

**HEAD TO TOE KIT- avobenzzone, homosalate, octisalate, octocrylene
System Beauty, 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.

Head-to-Toe Kit

Play Everyday Sunscreen SPF 50 with Sunflower extract Active ingredients

Active Ingredients Purpose

Avobenzzone 3% Sunscreen

Homosalate 10% Sunscreen

Octisalate 5% Sunscreen

Octocrylene 7.5% Sunscreen

Defense Refresh (Re)setting Mist SPF 40

ACTIVE INGREDIENT PURPOSE

Avobenzzone 2.8%.....Sunscreen

Homosalate 9.8%.....Sunscreen

Octisalate 4.9%.....Sunscreen

Octocrylene 9.5%.....Sunscreen

Unseen Sunscreen SPF 40 active ingredients

Active Ingredients Purpose

Avobenzzone 3% Sunscreen

Homosalate 8% Sunscreen

Octocrylene 4% Sunscreen

Octisalate 5% 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

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

Stop use and ask a doctor if rash occurs

Warnings

For External use only

Do not use on damaged or broken skin

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

Play Everyday Lotion SPF 50 with Sunflower Extract Directions

Directions

- Apply generously and evenly 15 minutes before sun exposure
- Reapply:after 80 minutes of swimming or sweating

immediately after towel drying

at least every 2 hours

- **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 broad spectrum SPF 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
- Children under 6 months: Ask a doctor

Directions

- Apply generously and evenly 15 minutes before sun exposure
- Reapply:after 40 minutes of swimming or sweating

immediately after towel drying

at least every 2 hours

- **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 broad spectrum SPF 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
- Children under 6 months: Ask a doctor

Unseen Sunscreen SPF 40 Inactive Ingredients

Inactive Ingredients

Isododecane, Dimethicone Crosspolymer, Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer, Polymethylsilsesquioxane, Isohexadecane, Dicrapyl Carbonate, Meadowfoam Estolide, Caprylic/Capric Triglyceride, Polyester-7, Neopentyl Glycol Diheptanoate, Lithothamnion Calcareum Extract, Butyrospermum Parkii (Shea) Butter, Jojoba Esters, Mannitol, Boswellia Serrata Resin Extract, Lecithin, Microcrystalline Cellulose, Diatomaceous Earth, Zinc Sulfate, Silica, Tocopherol

Defense Refresh (Re)setting Mist SPF 40 Inactive Ingredients

Inactive Ingredients

Alcohol Denat., Bisabolol, Brassica Campestris/Aleurites Fordi Oil Copolymer, Butyloctyl Salicylate, Caprylic/Capric Triglyceride, Capryloyl Glycerin/Sebacic Acid Copolymer, Dicaprylyl Carbonate, Diethylhexyl Syringylidenemalonate, Diheptyl Succinate, Diisooctyl Succinate, Ethyl Ferulate, Isododecane, Lauroyl Lysine, Mentha Piperita (Peppermint) Oil, Mentha Viridis (Spearmint) Leaf Oil, Nylon-12, PVP, Rosmarinus Officinalis (Rosemary) Leaf Oil, Silica Silylate

Play Everyday Sunscreen SPF 50 with sunflower Inactive ingredients

Inactive ingredients

Water, Acrylates Copolymer, Diisopropyl Sebacate, Glycerin, Isodecyl Neopentanoate, Isododecane, Lauryl Lactate, Cetyl Alcohol, Potassium Cetyl Phosphate, Brassica Campestris/Aleurites Fordi Copolymer, Oryza Sativa (Rice) Bran Extract, Cetearyl Oliviate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Hydroxyacetophenone, Sorbitan Oliviate, Diethylhexyl Syringylidenemalonate, Aniba Rosaedora (Rosewood) Wood Oil, Chlorphenesin, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Limon (Lemon) Peel Oil, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Ocimum Bascilicum (Basil) Flower/Leaf Extract, Pelargonium Graveolens Flower Oil, Pogostemon Cablin Oil, Pentylene Glycol, 1,2-hexanediol, Caprylyl Glycol, Xanthan Gum, Helianthus Annuus (Sunflower) Extract, Behenic Acid, Cetyl Behenate, Isostearyl Isostearate, Trisodium Ethylenediamene Disuccinate, Tocopherol, Allantoin, Rosmarinus Officinalis (Rosemary) Leaf Extract, Caprylic/Capric Triglyceride, Panthenol, Pentasodium Triphosphate, Citric Acid

Supergoop!

SPF FROM HEAD TO TOE

Three SPF essentials for happy, hydrated, and protected skin

Unseen Sunscreen SPF 40

0.5 fl.oz./ 15 ml

Defense Refresh (Re)setting Mist SPF 40

1 fl. oz. / 30 ml

Play Everyday Lotion SPF 50 with Sunflower Extract

1 fl. oz. / 30 ml

RECTO PRINT AREA

Supergoop!

SPF FROM HEAD-TO-TOE

Three SPF essentials for happy, hydrated, and protected skin.

SPF is the #1 thing you can do for your skin, so we put it first in all we do.

