

HEB SPF 50 BIRTHDAY CAKE SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene lotion
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.

HEB SPF 50 Birthday Cake Sunscreen Lotion

Active Ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 4.5%, Octocrylene 8.0%

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

- 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
 - 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

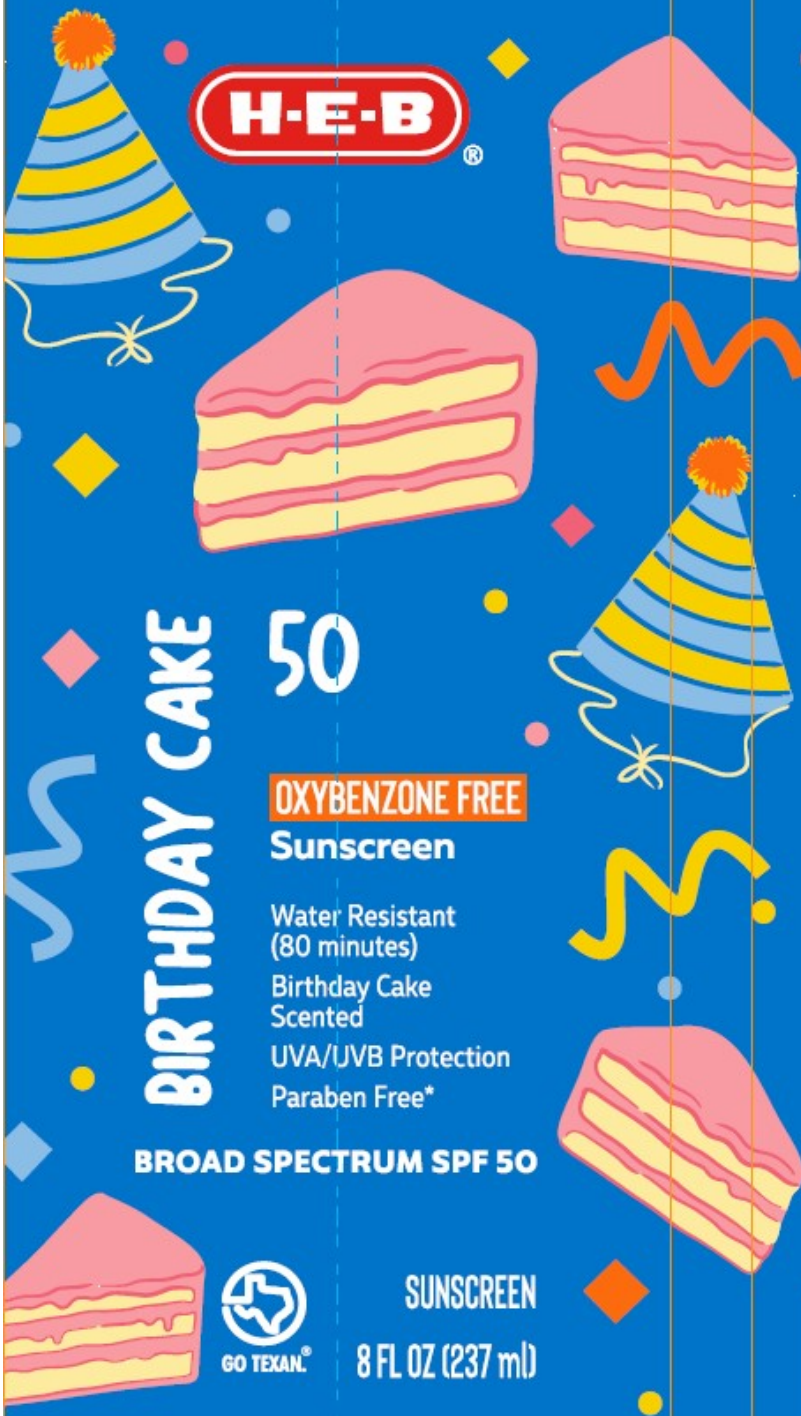
- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

Inactive Ingredient(s)

water, polyester-7, neopentyl glycol diheptanoate, glycerin, cetearyl olivate, styrene/acrylates copolymer, sorbitan olivate, aluminum starch octenylsuccinate, olive oil polyglyceryl-6 esters, saccharomyces/podophyllum peltatum ferment filtrate, butylene glycol, silica, phenoxyethanol, isododecane, sodium stearyl lactylate, cetearyl alcohol, cetyl palmitate, sorbitan palmitate, ethylhexylglycerin, acrylates/C10-30 alkyl acrylate crosspolymer, tocopherol (vitamin E), potassium hydroxide, sodium ascorbyl phosphate, fragrance.

Label

PABA Free & Retinyl Palmitate Free
Dermatologist Tested • Hypoallergenic



BIRTHDAY CAKE
50
SUNSCREEN

OXYBENZONE FREE

Sunscreen

- Water Resistant (80 minutes)
- Birthday Cake Scented
- UVA/UVB Protection
- Paraben Free*

BROAD SPECTRUM SPF 50



SUNSCREEN
8 FL OZ (237 ml)

Drug Facts	
Active ingredients	Purpose
Avobenzone 3% Homosalate 10% Octisalate 4.5% Octocrylene 8%	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.	
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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 water, polyester-7, neopentyl glycol diheptanoate, glycerin, cetearyl olivate, styrene/acrylates copolymer, sorbitan olivate, aluminum starch octenylsuccinate, olive oil polyglyceryl-6 esters, saccharomyces/podochyllum/pollitatum ferment filtrate, butylene glycol, silica, phenoxethanol, isododecane, sodium stearoyl lactylate, cetearyl alcohol, cetyl palmitate, sorbitan palmitate, ethylhexylglycerin, acrylates/C10-30 alkyl acrylate crosspolymer, tocopherol (vitamin E), potassium hydroxide, sodium ascorbyl phosphate, fragrance.	
Questions or comments? 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

12386 - 2201



HEB SPF 50 BIRTHDAY CAKE SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-074
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
POLYESTER-7 (UNII: 0841698D2F)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
ISODODECANE (UNII: A8289P68Y2)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PODOPHYLLUM (UNII: 2S713A4VP3)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
OLIVE OIL POLYGLYCERYL-6 ESTERS (UNII: 4KDO9AFM9I)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-074-12	237 mL in 1 TUBE; Type 0: Not a Combination Product	03/22/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	03/22/2021	

