LAGOM CELLUS SUN GEL- octinoxate, octocrylene, octisalate gel
SKINMED International Co., 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%

OCTOCRYLENE 5.00%

OCTISALATE 4.00%

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 of 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
Alcohol Denat.
Propanediol
Butyl Methoxydibenzoylmethane
Methyl Methacrylate Crosspolymer
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine
Methoxy PEG/PPG-25/4 Dimethicone
Bis-PEG/PPG-20/5 PEG/PPG-20/5 Dimethicone
Caprylic/Capric Triglyceride
Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer
Dimethicone
Isohexadecane
Acrylates/C10-30 Alkyl Acrylate Crosspolymer
Caprylyl Glycol
Citrus Aurantium Dulcis (Orange) Oil
Ethylhexylglycerin
Polysorbate 80
1,2-Hexanediol
BHT
Sodium Hydroxide
Lavandula Angustifolia (Lavender) Oil
Sorbitan Oleate
Disodium EDTA

Geranium Maculatum Oil
Citrus Aurantium Bergamia (Bergamot) Fruit Oil
Santalum Album (Sandalwood) Oil
Rose Flower Oil
Chamomilla Recutita (Matricaria) Flower Oil
Urea
Yeast Amino Acids
Trehalose
Betaine
Taurine
Inositol
Styrax Benzoin Gum
Commiphora Myrrha Oil
Phenoxyethanol
Potassium sorbate

LAGOM CELLUS SUN GEL

octinoxate, octocrylene, octisalate gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70738-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.5 mg in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.5 mg in 50 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
PROPANEDIOL (UNII: 5965N8W85T)	
AVOBENZONE (UNII: G63QQF2NOX)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
BIS-PEG/PPG-16/16 PEG/PPG-16/16 DIMETHICONE (UNII: 55A74AJ3KB)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ORANGE OIL (UNII: AKN3KSD11B)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GERANIUM MACULATUM ROOT OIL (UNII: H2E371EDYX)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
SANDALWOOD OIL (UNII: X7X01WMQ5F)	
ROSA RUGOSA FLOWER BUD (UNII: TZ0BE8I3MW)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
UREA (UNII: 8W8T17847W)	
TREHALOSE (UNII: B8WCK70T7I)	
BETAINE (UNII: 3SCV180C9W)	
TAURINE (UNII: 1EQV5MLY3D)	
INOSITOL (UNII: 4L6452S749)	
STYRAX BENZOIN RESIN (UNII: FE663Z8IRO)	
MYRRH OIL (UNII: H74221J5J4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70738-001-02	1 in 1 PACKAGE	01/08/2018	
1	NDC:70738-001-01	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	01/08/2018	

Labeler - SKINMED International Co., Ltd. (689846920)

Registrant - SKINMED International Co., Ltd. (689846920)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmecca Korea Co., Ltd.		688830827	manufacture(70738-001)

Revised: 1/2018 SKINMED International Co., Ltd.