

**UNIWELL AQUA SUNCREAM- octinoxate, octisalate cream
uniwell 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.

Drug Facts

OCTINOXATE 7.00%

OCTISALATE 4.50%

Sunscreen

Helps prevent sunburn

Apply liberally 15 minutes before sun exposure.

Reapply at least every two 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 of 15 or higher and other sun protection measures including: 1) Limited time in the sun, especially from 10 am to 2 pm. 2)

Wear long-sleeve shirts, pants, hats, and sunglasses

Ask a doctor to use for children under 6 months

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 using and ask a doctor if rash occurs.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

Water, Butylene Glycol, Diethylamino Hydroxybenzoyl Hexyl Benzoate, C12-15 Alkyl Benzoate, Niacinamide, Methyl Methacrylate Crosspolymer, Phenylbenzimidazole Sulfonic Acid, Cetearyl Alcohol, Glyceryl Stearate, Cetearyl Oliviate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Sorbitan Oliviate, Polysorbate 60, PEG-100 Stearate, Sorbitan Stearate, Dimethicone, Polyacrylate-13, Panthenol, Caprylyl Glycol, Sodium Hydroxide, Polyisobutene, Ethylhexylglycerin, Citrus Aurantium Dulcis (Orange) Oil, 1,2-Hexanediol, Disodium EDTA, Propolis Extract, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Camellia Sinensis Leaf Extract, Lavandula Angustifolia (Lavender) Oil, Adenosine, Polysorbate 20, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Sorbitan Isostearate, Panax Ginseng Root Extract, Portulaca Oleracea Extract, Ecklonia cava Extract, Codium Tomentosum Extract, Gelidium Cartilagineum Extract, Hizikia Fusiforme Extract, Glycerin, Geranium Maculatum Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Santalum Album (Sandalwood) Oil, Rose Flower Oil, Chamomilla Recutita (Matricaria) Flower Oil, Olea Europaea (Olive) Leaf Extract, Alcohol, Anthemis Nobilis Flower Extract, Brassica Oleracea Italica (Broccoli) Extract, Phenoxyethanol, Styrax Benzoin Gum, Commiphora Myrrha Oil, Aloe Barbadosensis Leaf Juice, Gossypium Herbaceum (Cotton) Extract, Potassium sorbate, Sodium Benzoate

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	3.5 mg in 50 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2.25 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ENSULIZOLE (UNII: 9YQ9D1W42)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Cetearyl Olivat e (UNII: 58B69Q84JO)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
Sorbitan Olivat e (UNII: MDL271E3GR)	
Polysorbate 60 (UNII: CAL22UVI4M)	
PEG-100 Stearate (UNII: YD01N1999R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
Panthenol (UNII: WV9CM0O67Z)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Sodium Hydroxide (UNII: 55X04QC32I)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
Ethylhexylglycerin (UNII: 147D247K3P)	
ORANGE OIL (UNII: AKN3KSD11B)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ADENOSINE (UNII: K72T3FS567)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
PURSLANE (UNII: M6S840WYG5)	
ECKLONIA CAVA (UNII: UXX2N5V39P)	
CODIUM TOMENTOSUM (UNII: B8B45BRU87)	
GELIDIUM CARTILAGINEUM (UNII: 37LBZ0E1UE)	
SARGASSUM FUSIFORME (UNII: X436TJ4A11)	
Glycerin (UNII: PDC6A3C0OX)	
GERANIUM MACULATUM ROOT OIL (UNII: H2E371EDYX)	

BERGAMOT OIL (UNII: 39W1PKE3J)	
SANDALWOOD OIL (UNII: X7X01WMQ5F)	
ROSA RUGOSA FLOWER BUD (UNII: TZ0BE8I3MW)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
Alcohol (UNII: 3K9958V90M)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STYRAX BENZOIN RESIN (UNII: FE663Z8IRO)	
MYRRH OIL (UNII: H74221J5J4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
LEVANT COTTON SEED (UNII: 550E4N439V)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71502-001-02	1 in 1 CARTON	06/12/2017	
1	NDC:71502-001-01	50 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/12/2017	

Labeler - uniwell LTD (694646565)

Registrant - uniwell LTD (694646565)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmecca Korea Co., Ltd.		688830827	manufacture(71502-001)

Revised: 6/2017

uniwell LTD