

KOPHER CALMING OCEAN SUN- ethylhexyl methoxycinnamate, zinc oxide, ethylhexyl salicylate, titanium dioxide cream
Best Innovation

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.

ACTIVE INGREDIENTS

Ethylhexyl Methoxycinnamate 7.50%
Zinc Oxide 4.00%
Ethylhexyl Salicylate 3.00%
Titanium Dioxide (CI 77891) 1.60%

INACTIVE INGREDIENTS

Glacier Water, Cyclopentasiloxane, Butylene Glycol, Dicaprylyl Carbonate, Isoamyl p-Methoxycinnamate, Cyclohexasiloxane, Cetyl PEG/PPG-10/1 Dimethicone, Niacinamide, Diphenylsiloxy Phenyl Trimethicone, Alcohol Denat., Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Centella Asiatica Extract, Sodium Chloride, Asiaticoside, Madecassic Acid, Asiatic Acid, Spirulina Platensis Extract, Scutellaria Baicalensis Root Extract, Cinnamomum Zeylanicum Bark Extract, Camellia Japonica Seed Oil, Ceresin, Allantoin, Disteardimonium Hectorite, Sorbitan Sesquioleate, Silica, Sorbitan Olivatate, Trihydroxystearin, Trimethylsiloxysilicate, Dipropylene Glycol, Propylene Carbonate, 1,2-Hexanediol, Hydroxyacetophenone, Phenyl Trimethicone, Triethoxycaprylylsilane, Dimethicone Crosspolymer, CI 77492, Dimethiconol, Adenosine, Dimethicone, CI 77491, Tocopherol, Menthyl Lactate, Butyl Methoxydibenzoylmethane, Butyl Avocadate, Tocopheryl Acetate, Horse Fat, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Capryloyl Glycine, Hexylene Glycol, Sarcosine, Chlorphenesin, Water, Talc, Fragrance(Parfum)

PURPOSE

Sunscreen

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

KEEP OUT OF REACH OF CHILDREN

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

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Retains SPF after 80 minutes of activity in the water or sweating

Directions

- Apply liberally and uniformly to all exposed areas 15-20 minutes before sun exposure.
- Reapply often (every 2 hours) and after swimming, excessive perspiration and washing to ensure maximum sun protection.


Other Information

- Do not store this product in an inappropriate place such as high or low temperatures or under direct sun light

