

## **ERADIKATE DAILY FOAMING CLEANSER ACNE TREATMENT- sulfur gel**

**Kate Somerville Skincare, LLC**

*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.*

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### **ACTIVE INGREDIENT**

SULFUR 3.0%

### **PURPOSE**

ACNE TREATMENT

### **USES**

- FOR THE TRETAMENT OF ACNE
- HELPS KEEP SKIN CLEAR OF NEW ACNE BLEMISHES

### **WARNINGS**

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT

- SKIN IRRITATION OR DRYNESS IS MORE LIKELY TO OCCUR IF YOU USE ANOTHER TOPICAL ACNE MEDICATION AT THE SAME TIME. IF IRRITATION OCCURS, ONLY USE ONE TOPICAL ACNE MEDICATION AT A TIME.

STOP USE AND ASK A DOCTOR IF RASH OCCURS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

### **DIRECTIONS**

- AM AND PM. USE TWICE A DAY. APPLY A SMALL AMOUNT TO WET FACE AND MASSAGE GENTLY FOR 30 SECONDS. RINSE AND GENTLY PAT DRY. AVOID CONTACT WITH EYE AREA. FOLLOW WITH ERADIKATE ACNE TREATMENT FOR MAXIMUM RESULTS.
- BECAUSE EXCESSIVE DRYNESS OF THE SKIN MAY OCCUR, START WITH ONE APPLICATION DAILY, THEN GRADUALLY INCREASE TO TWO OR THREE TIMES DAILY IF NEEDED OR AS DIRECTED BY A DOCTOR.
- IF BOTHERSOME DRYNESS OR PEELING OCCURS, REDUCE APPLICATION TO ONCE A DAY OR EVERY OTHER DAY.

### **OTHER INFORMATION**

- STORE IN A COOL, DRY PLACE. AVOID PRODUCT CONTACT WITH SILVER JEWELRY, WHICH MAY BE DISCOLORED BY THIS PRODUCT.

### **INACTIVE INGREDIENTS**

WATER/AQUA/EAU, SODIUM COCOYL ISETHIONATE, COCO-GLUCOSIDE, ACRYLATES COPOLYMER, COCONUT ALCOHOL, GLYCERETH-18 ETHYLHEXANOATE, GLYCERETH-

18, STEARYL ALCOHOL, HONEY EXTRACT/MEL/EXTRAIT DE MIEL, ORYZA SATIVA (OAT) KERNEL EXTRACT, OLIGOPEPTIDE-10, BOSWELLIA SERRATA EXTRACT, BEHENYL ALCOHOL, GLYCERIN, PHENOXYETHANOL, FRAGRANCE/PARFUM, CITRIC ACID, SODIUM HYDROXIDE, ETHYLHEXYLGLYCERIN, DISODIUM EDTA, DISODIUM CARBOXYETHYL SILICONATE, TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491)

## EradiKate® Daily<sup>o</sup> Foaming Cleanser

Acne Treatment  
Traitement anti-acné

This medicated, foaming acne cleanser with a unique "whipped" texture is formulated with 3% Sulfur to help clear and prevent blemishes, and draw out impurities to unclog congested pores. Honey and Rice Bran Extracts help calm and soothe acne-prone skin while Natural Oat Extract reduces, absorbs and balances sebum. With continued use, this gentle yet effective daily cleanser leaves skin visibly clearer and minimizes the appearance of pores without over-drying.

For maximum results follow daily with EradiKate® Acne Treatment or EradiKate® To-Go, and use EradiKate® Mask weekly as needed.

### Drug Facts

Active Ingredients	Purpose
Sulfur 3.0%	Acne treatment

#### Uses

- For the treatment of acne
- Helps keep skin clear of new acne blemishes

#### Warnings

For external use only.

#### When using this product

- Skin Irritation or dryness is more likely to occur if you use another topical acne medication at the same time. If Irritation occurs, only use one topical acne medication at a time.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- AM and PM. Use twice a day. Apply a small amount to wet face and massage gently for 30 seconds. Rinse and gently pat dry. Avoid contact with eye area. Follow with EradiKate® Acne Treatment for maximum results.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day

#### Inactive Ingredients

Water/Aqua/Eau, Sodium Cocoyl Isethionate, Coco-Glucoside, Acrylates Copolymer, Coconut Alcohol, Glycereth-18 Ethylhexanoate, Glycereth-18, Stearyl Alcohol, Honey Extract/Mel/Extrait de Miel, Oryza Sativa (Rice) Bran Extract, Avena Sativa (Oat) Kernel Extract, Oligopeptide-10, Boswellia Serrata Extract, Behenyl Alcohol, Glycerin, Xanthan Gum, Caprylyl Glycol, Hexylene Glycol, Butylene Glycol, Phenoxyethanol, Fragrance/Parfum, Citric Acid, Sodium Hydroxide, Ethylhexylglycerin, Disodium EDTA, Disodium Carboxyethyl Siliconate, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491)

#### Other Information

- Store in a cool, dry place. Avoid product contact with silver jewelry, which may be discolored by this product.

