

LATHER- DAILY DEFENSE MINERAL SPF 50- zinc oxide cream
Lather, 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.

LATHER - DAILY DEFENSE MINERAL SPF 50 (77394-202)

ACTIVE INGREDIENTS

Zinc Oxide 21%

PURPOSE

Sunscreen

USES

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

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

- Apply liberally 15 minutes before sun exposure
- reapply: after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 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:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months of age: ask a doctor

OTHER INFORMATION

- Protect this product from excessive heat and direct sun

INACTIVE INGREDIENTS

Water (aqua), Coco-Caprylate/Caprinate, Cetearyl Alcohol, Propanediol, Stearyl Alcohol, Polyhydroxystearic Acid, Mica, Butyrospermum Parkii (Shea) Butter, Cetearyl Oliviate, Sorbitan Oliviate, Camellia Sinensis (Green Tea) Extract, Olea Europaea (Olive) Leaf Extract, Equisetum Arvense (Horsetail) Extract, Rosmarinus Officinalis (rosemary) Extract, Centella Asiatica (Gotu Kola) Extract, Aesculus Hippocastanum (Horse Chestnut) Extract, Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Glyceryl Caprylate, Glycerin, Xanthan Gum, Tocopheryl Acetate, Citrus Nobilis (Mandarin Orange) Peel Oil, Silica, Caprylhydroxamic Acid, Triethoxycaprylylsilane, Ascorbyl Palmitate, Caprylic/Capric Triglyceride, Ascorbic Acid, Tocopherol, Potassium Sorbate, Sodium Phytate, Citric Acid, Iron Oxides

<p style="writing-mode: vertical-rl; transform: rotate(180deg);">green tea . antioxidant shea butter . moisturizing</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Sheer tinted, 100% mineral zinc-based sunscreen</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Use daily on face and neck as the last step, before applying makeup</p>	<p>daily defense mineral SPF 50 facial sunscreen with UVA/UVB protection</p>  <p>broad spectrum SPF 50 water resistant (80 minutes)</p> <p>Net Wt 2 oz / 56.7 g</p>	<p>Drug Facts (continued)</p> <p>Other information: • protect this product from excessive heat and direct sun</p> <p>Inactive ingredients: Water (Aqua), Coco-Caprylate/Caprinate, Cetearyl Alcohol, Propanediol, Stearyl Alcohol, Polyhydroxystearic Acid, Mica, Butyrospermum Parkii (Shea) Butter, Cetearyl Oliviate, Sorbitan Oliviate, Camellia Sinensis (Green Tea) Extract, Olea Europaea (Olive) Leaf Extract, Equisetum Arvense (Horsetail) Extract, Rosmarinus Officinalis (Rosemary) Extract, Centella Asiatica (Gotu Kola) Extract, Aesculus Hippocastanum (Horse Chestnut) Extract, Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Glyceryl Caprylate, Glycerin, Xanthan Gum, Tocopheryl Acetate, Citrus Nobilis (Mandarin Orange) Peel Oil, Silica, Caprylhydroxamic Acid, Triethoxycaprylylsilane, Ascorbyl Palmitate, Caprylic/Capric Triglyceride, Ascorbic Acid, Tocopherol, Potassium Sorbate, Sodium Phytate, Citric Acid, Iron Oxides</p> <p>NO synthetic fragrance or color NO parabens or sulfates • NO mineral oil NO animal testing</p>	<p>Drug Facts</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Active ingredients</th> <th style="text-align: left;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Zinc Oxide 21%.....</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun</p> <p>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</p> <p>Directions • apply liberally 15 minutes before sun exposure • reapply: after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 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: • limit time in the sun, especially from 10 a.m. – 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses. • children under 6 months: Ask a doctor</p> <p>←</p>	Active ingredients	Purpose	Zinc Oxide 21%.....	Sunscreen
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LATHER- DAILY DEFENSE MINERAL SPF 50

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77394-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	21 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPANEDIOL (UNII: 5965N8W85T)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
MICA (UNII: V8A1AW0880)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
EQUISETUM ARVENSE WHOLE (UNII: 73DM367W4P)	
ROSMARINUS OFFICINALIS FLOWER (UNII: NR1A27F29O)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
AESCULUS HIPPOCASTANUM FLOWER (UNII: KK0Z92II8M)	
COCOS NUCIFERA WHOLE (UNII: 245J88W96L)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CITRUS NOBILIS (UNII: 8MFF77J91V)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CAPRYLIC/CAPRIC/SUCCINIC TRIGLYCERIDE (UNII: J4BY50FL78)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
TOCOPHEROL (UNII: ROZB2556P8)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77394-202-13	1 in 1 BOX	04/28/2021	
1		57 g in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:77394-202-01	17 g in 1 BOTTLE; Type 0: Not a Combination Product	04/28/2021	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part352	04/28/2021	

Labeler - Lather, Inc. (100666606)

Revised: 10/2023

Lather, Inc.