

SEKKISEI TREATMENT BB 00- octinoxate, zinc oxide cream
SEKKISEI TREATMENT BB 01- octinoxate, zinc oxide cream
KOSE AMERICA, 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.

Drug Facts

Active Ingredients

OCTINOXATE 7.4%

ZINC OXIDE 5.9%

Purpose

Sunscreen

Sunscreen

Use

helps prevent sunburn

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.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients

WATER/AQUA/EAU · CYCLOMETHICONE · METHYL TRIMETHICONE · ALCOHOL · GLYCERIN · ETHYLHEXYL PALMITATE · DIISOSTEARYL MALATE · PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE · DISTEARDIMONIUM HECTORITE · TRIETHYLHEXANOIN · ALPINIA SPECIOSA LEAF EXTRACT · ANGELICA ACUTILOBA ROOT EXTRACT · CARTHAMUS TINCTORIUS (SAFFLOWER) FLOWER EXTRACT · COIX LACRYMA-JOBI MA-YUEN SEED EXTRACT · MELOTHRIA HETEROPHYLLA ROOT EXTRACT · TOCOPHEROL · ACRYLATES/ETHYLHEXYL ACRYLATE/DIMETHICONE METHACRYLATE COPOLYMER · ALUMINUM HYDROXIDE · BHT · BUTYLENE GLYCOL · DIMETHICONE · DISODIUM STEAROYL GLUTAMATE · HYDROGEN DIMETHICONE · LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE · METHYL METHACRYLATE CROSSPOLYMER · PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE · PHYTOSTERYL/ISOSTERYL/CETYL/STEARYL/BEHENYL DIMER DILINOLEATE · POLYISOPRENE · POLYPROPYLENE · SILICA · SODIUM CHLORIDE · STEARALKONIUM HECTORITE · TALC · TRIETHOXYCAPRYLYLSILANE · METHYLPARABEN · FRAGRANCE (PARFUM) · MAY CONTAIN (+/-): IRON OXIDES (CI 77491) · IRON OXIDES (CI 77492) · IRON OXIDES (CI 77499) · TITANIUM DIOXIDE (CI77891)

Other information

Protect this product from excessive heat and direct sun

Principal Display Panel - 00 Carton Label

BB

SEKKISEI

TRETMET BB CREAM

Broad Spectrum SPF 37
Sunscreen

KOSE

e 26 mL NET WT. 1 OZ.

00 VERY LIGHT OCHRE

雪肌精
SEKKISEI

OPEN

**Drug Facts
(continued)**

PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE · DISTEARDIMONIUM HECTORITE · TRIETHYLHEXANOIN · ALPINA SPECIOSA LEAF EXTRACT · ANGELICA ACUTILOBA ROOT EXTRACT · CARTHAMUS TINCTORIUS (SAFFLOWER) FLOWER EXTRACT · COIX LACRYMA-JOBI MA-YUEN SEED EXTRACT · MELOTHRHA HETEROPHYLLA ROOT EXTRACT · TOCOPHEROL · ACRYLATES/ETHYLHEXYL ACRYLATE/ DIMETHICONE METHACRYLATE COPOLYMER · ALUMINUM HYDROXIDE · BHT · BUTYLENE GLYCOL · DIMETHICONE · DISODIUM STEAROYL GLUTAMATE · HYDROGEN DIMETHICONE · LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE · METHYL METHACRYLATE CROSSPOLYMER · PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE · PHYTOSTERYL/ISOSTEARYL/CETYL/ STEARYL/BEHENYL DIMER DILINOLEATE · POLYISOPRENE · POLYPROPYLENE · SILICA · SODIUM CHLORIDE · STEARALKONIUM HECTORITE · TALC · TRIETHOXYCAPRYLYLSILANE · METHYL PARABEN · FRAGRANCE (PARFUM) · MAY CONTAIN (+/-): IRON OXIDES (CI 77491) · IRON OXIDES (CI 77492) · IRON OXIDES (CI 77499) · TITANIUM DIOXIDE (CI 77891)

Other information

• Protect this product from excessive heat and direct sun

雪肌精
BB

SEKKISEI
TREATMENT BB CREAM

Broad Spectrum SPF 37
Sunscreen

KOSÉ

e 26 mL NET WT. 1 OZ.



SEKKISEI
TREATMENT BB CREAM
00

BB cream that covers skin imperfections while providing UV protection and skincare benefits. In one easy step, it provides dewy, radiant, and naturally flawless skin.

• A multi-tasking formula to hydrate, protect, prime, conceal and cover the skin.

TO USE: It is recommended to use after toning skin with lotion. Take an appropriate amount and spread evenly over face. For more coverage, lightly apply additional layers and blend into skin. Use makeup remover for removal. Close cap after each use. Store away from high temperatures.