Defense Refresh (Re)setting Mist SPF 40 1 fl. oz. / 30 ml
 Defense Sunscreen SPF 40 0.5 fl. oz. / 15 ml
 Defense Everday Lotion SPF 50 with Sunflower Extract 1 fl. oz. / 30 ml

Drug Facts	Drug Facts	Drug Facts
Active ingredients Avobenzone 3%, Homosalate 8%, Octisalate 5%, Octocrylene 5%	Purpose Sunscreens	Purpose Sunscreens
Uses • Helps prevent sunburn • Used as directed with other sun protection measures (see Directions). • 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	Warnings For external use only
Do not use on damaged or broken skin When using this product keep out of eyes. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs. Stop use and ask a doctor if rash occurs. Rinse with water to remove.	Directions • Apply generously and evenly 15 minutes before sun exposure • Reapply after 40 minutes of swimming or sweating, immediately after towel drying, at least every 2 hours • 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: wearing long-sleeved shirts, pants, hats, and sunglasses	Directions • Apply generously and evenly 15 minutes before sun exposure • Reapply after 40 minutes of swimming or sweating, immediately after towel drying, at least every 2 hours • 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: wearing long-sleeved shirts, pants, hats, and sunglasses

Drug Facts	Drug Facts	Drug Facts
Active ingredients Avobenzone 2.9%, Homosalate 8.9%, Octisalate 4.9%, Octocrylene 9.5%	Purpose Sunscreens	Purpose Sunscreens
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Other Information	Other Information	Other Information
Protect the product in the container from excessive heat and direct sun. Questions or Comments? Contact our Sun Specialists 877-564-7330	Protect the product in the container from excessive heat and direct sun. Questions or Comments? Contact our Sun Specialists 877-564-7330	Protect the product in the container from excessive heat and direct sun. Questions or Comments? Contact our Sun Specialists 877-564-7330
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FORMULATED WITHOUT PARABENS, SYNTHETIC FRAGRANCE, OXYBENZONE, OR OCTINOXATE. REEF SAFE.
Non-Irritating Allergy-Tested.
Supergoop!
 San Antonio, TX 78215
 Distributed by Taylor James, LLC
Supergoop!
 San Antonio, TX 78215
 Contact our Sun Specialists 877-564-7330

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1.5cm

2.5cm

13.5cm



HEAD TO TOE KIT

avobenzone, homosalate, octisalate, octocrylene kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82384-0001
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82384-0001-1	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	03/20/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	0 TUBE	1 mL
Part 2	0 BOTTLE, SPRAY	1 mL
Part 3	0 TUBE	1 mL

Part 1 of 3

UNSEEN SUNSCREEN SPF 40

avobenzone, homosalate, octisalate, octocrylene cream

Product Information

Item Code (Source)	NDC:82384-0002
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	4 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISODODECANE (UNII: A8289P68Y2)	
DIATOMACEOUS EARTH (UNII: 2RF6EJ0M85)	
ZINC SULFATE (UNII: 89DS0H96TB)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
PHYMATOLITHON CALCAREUM (UNII: 6J1M3WA0ZK)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SHEA BUTTER (UNII: K49155WL9Y)	
MANNITOL (UNII: 3OWL53L36A)	
POLYESTER-7 (UNII: 0841698D2F)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	

DIMETHICONE/BIS-ISOBUTYL PPG-20 CROSSPOLYMER (UNII: O4I3UFO6ZF)

ISOHEXADECANE (UNII: 918X1OUF1E)

TOCOPHEROL (UNII: R0ZB2556P8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82384-0002-1	15 mL in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/20/2021	

Part 2 of 3

DEFENSE REFRESH (RE)SETTING MIST SPF 40

avobenzone, homosalate, octisalate, octocrylene cream

Product Information

Item Code (Source) NDC:82384-0003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.8 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	9.8 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.9 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
ISODODECANE (UNII: A8289P68Y2)	
SPEARMINT OIL (UNII: C3M81465G5)	
LEVOMENOL (UNII: 24WE03BX2T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LAUROYL LYSINE (UNII: 113171Q70B)	

CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
ALCOHOL (UNII: 3K9958V90M)	
ETHYL FERULATE (UNII: 5B8915UELW)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
NYLON-12 (UNII: 446U8J075B)	
ROSEMARY OIL (UNII: 8LGU7VM393)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82384-0003-1	30 mL in 1 BOTTLE, SPRAY; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/20/2021	

Part 3 of 3

PLAY EVERYDAY SPF 50 WITH SUNFLOWER EXTRACT

avobenzone, homosalate, octisalate, octocrylene cream

Product Information

Item Code (Source)	NDC:82384-0004
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
POGOSTEMON CABLIN LEAF OIL (UNII: F3IN55X5PO)	

PENTYLENE GLYCOL (UNII: 50C1307PZG)
ALLANTOIN (UNII: 344S277G0Z)
LEMON OIL, COLD PRESSED (UNII: I9GRO824LL)
EUCALYPTUS OIL (UNII: 2R04ONI662)
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)
BEHENIC ACID (UNII: H390488X0A)
CETYL BEHENATE (UNII: WFM51TRO3E)
RICE BRAN (UNII: R60QEP13IC)
CETEARYL OLIVATE (UNII: 58B69Q84JO)
ROSEWOOD OIL (UNII: F2522O5L7B)
CHLORPHENESIN (UNII: I670DAL4SZ)
ROSEMARY (UNII: IJ67X351P9)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
XANTHAN GUM (UNII: TTV12P4NEE)
ISOSTEARYL ISOSTEARATE (UNII: IV0Z586Z4Y)
TOCOPHEROL (UNII: R0ZB2556P8)
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)
ISODODECANE (UNII: A8289P68Y2)
CETYL ALCOHOL (UNII: 936JST6JCN)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)
SORBITAN OLIVATE (UNII: MDL271E3GR)
PANTHENOL (UNII: WW9CM0O67Z)
LAURYL LACTATE (UNII: G5SU0BFBK7O)
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)
OCIMUM BASILICUM FLOWERING TOP (UNII: 7SAB275FP2)
WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82384-0004-1	30 mL in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part352	03/20/2021	
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/20/2021	

Labeler - System Beauty, LLC (809198398)

Revised: 12/2021

System Beauty, LLC