

COTZ BABY- zinc oxide cream
Fallien Cosmeceuticals, LTD

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.

DRUG FACTS

Active Ingredients:

Zinc Oxide 20%

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.

Stop use and ask a doctor if rash occurs.

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

Keep out of the 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 40 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every two hours
- Children under 6 months: 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

Inactive Ingredients:

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl

Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipoly-hydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexydecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

Other Information:

- Protect this product from excessive heat and direct sun.
- May stain some fabrics.

Manufactured Exclusively For:

CoTZ® Skincare
Norristown, PA 19403
www.cotzskincare.com

Principal Display Panel – CoTZ Baby Tube Label

CoTZ®

the HEALTHIER
SUNSCREEN®

Baby

Non-Tinted

SPF

40

Soothing & Gentle

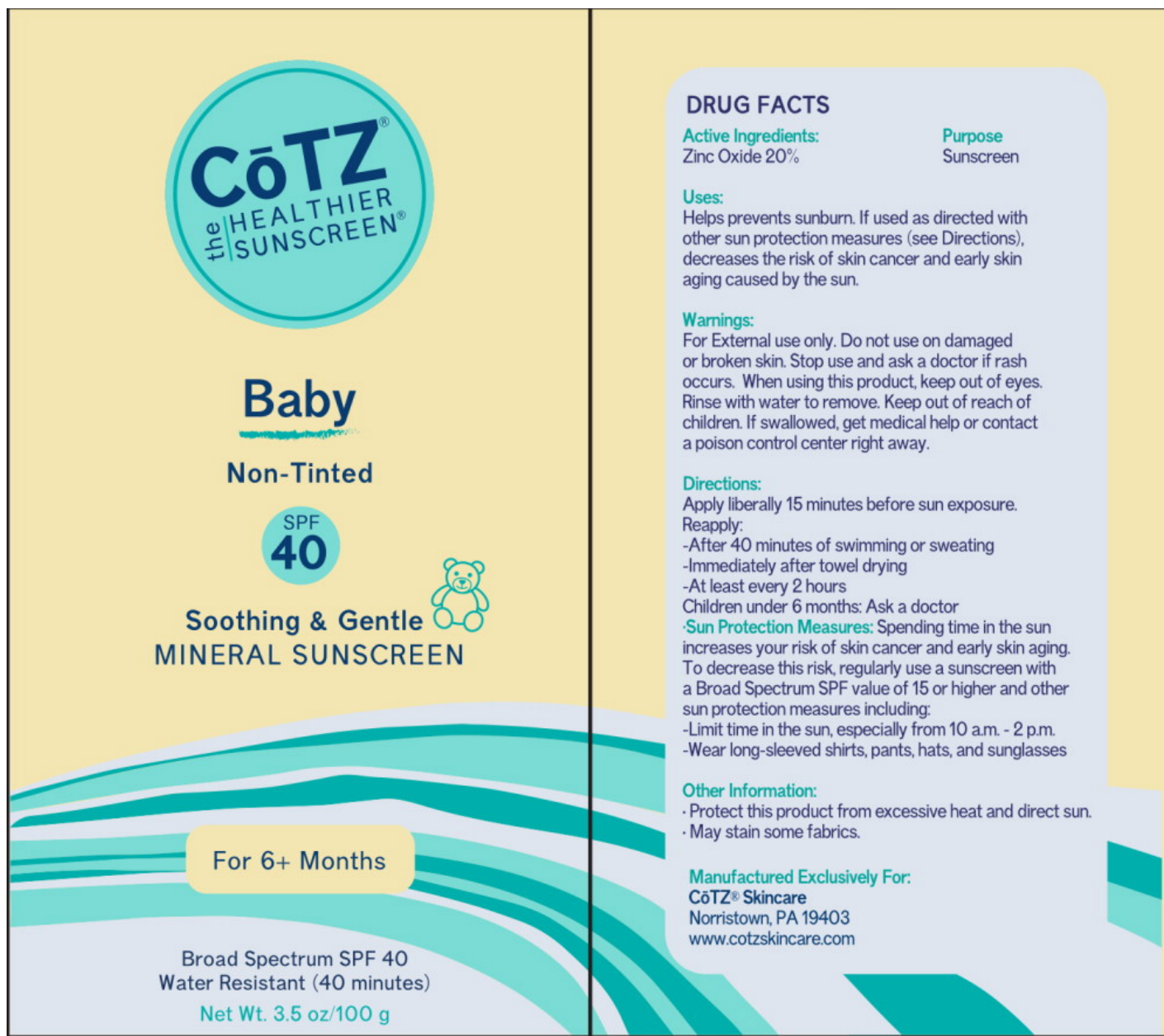
MINERAL SUNSCREEN

For 6+ Months

Broad Spectrum SPF 40

Water Resistant (40 minutes)

Net Wt. 3.5 oz/100 g



Principal Display Panel – CoTZ Baby Carton Label

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CōTZ[®] Skincare
Norristown, PA 19403

www.cotzskincare.com

CōTZ[®] The Healthier Sunscreen works by reflecting harmful UVA-UVB rays before they can penetrate the skin.



MINERAL SUNSCREEN

100% FREE OF:

Chemical Sunscreens,
Oils, Preservatives, Fragrances,
Parabens, Gluten, Phthalates

CōTZ[®] Baby SPF 40 Mineral Sunscreen is extra gentle to protect delicate skin from damaging UV rays. 20% Zinc Oxide is Pediatric Dermatologist recommended to protect children's sensitive skin. Soft, sheer cream is soothing and easy to apply.
Non-tinted.

- Extra Gentle
- Zinc Oxide: #1 rated UV protection
- Water resistant (40 minutes)



Baby

Non-Tinted

SPF
40

Soothing & Gentle
MINERAL SUNSCREEN

For 6+ Months

Broad Spectrum SPF 40
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Net Wt. 3.5 oz/100 g



REEF FRIENDLY



WATER RESISTANT



NO ANIMAL TESTING



PRESERVATIVE FREE



3 58892 61801 9

COTZ BABY

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-618
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
DIMETHICONE 100 (UNII: RO266O364U)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARYL DIMETHICONE (400 MPAS AT 50C) (UNII: R327X197HY)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-618-01	1 in 1 CARTON	01/02/2019	
1		100 g 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 not final	part352	01/02/2019	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-618)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-618) , PACK(58892-618)

Revised: 1/2021

Fallien Cosmeceuticals, LTD