KOSÉ Corporation
3-6-2 Nihonbashi, Tokyo
Dist. by KOSÉ America, Inc.
New York, NY 10012
MADE IN JAPAN

FEMA#000



4971710 48889 0

Drug Facts

Active ingredients Purpose
OCTINOXATE 7.4%.....Sunscreen
ZINC OXIDE 5.9%.....Sunscreen

Use • helps prevent sunburn

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.

Stop use and ask a doctor if rash occurs.

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

Directions For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive ingredients

WATER/AQUA/EAU · CYCLOMETHICONE · METHYL TRIMETHICONE · ALCOHOL · GLYCERIN · ETHYLHEXYL PALMITATE · DIISOSTEARYL MALATE



Principal Display Panel - 00 Tube Label

BB

SEKKISEI

TRETMENT BB CREAM

Broad Spectrum SPF 37
Sunscreen

KOSE

雪
肌
精

BB

SEKKISEI
TREATMENT BB CREAM

Broad Spectrum SPF 37
Sunscreen

KOSÉ



**SEKKISEI
TREATMENT BB CREAM**

00 VERY LIGHT OCHRE

ACTIVE INGREDIENTS:

OCTINOXATE 7.4% • ZINC OXIDE 5.9%

WARNING: For external use only.
Do not use on damaged or broken
skin. Stop use and ask doctor if
rash occurs. When using this
product keep out of eyes. Rinse
with water to remove. Keep out of
reach of children. If product is
swallowed, get medical help or
contact a Poison Control Center
right away.

KOSÉ Corporation
3-6-2 Nihonbashi, Tokyo
Dist. by KOSÉ America, Inc.
New York, NY 10012
MADE IN JAPAN

e 26 mL NET WT. 1 OZ.

Principal Display Panel - 01 Carton Label

BB

SEKKISEI

TREATMENT BB CREAM

Broad Spectrum SPF 37

Sunscreen

KOSE

e 26 mL NET WT. 1 OZ.

01 LIGHT OCHRE

雪肌精
SEKKISEI

OPEN

**Drug Facts
(continued)**

PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE · DISTEARDIMONIUM
HECTORITE · TRIETHYLHEXANOIN ·
ALPINA SPECIOSA LEAF EXTRACT ·
ANGELICA ACUTILOBA ROOT EXTRACT ·
· CARTHAMUS TINCTORIUS
(SAFFLOWER) FLOWER EXTRACT ·
COIX LACRYMA-JOBI MA-YUEN SEED
EXTRACT · MELOTHRIA
HETEROPHYLLA ROOT EXTRACT ·
TOCOPHEROL · ACRYLATES/
ETHYLHEXYL ACRYLATE/
DIMETHICONE METHACRYLATE
COPOLYMER · ALUMINUM HYDROXIDE
· BHT · BUTYLENE GLYCOL ·
DIMETHICONE · DISODIUM STEAROYL
GLUTAMATE · HYDROGEN
DIMETHICONE · LAURYL PEG-9
POLYDIMETHYLSILOXYETHYL
DIMETHICONE · METHYL
METHACRYLATE CROSSPOLYMER ·
PENTAERYTHRITYL TETRA-DI-T-BUTYL
HYDROXYHYDROCINNAMATE ·
PHYTOSTERYL/ISOSTEARYL/CETYL/
STEARYL/BEHENYL DIMER
DILINOLEATE · POLYISOPRENE ·
POLYPROPYLENE · SILICA · SODIUM
CHLORIDE · STEARALKONIUM
HECTORITE · TALC ·
TRIETHOXYCAPRYLYLSILANE ·
METHYL PARABEN · FRAGRANCE
(PARFUM) · MAY CONTAIN (+/-): IRON
OXIDES (CI 77491) · IRON OXIDES (CI
77492) · IRON OXIDES (CI 77499) ·
TITANIUM DIOXIDE (CI 77891)

Other information

• Protect this product
from excessive heat and
direct sun

雪
肌
精

BB

SEKKISEI
TREATMENT BB CREAM

Broad Spectrum SPF 37
Sunscreen

KOSÉ

e 26 mL NET WT. 1 OZ.



SEKKISEI
TREATMENT BB CREAM
01

**BB cream that covers
skin imperfections
while providing UV
protection and
skincare benefits. In
one easy step, it
provides dewy,
radiant, and naturally
flawless skin.**

• A multi-tasking formula to
hydrate, protect, prime,
conceal and cover the skin.

TO USE: It is recommended
to use after toning skin with
lotion. Take an appropriate
amount and spread evenly
over face. For more coverage,
lightly apply additional layers
and blend into skin. Use
makeup remover for removal.
Close cap after each use.
Store away from high
temperatures.

