

**DECORTE AQ UV PROTECTION- titanium dioxide, 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.*

-----  
**DECORTE AQ UV PROTECTION-titanium dioxide, zinc oxide cream**

**Active Ingredients**

TITANIUM DIOXIDE 10.79%

ZINC OXIDE 6.51%

**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 · DIPHENYLSILOXY PHENYL TRIMETHICONE ·  
 CYCLOPENTASILOXANE · DIMETHICONE · NEOPENTYL GLYCOL DIETHYLHEXANOATE ·  
 PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE · VINYL DIMETHICONE/METHICONE  
 SILSESQUIOXANE CROSSPOLYMER · GLYCERIN · TALC · BUTYLENE GLYCOL ·  
 PENTYLENE GLYCOL · POLYMETHYLSILSESQUIOXANE · ALUMINUM HYDROXIDE ·  
 STEARIC ACID · MAGNESIUM SULFATE · SORBITAN SESQUIISOSTEARATE · DISODIUM  
 ADENOSINE TRIPHOSPHATE · HYDROLYZED COLLAGEN · IMPATIENS BALSAMINA  
 FLOWER/LEAF/STEM EXTRACT · LONICERA CAERULEA FRUIT JUICE · MALVA  
 SYLVESTRIS (MALLOW) EXTRACT · MUCUNA BIRDWOODIANA STEM EXTRACT · OLEA  
 EUROPAEA (OLIVE) LEAF EXTRACT · PALMITOYL PENTAPEPTIDE-4 · SANTALUM ALBUM  
 (SANDALWOOD) WOOD EXTRACT · TILIA EUROPAEA FLOWER EXTRACT ·  
 TOCOPHEROL · URTICA DIOICA (NETTLE) LEAF EXTRACT · ACRYLATES/DIMETHICONE  
 COPOLYMER · ALCOHOL · ALGIN · CARBOMER · DIMETHICONE/PEG-10/15  
 CROSSPOLYMER · DIMETHICONE/PHENYL VINYL DIMETHICONE CROSSPOLYMER ·  
 DIPROPYLENE GLYCOL · ECTOIN · HYDROGEN DIMETHICONE · POLYSORBATE 20 ·  
 SODIUM CITRATE · SODIUM LACTATE · XANTHAN GUM · PHENOXYETHANOL ·  
 FRAGRANCE (PARFUM) · IRON OXIDES (CI 77491) · IRON OXIDES (CI 77492) · IRON  
 OXIDES (CI 77499)

## Other information

Protect this product from excessive heat and direct sun

## Principal Display Panel

0.5 mL Packet

### **DECORTE AQ**

UV PROTECTION

Chemical UV Absorber Free

Broad Spectrum SPF 40

Sunscreen

0.5 mL NET WT. .02 OZ.

5 mL Tube

### **DECORTE AQ**

UV PROTECTION

Chemical UV Absorber Free

Broad Spectrum SPF 40

Sunscreen

e 5 mL NET WT. .21 OZ.

50 mL Carton

**DECORTE AQ**

UV PROTECTION

Chemical UV Absorber Free

Broad Spectrum SPF 40

Sunscreen

e 50 mL NET WT. 2.1 OZ.

UV PROTECTION

**Drug Facts**

**Active ingredients Purpose**  
TITANIUM DIOXIDE 10.79% .....Sunscreen  
ZINC OXIDE 6.51% .....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 · DIPHENYLSILOXY PHENYL TRIMETHICONE · CYCLOPENTASILOXANE · DIMETHICONE · NEOPENTYL GLYCOL DIETHYLHEXANOATE · PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE · VINYL DIMETHICONE/METHICONE SILSESQUIOXANE



**Drug Facts (continued)**

CROSSPOLYMER · GLYCERIN · TALC · BUTYLENE GLYCOL · PENTYLENE GLYCOL · POLYMETHYLSILSESQUIOXANE · ALUMINUM HYDROXIDE · STEARIC ACID · MAGNESIUM SULFATE · SORBITAN SESQUISOSTEARATE · DISODIUM ADENOSINE TRIPHOSPHATE · HYDROLYZED COLLAGEN · IMPATIENS BALSAMINA FLOWER/LEAF/STEM EXTRACT · LONICERA CAERULEA FRUIT JUICE · MALVA SYLVESTRIS (MALLOW) EXTRACT · MUCUNA BIRDWOODIANA STEM EXTRACT · OLEA EUROPAEA (OLIVE) LEAF EXTRACT · PALMITOYL PENTAPEPTIDE-4 · SANTALUM ALBUM (SANDALWOOD) WOOD EXTRACT · TILIA EUROPAEA FLOWER EXTRACT · TOCOPHEROL · URTICA DIOICA (NETTLE) LEAF EXTRACT · ACRYLATES/DIMETHICONE COPOLYMER · ALCOHOL · ALGIN · CARBOMER · DIMETHICONE/PEG-10/15 CROSSPOLYMER · DIMETHICONE/PHENYL VINYL DIMETHICONE CROSSPOLYMER · DIPROPYLENE GLYCOL · ECTOIN · HYDROGEN DIMETHICONE · POLYSORBATE 20 · SODIUM CITRATE · SODIUM LACTATE · XANTHAN GUM · PHENOXYETHANOL · FRAGRANCE (PARFUM) · IRON OXIDES (CI 77491) · IRON OXIDES (CI 77492) · IRON OXIDES (CI 77499)

