

**BABY GENTLE SUNSCREEN SPF 50- avobenzone - 3.0% homosalate - 13.0% octisalate - 5.0% octocrylene - 7.0% oxybenzone 4% lotion**

**TopCo**

*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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**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3.0%.....	Sunscreen
Homosalate 13.0%.....	Sunscreen
Octisalate 5.0%.....	Sunscreen
Octocrylene 7.0%.....	Sunscreen
Oxybenzone 4.0%.....	Sunscreen

**Uses** • helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 80 minutes of activity in the water or sweating • provides high protection against sunburn

**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 product is 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
- **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 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-sleeve shirts, pants, hats, and sunglasses
  - children under 6 months: Ask a doctor

**Other information** • protect the product in this container from excessive heat and direct sun • may stain fabrics

**Inactive ingredients \**

Aluminum Starch

Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone,

Disodium EDTA, Fragrance, Methylparaben, Polyglyceryl-3 Distearate, Propylparaben, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

Questions? 1-888-423-0139



**TopCare<sup>®</sup> baby**

**GENTLE Sunscreen Lotion**

Water Resistant (80 minutes)  
UVA / UVB Protection  
With Vitamin E

**Broad Spectrum SPF 50**

8 FL OZ (237 mL)

**Drug Facts**

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Homosalate 13%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7%	Sunscreen
Oxybenzone 4%	Sunscreen

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**Directions** • Apply liberally 15 minutes before sun exposure and as needed. • Reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • 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** • protect the product in this container from excessive heat and direct sun • may stain fabrics.

**Inactive ingredients** Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Fragrance, Methylparaben, Polyglyceryl-3 Distearate, Propylparaben, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water.

**Questions?** 1-888-423-0139

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**BABY GENTLE SUNSCREEN SPF 50**

avobenzone - 3.0% homosalate - 13.0% octisalate - 5.0% octocrylene - 7.0% oxybenzone 4% lotion

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-870
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Avobenzon</b> (UNII: G63QQF2NOX) (AVOBENZON - UNII:G63QQF2NOX)	Avobenzon	3 g in 100 mL
<b>Homosalat</b> (UNII: V06SV4M95S) (HOMOSALAT - UNII:V06SV4M95S)	Homosalat	13 g in 100 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	5 g in 100 mL
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	7 g in 100 mL
<b>Oxybenzon</b> (UNII: 95OOS7VE0Y) (OXYBENZON - UNII:95OOS7VE0Y)	Oxybenzon	4 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>Aluminum Starch Octenylsuccinate</b> (UNII: I9PJ0O6294)	
<b>Benzyl Alcohol</b> (UNII: LKG8494WBH)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)</b> (UNII: Z135WT9208)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>Methylparaben</b> (UNII: A2I8C7HI9T)	
<b>Polyglyceryl-3 Distearate</b> (UNII: ZIILK470XV)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>Sorbitan Isostearate</b> (UNII: 01S2G2C1E4)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>Tocopherol</b> (UNII: R0ZB2556P8)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>VINYLPYRROLIDONE/EICOSENE COPOLYMER</b> (UNII: 035MV9S1C3)	
<b>Water</b> (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-870-06	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/21/2016	

**Labeler** - TopCo (006935977)**Registrant** - Product Quest Mfg. (927768135)**Establishment**

Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(36800-870) , label(36800-870)

