

BULLET LINE- lip balm spf 15 stick
Raining Rose, Inc

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.

Bullet Line

Drug Facts

Active ingredient

Purpose

Uses

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

Directions

• Apply liberally 15 minutes before sun exposure • Use a water-resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months of age: **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 protection measures including: • limit time in the sun, especially from 10a.m. - 2p.m. • wear long sleeved shirts, pants, hat, and sunglasses.

Inactive ingredients: Mineral oil, Beeswax, Petrolatum, Paraffin

Ethylhexyl Palmitate, Ceresin, Cetyl Alcohol, Tocopheryl Acetate, Propylparaben, Aloe Juice.

Other Information

Protect this product from excessive heat and direct sun.

Package Labeling

Twist Cap to Break Seal

☐ *Broad Spectrum SPF 15 Sunscreen*

Mfg. for Bullet, Hialeah, FL 33013

Made in the USA

Net Wt. .15 oz.

No-flavor

Twist Cap to Break Seal

FEEL HERE FOR DRUG FACTS Mfg. for Bullseye, Hollywood, FL 33013
Broad Spectrum SPF 15 Sunscreen Made in the USA
Net Wt. .15 oz.

Drug Facts

Active Ingredients:	Purpose
Avobenzone 2.0%	Sunscreen
Octinoxate 6.5%	
Octisalate 5.0%	
Octocrylene 1.5%	



Twist Cap to Break Seal - No Flavor

Drug Facts (continued)

Uses • Helps prevent sunburn

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

Directions • apply liberally 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months of age: 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 10a.m. - 2p.m. • wear long sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients: Mineral Oil, Beeswax, Petrolatum, Paraffin, Ethylhexyl Palmitate, Ceresin, Cetyl Alcohol, Tocopheryl Acetate, Propylparaben, Aloe Juice.

Other Information

Protect this product from excessive heat and direct sun.

Berry

▼ PEEL HERE FOR DRUG FACTS Mfg. for Bulet, Hialeah, FL 33013
Broad Spectrum SPF 15 Sunscreen Made in the USA
Net Wt. 1.5 oz.

Drug Facts

Active Ingredients:	Purpose
Avobenzone 2.0%	Sunscreen
Octinoxate 6.5%	
Octisalate 5.0%	
Octocrylene 1.5%	



Drug Facts (continued)

Uses • Helps prevent sunburn

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

Directions • apply liberally 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months of age: 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 10am - 2pm • wear long sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients: Mineral Oil, Beeswax, Petrolatum, Pectin, Flax, Ethylhexyl Palmitate, Ceresin, Cetyl Alcohol, Tocopherol Acetate, Propylparaben, Aloe Juice.

Other Information

Protect this product from excessive heat and direct sun.

Twist Cap to Break Seal - Berry

Cherry

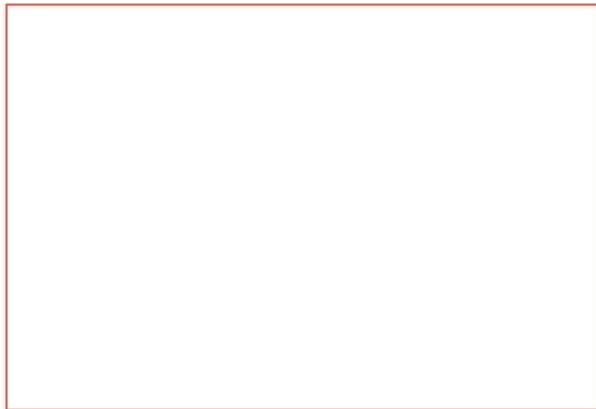
PEEL HERE FOR DRUG FACTS Mfg. for Bullet, Hialeah, FL 33013

Made in the USA

Broad Spectrum SPF 15 Sunscreen Net Wt. .15 oz.

Drug Facts

Active Ingredients:	Purpose
Avobenzone 2.0%	}..... Sunscreen
Octinoxate 6.5%	
Octisalate 5.0%	
Octocrylene 1.5%	



Twist Cap to Break Seal - Cherry

Drug Facts (continued)

Uses • Helps prevent sunburn

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

Directions • apply liberally 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months of age: 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 10a.m. - 2p.m. • wear long sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients: Mineral Oil, Beeswax, Petrolatum, Paraffin, Flavor Ethylhexyl Palmitate, Ceresin, Cetyl Alcohol, Tocopheryl Acetate, Propylparaben, Aloe Juice.

Other Information

Protect this product from excessive heat and direct sun.

Mint

PEEL HERE FOR DRUG FACTS Mfg. for Bulletin, Hialeah, FL 33013
Broad Spectrum SPF 15 Sunscreen Made in the USA
Net Wt. .15 oz.

Drug Facts

Active Ingredients:	Purpose
Avobenzone 2.0%	Sunscreen
Octinoxate 6.5%	
Octisalate 5.0%	
Octocrylene 1.5%	



Drug Facts (continued)

Uses • Helps prevent sunburn

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

Directions • apply liberally 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months of age: 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 10a.m. - 2p.m. • wear long sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients: Mineral Oil, Beeswax, Petrolatum, Paraffin, Flavor Ethylhexyl Palmitate, Ceresin, Cetyl Alcohol, Tocopheryl Acetate, Propylparaben, Aloe Juice.

