

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

**Norwood Packaging 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.*

-----  
**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**

**LIP BALM**

**ALOE & VITAMIN E**

**UVA / UVB PROTECTION**

**SPF 30**



## BIRDS GARDEN LIP BALM DARK EYED JUNCO SPF 30

octinoxate, octocrylene, octisalate, and oxybenzone stick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55143-011
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)	

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55143-011-50	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** - Norwood Packaging Ltd. (243693926)