

BIRDS GARDEN LIP BALM DARK EYED JUNCO SPF 30- octinoxate, octocrylene, octisalate, and oxybenzone stick

GANZ U.S.A., LLC

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.

LIP BALM

ALOE & VITAMIN E

UVA / UVB PROTECTION

SPF 30

INGREDIENTS

MEDICINAL INGREDIENTS (W/W)

Octinoxate 7.5%, Octocrylene 7.0%, Octyl Salicylate 5.0%, Oxybenzone 5.0%.

NON-MEDICINAL INGREDIENTS

Petrolatum, Isopropyl Myristate, Paraffin, Candelilla Cera, Synthetic Beeswax, Polyethylene, Cetyl Alcohol, Lanolin, Isopropyl Lanolate, Oleyl Alcohol, Octyldodecanol, Phenyl Trimethicone, Flavor, Tocopheryl Acetate, Aloe Barbadensis Leaf Extract, Glycine Soja (Soybean) Oil, Titanium Dioxide, Methylparaben, Propylparaben, Silica, Saccharin, DEA-Oleth-3 Phosphate.

CONTAINS

Soy

Store between 15°C and 30°C

PRECAUTIONS

Avoid eye contact. For external use only.

Keep out of reach of children.

PRINCIPAL DISPLAY PANEL - 4 g Carton

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75862-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

PARAFFIN (UNII: I9O0E3H2ZE)
CANDELILLA WAX (UNII: WL0328HX19)
LOW DENSITY POLYETHYLENE (UNII: J245LN42A1)
CETYL ALCOHOL (UNII: 936JST6JCN)
LANOLIN (UNII: 7EV65EAW6H)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
OCTYLDODECANOL (UNII: 461N1O614Y)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SOYBEAN OIL (UNII: 241ATL177A)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SACCHARIN (UNII: FST467XS7D)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75862-011-50	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2011	

Labeler - GANZ U.S.A., LLC (798785242)