

**BILBOA KIDS SUNSCREEN SPF 50 PLUS - homosalate, octisalate, oxybenzone, zinc oxide lotion**

**Cadey S.r.l.**

*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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**Bilboa Kids Sunscreen Lotion SPF 50 Plus**

Active Ingredients	Purpose
Homosalate 13%, Octisalate 3%, Oxybenzone 6%, Zinc Oxide 11.52%	Sunscreen

**Uses**

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Provides high protection against sunburn
- Retains SPF after 40 minutes of activity in the water

**Warnings**

For external use only

UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen

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

Stop use and ask a doctor if - rash or irritation develops and lasts

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away

**Directions**

- Apply generously and evenly before sun exposure and as needed
- Children under 6 months of age: ask a doctor
- Reapply as need or after toweling drying, swimming, or perspiring

Inactive ingredients Water, Dicaprylyl Carbonate, Butyloctyl Salicylate, Glycerin, Polyglyceryl-2 Dipolyhydroxystearate, Polyglyceryl-3 Diisostearate, Hydrogenated Castor Oil, Stearyl/Octadodecyl Citrate Crosspolymer, Potassium Olivoyl Pca, Shorea Stenoptera Seed Butter, Dimethicone, Phenoxyethanol, Magnesium Sulfate, Sodium Chloride, Synthetic Beeswax, Triethoxycaprylylsilane, Fragrance, Ethylhexylglycerin, Stearalkonium Hectorite, Tropolone, Propylene Carbonate, Benzyl Salicylate, Limonene, Linalool, Geraniol, Butylphenyl Methylpropional, Citronellol, Coumarin, Hexyl Cinnamal, Alpha-Isomethyl Ionone, Hydroxyisoheptyl 3-Cyclohexene Carboxaldehyde.

Questions? visit [www.cadeyusa.com](http://www.cadeyusa.com)

Bilboa Kids Sunscreen Lotion Spf 50+ comes from Cadey's Italian experience and is specifically developed to protect kids' delicate skin. Provides your child with broad spectrum UVA/UVB protection and water-resistant. Dermatologically tested - Aminobenzoic acid (PABA) - free

Made In Italy

Manufactured for Cadey Srl

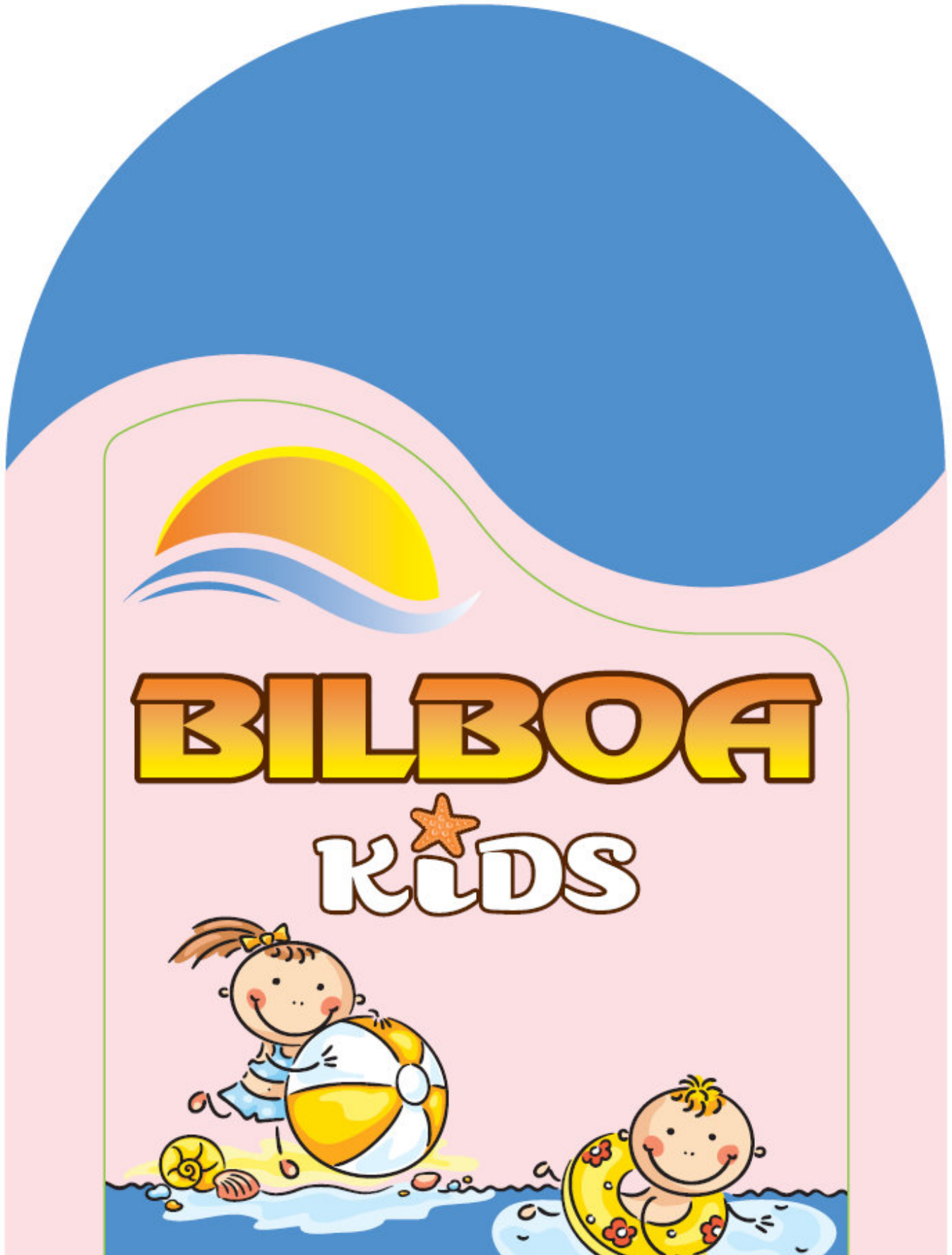
Distributed by RBY LLC

5816 Avian Place

Concord NC 28025

cadey

BILBOA KIDS 6 months of age and up Sunscreen Lotion Broad spectrum UVA/UVB protection  
Moisturizing and soothing formula Protects delicate skin against sunburn 50+ SPF Water-resistant  
6.76 fl oz (200 ML) Made In Italy Manufactured for Cadey Srl Distributed by RBY LLC 5816 Avian  
Place Concord NC 28025 cadey 8 51055 00306 1



6 months of age and up



# Sunscreen Lotion

**Broad spectrum UVA/UVB protection**

Moisturizing and soothing formula  
Protects delicate skin against sunburn  
Water-resistant



**6.76 fl oz (200 ML)**

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### Drug Facts

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**Questions?** visit [www.bilboacapri.com](http://www.bilboacapri.com)

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<b>BILBOA KIDS SUNSCREEN SPF 50 PLUS</b>			
homosalate, octisalate, oxybenzone, zinc oxide lotion			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76070-130
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 mL in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 mL in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 mL in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	11.52 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TROPOLONE (UNII: 7L6DL16P1T)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
LINALOOL, DL- (UNII: D81QY6I88E)	
GERANIOL (UNII: L837108USY)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
COUMARIN (UNII: A4VZ22K1WT)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76070-130-06	1 in 1 PACKAGE		
1		200 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/08/2011	

**Labeler** - Cadey S.r.l. (428414261)

### Establishment

Name	Address	ID/FEI	Business Operations
Safosa S.p.A.		429518632	manufacture