KOSÉ Corporation
3-6-2 Nihonbashi, Tokyo
Dist. by KOSÉ America, Inc.
New York, NY 10012
MADE IN JAPAN

FEMA#001



4971710 48890 6

Drug Facts

Active ingredients Purpose
OCTINOXATE 7.4%.....Sunscreen
ZINC OXIDE 5.9%.....Sunscreen

Use • helps prevent sunburn

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.

Stop use and ask a doctor if rash
occurs.

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

Directions For sunscreen use:

• apply liberally 15 minutes before
sun exposure • reapply at least
every 2 hours • use a water
resistant sunscreen if swimming
or sweating • **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 10 a.m. – 2 p.m. • wear
long-sleeved shirts, pants, hats,
and sunglasses • children under 6
months: Ask a doctor

Inactive ingredients

WATER/AQUA/EAU · CYCLOMETHICONE · METHYL
TRIMETHICONE · ALCOHOL · GLYCERIN · ETHYLHEXYL
PALMITATE · DIISOSTEARYL MALATE



Principal Display Panel - 01 Tube Label

BB

SEKKISEI

TRETMET BB CREAM

Broad Spectrum SPF 37
Sunscreen

KOSE

雪肌精
BB

SEKKISEI
TREATMENT BB CREAM

Broad Spectrum SPF 37
Sunscreen

KOSÉ



SEKKISEI
TREATMENT BB CREAM
01 LIGHT OCHRE

ACTIVE INGREDIENTS:

OCTINOXATE 7.4% • ZINC OXIDE 5.9%

WARNING: For external use only.
Do not use on damaged or broken
skin. Stop use and ask doctor if
rash occurs. When using this
product keep out of eyes. Rinse
with water to remove. Keep out of
reach of children. If product is
swallowed, get medical help or
contact a Poison Control Center
right away.

KOSÉ Corporation
3-6-2 Nihonbashi, Tokyo
Dist. by KOSÉ America, Inc.
New York, NY 10012
MADE IN JAPAN

e 26 mL NET WT. 1 OZ.

SEKKISEI TREATMENT BB 00

octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66820-0200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	83 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	66 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
ALPINIA ZERUMBET LEAF (UNII: MS8P33AMKX)	
ANGELICA ACUTILOBA ROOT (UNII: 3W51R3EK30)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
COIX LACRYMA-JOBI VAR. MA-YUEN SEED (UNII: 8DW238I7ZI)	
MELOTHRIA HETEROPHYLLA ROOT (UNII: RHN4J0C1KF)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ACRYLIC ACID/DIMETHICONE METHACRYLATE/ETHYLHEXYL ACRYLATE COPOLYMER (UNII: E5024Y9FFQ)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IU0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLENE GLYCOL (UNII: 3XUS85KORA)	
DIMETHICONE (UNII: 92RU3N3Y10)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
PHYTOSTERYL/ISOSTEARYL/CETYL/STEARYL/BEHENYL DIMER DILINOLEATE (UNII: 8N725H4EFN)	
POLYISOPRENE (34000 MW) (UNII: 2HD3GI8VII)	
POLYPROPYLENE (30000 MW) (UNII: T71QXI2O62)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARKONIUM HECTORITE (UNII: O LX698AH5P)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66820-0200-1	1 in 1 CARTON	03/01/2019	
1		26 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2019	

SEKKISEI TREATMENT BB 01

octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66820-0201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	83 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	66 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
PHYTOSTERYL/ISOSTEARYL/CETYL/STEARYL/BEHENYL DIMER DILINOLEATE (UNII: 8N725H4EFN)	
POLYISOPRENE (34000 MW) (UNII: 2HD3GI8VII)	
POLYPROPYLENE (30000 MW) (UNII: T71QXI2O62)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
WATER (UNII: 059QF0KO0R)
CYCLOMETHICONE (UNII: NMQ347994Z)
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)
ALCOHOL (UNII: 3K9958V90M)
GLYCERIN (UNII: PDC6A3C0OX)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)
ALPINIA ZERUMBET LEAF (UNII: MS8P33AMKX)
ANGELICA ACUTILOBA ROOT (UNII: 3W51R3EK30)
SAFFLOWER (UNII: 4VBL71TY4Y)
COIX LACRYMA-JOBI VAR. MA-YUEN SEED (UNII: 8DW238I7Z1)
MELOTHRIA HETEROPHYLLA ROOT (UNII: RHN4J0C1KF)
TOCOPHEROL (UNII: ROZB2556P8)
ACRYLIC ACID/DIMETHICONE METHACRYLATE/ETHYLHEXYL ACRYLATE COPOLYMER (UNII: E5024Y9FFQ)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
DIMETHICONE (UNII: 92RU3N3Y1O)
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66820-0201-1	1 in 1 CARTON	03/01/2019	
1		26 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2019	

Labeler - KOSE AMERICA, INC. (080407621)