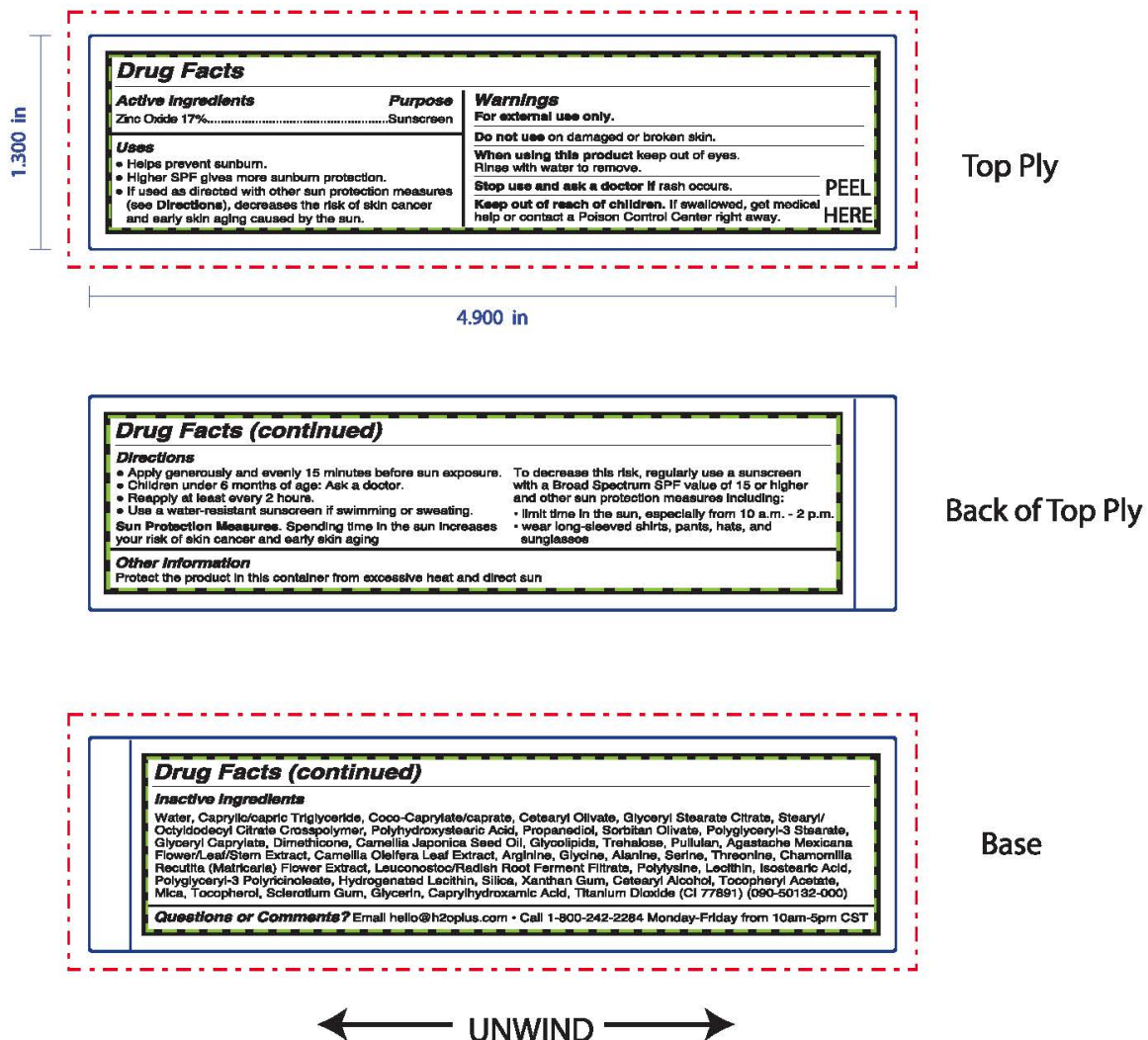
H2O+ TM	Job Name: HYDRATION SENSITIVE SUNSCREEN LOTION SPF 30 OVL	Fonts: Source Serif Pro, Karla Reg, Karla Bold
	Process: Multi-Layer Label	NOTES: US VERSION
	Colors Used:	 4-Color Process
	Finishes:	
Part Number: 060-50132-000	Substrate:	
Release Date: 08/27/21		
Vendor: Master Tape Printers		

TR10990

TEMPLATE # 2 7/21/21
WITH LARGER PRINT AREA ON
BACK OF TOP PLY

NOTE:
DOCUMENT RASTER EFFECTS SETTINGS
SHOULD BE SET AT 300 RESOLUTION

NOTE TO CLIENT:
If submitting
an InDesign file,
INCLUDE A HI-RES PDF Copy.



NOTE: Please do not modify template

		EMBED IMAGES OR INCLUDE LINKS
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DRAWING KEYS

OP1 is Outside Panel
IP is "Inside Panel"

Cut/Fold Lines

1/8" Bleed Lines

Text Limit Lines

OP1 Bleed Line

& OUTLINE YOUR FONTS

Some Notes to the Designer:

1. Hold all text 1/8" from Cut Marks. (Also critical graphic elements.)

2. Bleed full coverage background graphics 1/8" beyond Cut Marks.

3. PEEL HERE verbage recommended for upper right corner of OP1.

4. If OP1 has full coverage graphics, bleed 1/16" to 3/32" onto OP2.

5. This Template is provided in 2 layers. Simply turn off the text layer to use the layout only as a placed image in your document.

Die Number: NEW
Die Cut Size: 1.300"x 4.900"
Corner Radius: .016"
Hinge: .250"
Hold Down Area: .250"
Tech: akd

MOISTURIZER

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-042
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.68 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	5 mg in 100 mg
SORBITAN OLIVATE (UNII: MDL271E3GR)	1.52 mg in 100 mg
POLYGLYCERYL-3 STEARATE (UNII: 8FDA8C98S3)	1.2 mg in 100 mg
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	0.6 mg in 100 mg
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.51 mg in 100 mg
DIMETHICONE (UNII: 92RU3N3Y1O)	1 mg in 100 mg
ISOSTEARIC ACID (UNII: X33R8U0062)	0.78 mg in 100 mg
PROPANEDIOL (UNII: 5965N8W85T)	1.6 mg in 100 mg
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	0.78 mg in 100 mg
GLYCERIN (UNII: PDC6A3C0OX)	0.65 mg in 100 mg
WATER (UNII: 059QF0KO0R)	51.72 mg in 100 mg
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	5.2 mg in 100 mg
STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: PN88NW0KPK)	2 mg in 100 mg
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	1.78 mg in 100 mg
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	2.19 mg in 100 mg

LECITHIN, SUNFLOWER (UNII: 834K0W0S5G)			0.88 mg	in 100 mg
CETEARYL OLIVATE (UNII: 58B69Q84JO)			2.28 mg	in 100 mg
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)			1.12 mg	in 100 mg
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-042-02	1 in 1 CARTON	01/04/2022	
1	NDC:61354-042-01	100 mg 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 final		part352	01/04/2022	

Labeler - Oxygen Development LLC (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-042)

Revised: 1/2022

Oxygen Development LLC