Other Information

Protect this product from excessive heat and direct sun.

Twist Cap to Break Seal - Mint

Strawberry

▼ PEEL HERE FOR DRUG FACTS Mfg. for Bullet, Hialeah, FL 33013
Made in the USA
Broad Spectrum SPF 15 Sunscreen Net Wt. .15 oz.

Drug Facts

Active Ingredients:	Purpose
Avobenzone 2.0%	}..... Sunscreen
Octinoxate 6.5%	
Octisalate 5.0%	
Octocrylene 1.5%	



Twist Cap to Break Seal - Strawberry

Drug Facts (continued)

Uses • Helps prevent sunburn

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

Directions • apply liberally 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months of age: 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 10a.m.-2p.m. • wear long sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients: Mineral Oil, Beeswax, Petrolatum, Paraffin, Flavor Ethylhexyl Palmitate, Ceresin, Cetyl Alcohol, Tocopheryl Acetate, Propylparaben, Aloe Juice.

Other Information

Protect this product from excessive heat and direct sun.

Tropical

▼ PEEL HERE FOR DRUG FACTS Mfg. for Bulletin, Hialeah, FL 33013
Broad Spectrum SPF 15 Sunscreen Made in the USA
Net Wt. .15 oz.

Drug Facts

Active Ingredients:	Purpose
Avobenzone 2.0%	}..... Sunscreen
Octinoxate 6.5%	
Octisalate 5.0%	
Octocrylene 1.5%	



Drug Facts (continued)

Uses • Helps prevent sunburn

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

Directions • apply liberally 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months of age: Ask a doctor
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Inactive Ingredients: Mineral Oil, Beeswax, Petrolatum, Paraffin, Flavor Ethylhexyl Palmitate, Ceresin, Cetyl Alcohol, Tocopheryl Acetate, Propylparaben, Aloe Juice.

Other Information

Protect this product from excessive heat and direct sun.

Twist Cap to Break Seal - Tropical

Vanilla

PEEL HERE FOR DRUG FACTS Mfg. for Bullet, Hialeah, FL 33013
 Made in the USA
Broad Spectrum SPF 15 Sunscreen Net Wt. .15 oz.

Drug Facts

Active Ingredients:	Purpose
Avobenzone 2.0%	Sunscreen
Octinoxate 6.5%	
Octisalate 5.0%	
Octocrylene 1.5%	

Drug Facts (continued)

Uses • Helps prevent sunburn

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

Directions • apply liberally 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months of age: 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 10a.m.-2p.m. • wear long sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients: Mineral Oil, Beeswax, Petrolatum, Paraffin, Flavor Ethylhexyl Palmitate, Ceresin, Cetyl Alcohol, Tocopheryl Acetate, Propylparaben, Aloe Juice.

Other Information

Protect this product from excessive heat and direct sun.

Twist Cap to Break Seal -Vanilla

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BULLET LINE

lip balm spf 15 stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-1006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.0 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5.0 mg in 1 g

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	1.5 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
MINERAL OIL (UNII: T5L8T28FGP)				
WHITE WAX (UNII: 7G1J5DA97F)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
PETROLATUM (UNII: 4T6H12BN9U)				
PARAFFIN (UNII: I9O0E3H2ZE)				
ETHYLHEXYL PALMITATE (UNII: 2865993309)				
CERESIN (UNII: Q1LS2UJO3A)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-1006-1	4 g in 1 TUBE; Type 0: Not a Combination Product	02/18/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	02/18/2020		

BULLET LINE			
lip balm spf 15 stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-1007
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	2.0 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	6.5 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		OCTISALATE	5.0 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	1.5 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength

MINERAL OIL (UNII: T5L8T28FGP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-1007-1	4 g in 1 TUBE; Type 0: Not a Combination Product	02/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/18/2020	

BULLET LINE

lip balm spf 15 stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-1008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.0 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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MINERAL OIL (UNII: T5L8T28FGP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-1008-1	4 g in 1 TUBE; Type 0: Not a Combination Product	02/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/18/2020	

BULLET LINE

lip balm spf 15 stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-1009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.0 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJ03A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-1009-1	4 g in 1 TUBE; Type 0; Not a Combination Product	02/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/18/2020	

BULLET LINE

lip balm spf 15 stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-1010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.0 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-1010-1	4 g in 1 TUBE; Type 0: Not a Combination Product	02/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/18/2020	

BULLET LINE

lip balm spf 15 stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-1011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.0 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5.0 mg in 1 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	TROPICAL FRUIT PUNCH (TROPICAL)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-1011-1	4 g in 1 TUBE; Type 0: Not a Combination Product	02/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/18/2020	

BULLET LINE

lip balm spf 15 stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-1012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.0 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-1012-1	4 g in 1 TUBE; Type 0: Not a Combination Product	02/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/18/2020	

Labeler - Raining Rose, Inc (083819404)

Revised: 5/2020

Raining Rose, Inc