Questions

- www.bestinnovation.co.kr

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Drug Facts	[Ingredients] Water(Glacier Water), Ethylhexyl Methoxycinnamate, Cyclopentasiloxane, Zinc Oxide (CI 77947), Butylene Glycol, Dicaprylyl Carbonate, Ethylhexyl Salicylate, Isoamyl p-Methoxycinnamate, Cyclohexasiloxane, Cetyl PEG/PPG-10/1 Dimethicone, Niacinamide, Diphenylsiloxy Phenyl Trimethicone, Alcohol Denat., Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Titanium Dioxide (CI 77891), Centella Asiatica Extract, Sodium Chloride, Asiaticoside, Madecassic Acid, Spirulina Platensis Extract, Scutellaria Baicalensis Root Extract, Cinnamomum Zeylanicum Bark Extract, Camellia Japonica Seed Oil, Ceresin, Allantoin, Distearidimonium Hectorite, Sorbitan Sesquiolate, Silica, Sorbitan Oliviate, Trihydroxystearin, Trimethylsilylsilicate, Dipropylene Glycol, Propylene Carbonate, 1,2-Hexanediol, Hydroxyacetophenone, Phenyl Trimethicone, Triethoxycaprylylsilane, Dimethicone Crosspolymer, CI 77492, Dimethiconol, Adenosine, Dimethicone, CI 77491, Tocopherol, Menthyl Lactate, Butyl Methoxydibenzoylmethane, Butyl Avocadate, Tocopheryl Acetate, Horse Fat, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Capryloyl Glycine, Hexylene Glycol, Sarcosine, Chlorphenesin, Water, Talc, Fragrance(Parfum)		CALMING OCEAN SUNCREAM	<p>용량 : 50 mL / 1.69 FL. OZ 화장품책임판매업자 : (주)베스티노베이션 충청남도 아산시 번영로 130 화장품제조업자 : (주)아이티 충청남도 당진시 함덕읍 함덕산단1로 110 제조번호 및 사용기한 : 별도표기</p> <p>[사용할 때의 주의사항] 1. 화장품 사용 시 또는 사용 후 직사광선에 의하여 사용부위가 붉은 반점, 부어오름 또는 가려움증 등의 이상 증상이나 부작용이 있는 경우에는 전문의 등과 상담할 것 2. 상처가 있는 부위 등에는 사용을 자제할 것 3. 보관 및 취급 시 주의사항 가. 어린이의 손이 닿지 않는 곳에 보관할 것 나. 직사광선을 피해서 보관할 것</p> <p>본 제품에 이상이 있을 경우 공정거래위원회 고시 소비자분쟁해결 기준에 의해 보상해 드립니다. [소비자상담실] 070-4299-0898</p> <p>MADE IN KOREA</p>								
<p>Active ingredients</p> <table border="1"> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> <tr> <td>Ethylhexyl Methoxycinnamate 7.50%</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc Oxide 4.00%</td> <td>Sunscreen</td> </tr> <tr> <td>Ethylhexyl Salicylate 3.00%</td> <td>Sunscreen</td> </tr> <tr> <td>Titanium Dioxide (CI 77891) 1.60%</td> <td>Sunscreen</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> Helps prevent sunburn Higher SPF gives more sunburn protection Retains SPF after 80 minutes of activity in the water or sweating <p>Warnings</p> <ul style="list-style-type: none"> 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 <p>Directions</p> <ul style="list-style-type: none"> Apply liberally and uniformly to all exposed areas 15-20 min before sun exposure. Reapply often (every 2 hours) and after swimming, excessive perspiration and washing to ensure maximum sun protection. <p>Other Information</p> <ul style="list-style-type: none"> Do not store this product in an inappropriate place such as high or low temperatures or under direct sunlight <p>Questions</p> <ul style="list-style-type: none"> www.bestinnovation.co.kr <p>Inactive ingredients</p> <p>Glacier Water, Cyclopentasiloxane, Butylene Glycol, Dicaprylyl Carbonate, Isoamyl p-Methoxycinnamate, Cyclohexasiloxane, Cetyl PEG/PPG-10/1 Dimethicone, Niacinamide, Diphenylsiloxy Phenyl Trimethicone, Alcohol Denat., Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Centella Asiatica Extract, Sodium Chloride, Asiaticoside, Madecassic Acid, Asiatic Acid, Spirulina Platensis Extract, Scutellaria Baicalensis Root Extract, Cinnamomum Zeylanicum Bark Extract, Camellia Japonica Seed Oil, Ceresin, Allantoin, Distearidimonium Hectorite, Sorbitan Sesquiolate, Silica, Sorbitan Oliviate, Trihydroxystearin, Trimethylsilylsilicate, Dipropylene Glycol, Propylene Carbonate, 1,2-Hexanediol, Hydroxyacetophenone, Phenyl Trimethicone, Triethoxycaprylylsilane, Dimethicone Crosspolymer, CI 77492, Dimethiconol, Adenosine, Dimethicone, CI 77491, Tocopherol, Menthyl Lactate, Butyl Methoxydibenzoylmethane, Butyl Avocadate, Tocopheryl Acetate, Horse Fat, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Capryloyl Glycine, Hexylene Glycol, Sarcosine, Chlorphenesin, Water, Talc, Fragrance(Parfum)</p> <p>Distributor Bestinnovation Co., Ltd 130 Beonyeong-ro Asan-si, Chungcheongnam-do, Republic of Korea</p> <p>Manufacturer Cit Co., Ltd. 110 Hapdeoksandan 1-ro Hapdeok-eup, Dangjin, Chungnam, S. Korea</p>					Active ingredients	Purpose	Ethylhexyl Methoxycinnamate 7.50%	Sunscreen	Zinc Oxide 4.00%	Sunscreen	Ethylhexyl Salicylate 3.00%	Sunscreen
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KOPHER CALMING OCEAN SUN

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83069-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.50 g in 100 mL
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	4.0 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3.0 g in 100 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	1.60 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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Water (UNII: 059QF0K00R)				
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)				
Butylene Glycol (UNII: 3XUS85K0RA)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83069-010-02	1 in 1 CARTON	10/01/2022	
1	NDC:83069-010-01	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	10/01/2022		

Labeler - Best Innovation (695668556)

Registrant - Best Innovation (695668556)

Establishment			
Name	Address	ID/FEI	Business Operations
Cit Co., Ltd.		690081646	manufacture(83069-010)

Revised: 10/2022

Best Innovation