

**HEB SPF 50 ROSEWATER SCENTED CONTINUOUS SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene spray**

**H.E.B**

*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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**HEB SPF 50 Rosewater Scented Continuous Sunscreen Spray**

***Active Ingredients***

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 4.0%

***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**

**FLAMMABLE:**

- do not use near heat, flame or while smoking
- avoid long term storage above 104°F (40°C)

**Do not use**

- on damaged or broken skin.

**When using this product**

- keep out of eyes. Rinse with water to remove.
- do not puncture or incinerate. Contents under pressure.
- do not store at temperatures above 120°F.

**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
- hold can 4-6 inches away from body, spray evenly to ensure complete coverage
- do not spray into face. Spray into hand and apply to face.
- use in well ventilated, but not windy areas
- reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
  - children under 6 months of age: 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 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
- may stain or damage some fabrics, materials or surfaces

### ***Inactive Ingredients***

acrylates/octylacrylamide copolymer, butylene glycol, butyloctyl salicylate, caprylic/capric triglyceride, fragrance, glycerin, panthenol, saccharomyces/podophyllum peltatum ferment filtrate, SD alcohol 40-B, tocopherol.

### **Label**

PABA Free, Retinyl Palmitate Free  
& Paraben Free\*  
No Oxybenzone or Octinoxate  
Dermatologist Tested

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 4%	Sunscreen
<b>Uses</b> • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b> For external use only	
<b>Flammable:</b> • do not use near heat, flame or while smoking • avoid long term storage above 104°F (40°C)	
Do not use • on damaged or broken skin	
<b>When using this product</b> • keep out of eyes. Rinse with water to remove. • Keep away from face to avoid breathing it. • do not puncture or incinerate. Contents under pressure. • do not store at temperatures above 120° F.	
<b>Stop use and ask a doctor if</b> • rash occurs	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • spray liberally and spread evenly by hand 15 minutes before sun exposure • hold container 4-6 inches away from the skin to apply • do not spray directly into face. Spray into hands then apply to face • do not apply in windy conditions • use in a well-ventilated area • reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • children under 6 months of age: Ask a doctor • <b>Sun Protection Measures.</b> 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	
<b>Other information</b> • protect the product in this container from excessive heat and direct sun • may stain or damage some fabrics, materials or surfaces	
<b>Inactive ingredients</b> acrylates/octylacrylamide copolymer, butylene glycol, butylacetyl salicylate, caprylic/capric triglyceride, fragrance, glycerin, panthenol, saccharomyces/iodophyllum pollatum ferment filtrate, SD alcohol 40-B, tocopherol	
<b>Questions or Comments?</b> Call toll free 1-800-527-7731	

\*NO PARABENS SEPARATELY ADDED TO PRESERVE THIS PRODUCT

MADE WITH PRIDE AND  
CARE FOR H-E-B®,  
SAN ANTONIO, TEXAS 78204



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18355-0192



**ROSEWATER**  
**50**  
**ROSEWATER**  
**SCENTED**

Water Resistant  
(80 MINUTES)

Contains Vitamins B5 & E

Hypoallergenic

UVA/UVB Protection

**BROAD SPECTRUM SPF 50**  
**SCENTED SUNSCREEN**



NET WT.  
5.5 OZ (156 g)

## HEB SPF 50 ROSEWATER SCENTED CONTINUOUS SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37808-125
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g

<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	40 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW)</b> (UNII: JU3XHR8VWK)	
<b>.ALPHA.-TOCOPHEROL, DL-</b> (UNII: 7QWA1RIO01)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>PODOPHYLLUM</b> (UNII: 2S713A4VP3)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-125-37	156 g in 1 CAN; Type 0: Not a Combination Product	01/25/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	01/25/2023	

**Labeler - H.E.B (007924756)**

Revised: 3/2023

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