**Other Information**

- Protect this product from excessive heat and direct sun

**DECORTÉ AQ**

UV PROTECTION

Chemical UV Absorber Free

Broad Spectrum SPF 40 Sunscreen

e 50 mL NET WT. 2.1 OZ.

**DECORTÉ AQ UV PROTECTION**

A deeply nourishing sunscreen that protects skin from UVA/UVB rays and helps prevent the formation of dark spots. With remarkable skincare benefits, the silky formula helps reduce the appearance of wrinkles and photoaging, keeping skin incredibly radiant and firm.

Contains: \*White mucuna extract (Mucuna birdwoodiana stem extract) \*Sandalwood extract \*Haskaap fruit juice \*Ectoin \*ATP disodium \*Garden balsam flower/leaf/stem extract \*Linden extract \*Olive leaf extract \*Malva sylvestris (Mallow) extract

- Fragranced with a comforting blend of natural essential oils and aromatics.
- Chemical UV absorber free.
- Dermatologically tested.
- Paraben free.

TO USE: Apply evenly over face before sun exposure. Close cap after each use.

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



**DECORTE AQ UV PROTECTION**

titanium dioxide, zinc oxide cream

**Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:66820-0300

**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	128.452381 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	77.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIPHENYLSILOXY PHENYL TRIMETHICONE</b> (UNII: I445L28B12)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>NEOPENTYL GLYCOL DIETHYLHEXANOATE</b> (UNII: U68ZV6W62C)	
<b>PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: TYP81E471F)	
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>SORBITAN SESQUISTEARATE</b> (UNII: VU97D01BF9)	
<b>ADENOSINE TRIPHOSPHATE DISODIUM</b> (UNII: 5L51B4DR1G)	
<b>MARINE NON-GELLING GELATIN</b> (UNII: JSM64OJO9B)	
<b>IMPATIENS BALSAMINA FLOWERING TOP</b> (UNII: 7S287B0Z5V)	
<b>LONICERA CAERULEA FRUIT JUICE</b> (UNII: NZG59YZW09)	
<b>MALVA SYLVESTRIS FLOWERING TOP</b> (UNII: X1U1U0N90J)	
<b>MUCUNA BIRDWOODIANA STEM</b> (UNII: 6W7VXE8RS6)	
<b>OLEA EUROPAEA LEAF</b> (UNII: MJ95C3OH47)	
<b>PALMITOYL PENTAPEPTIDE-4</b> (UNII: KK181SM5JG)	
<b>SANDALWOOD</b> (UNII: 3641YW25N2)	
<b>TILIA X EUROPAEA FLOWER</b> (UNII: NHV2K1OUDH)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>URTICA DIOICA LEAF</b> (UNII: X6M0DRN46Q)	
<b>2-ETHYLHEXYL ACRYLATE, METHACRYLATE, METHYL METHACRYLATE, OR BUTYL METHACRYLATE/HYDROXYPROPYL DIMETHICONE COPOLYMER (30000-300000 MW)</b> (UNII: S7ZA3CCJ4M)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>DIMETHICONE/PEG-10/15 CROSSPOLYMER</b> (UNII: 21AS8B1BSS)	
<b>DIMETHICONE/PHENYL VINYL DIMETHICONE CROSSPOLYMER</b> (UNII: ST6ZC4KVH2)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	

<b>ECTOINE</b> (UNII: 7GXZ3858RY)
<b>HYDROGEN DIMETHICONE (13 CST)</b> (UNII: 4QGR4P2YOI)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)
<b>SODIUM LACTATE</b> (UNII: TU7HW0W0QT)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66820-0300-1	1 in 1 CARTON	03/01/2022	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:66820-0300-2	5 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2022	
3	NDC:66820-0300-3	0.5 mL in 1 PACKET; Type 0: Not a Combination Product	03/01/2022	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2022	

**Labeler** - KOSE AMERICA, INC. (080407621)