

**MOISTURIZER- avobenzone cream**  
**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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**Revive Sensitif Renewal Daily Cellular Protection Broad Spectrum Spf 30 Sunscreen**

**Active ingredients**

Avobenzone 3.0%. Hosmosalate 10.0%. Octisalate 5.0%. Octocrylene 1.0%.  
Oxybenzone 5.0%

**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**

Do not use on damage or broken skin

**When using this product**

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

**Stop use and ask a doctor**

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**

For sunscreen use: apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours.

Sun protections 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 of age: Ask a doctor.

### **Other information**

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

### **Inactive ingredients**

Water, Butylene Glycol, Glyceryl Stearate, Cetearyl Alcohol, Glycerin, Potassium Cetyl Phosphate, Stearic Acid, Oligopeptide-24, Polysorbate 60, Polyester-8, Sclerotium gum, Bisabolol, Phenoxyethanol, Dimethicone, Sodium PCA, Squalane, Tocopheryl Acetate, Helianthus Annuus (Sunflower) Seed Oil, Persea Gratissima (Avocado) Oil, Allantoin, Caprylyl Glycol, Phytosterols, Chlorphenesin, Olea Europaea (Olive) Fruit Oil, Disodium EDTA, Glycolipids, Sodium Hyaluronate, Citrus Aurantium Dulcis (Orange) Oil, Zingiber Officinale (Ginger) Root Extract, Tocopherol, Citral, Linalool, Limonene.

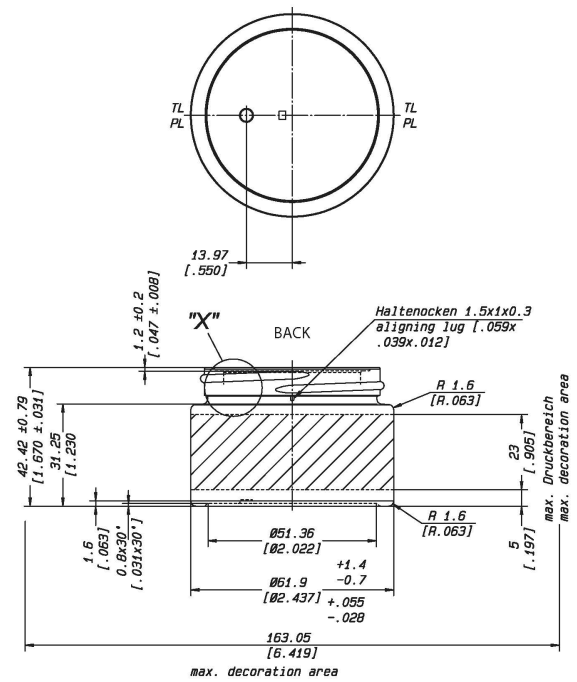
### **Package label principal display panel**

**ReVive**  
 Sensitive Renewal Cream - International  
 50 mL/1.7 FL.OZ. full size jar  
 09/24/2013  
 Heinz Glas  
 F12134\_0a  
 Component Code  
 12613274  
 Jar deco = PMS 5535 silk screen  
 Jar material = Clear  
 Lid material = Shiny Silver  
 live area  
 Scale 100%

RENDERING



FRONT



Änderung: S-18915/10-12134-0 umm., Passer entf., Stat.Nr. versetzt lt. S.Wild am 06.05.13 S.B.:0/0a:Druckbereich  
 erg. lt. S.Wild am 13.05.13 S.B.;

"ReVive" jar		Inhalt:	Qualitätsgewicht:	Maßstab
Artikel Nr. F 12134		50ml füllvoll	ca. 135g	1:1
Kunde : Gurwitch Products		62±2.0ml randvoll		10:1
Diese Zeichnung darf ohne unsere Genehmigung weder kopiert noch vervielfältigt nach dritten Personen oder Konkurrenzfirmen zugänglich gemacht werden. §§. 11, 36 ff, Gesetz über Urheberrecht				
ISO 9001 zertifiziert		HEINZGLAS		Ersetzt für: Zeichn. Nr.
2013	Tag	16  22		IS-
Bearb.	11.04.	A. Freyer		12134-0a

Package label principal display panel



SENSITIV™  
RENEWAL CREAM  
**RéVive**

Daily Cellular Protection  
Broad Spectrum SPF 30 Sunscreen

50 g / net wt. 1.7 oz.

**Drug Facts** (continued)

**Directions**

- For sunscreen use:
- apply liberally 15 minutes before sun exposure.
- use a water resistant sunscreen if swimming or sweating
- reapply 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 of age: Ask a doctor

**Other information**

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**Questions or comments?** Call 1-866-986-7083, M – F 9am – 5pm CST.



**Drug Facts**

**Active ingredients**

Azobenzene 3.0%  
Homosalate 10.0%  
Octisalate 5.0%  
Octocrylene 1.0%  
Oxybenzone 5.0%

**Purpose**

Sunscreen  
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**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.

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**MOISTURIZER**

avobenzone cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61354-041
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1 g in 100 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	1.2 g in 100 g
<b>SQUALANE</b> (UNII: GW89575KF9)	0.5 g in 100 g
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	1.75 g in 100 g
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	3 g in 100 g
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	1 g in 100 g
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	0.99 g in 100 g
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	0.64 g in 100 g
<b>WATER</b> (UNII: 059QF0K00R)	59.89 g in 100 g
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	1 g in 100 g
<b>BETASIZOFIRAN</b> (UNII: 2X51AD1X3T)	0.7 g in 100 g
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	0.64 g in 100 g
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	0.5 g in 100 g
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	0.5 g in 100 g
<b>POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED)</b> (UNII: T9296U138P)	0.75 g in 100 g
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	0.8 g in 100 g

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-041-02	1 in 1 CARTON	01/04/2022	
1	NDC:61354-041-01	100 g in 1 JAR; 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(61354-041)

Revised: 1/2022

Oxygen Development LLC