1-800-984-KATE katesomerville.com  
MADE IN U.S.A./FAIT AUX É.U.  
This product has not been tested on animals.  
Ce produit n'a pas été testé sur des animaux.  
Dist. by/par Kate Somerville Skincare, LLC, Beverly Hills, CA 90212 EU Dist./Dist. dans l'UE Nierwag 165, 1043 BW Amsterdam The Netherlands

Kate  
Somerville  
Skin Health Experts<sup>o</sup>

Acne / Peau acnéique



## EradiKate® Daily<sup>o</sup> Foaming Cleanser

Acne Treatment  
Traitement anti-acné

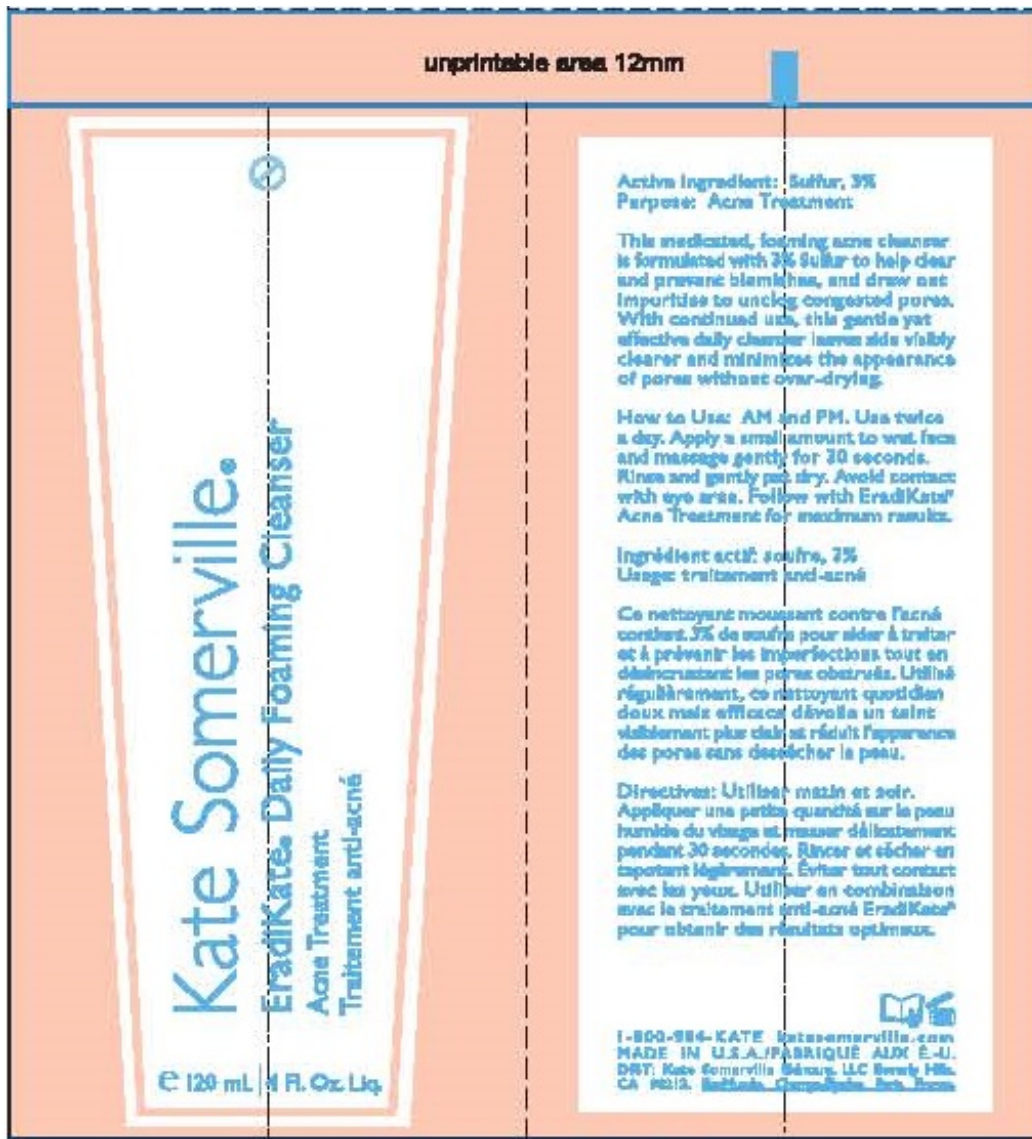
Ce nettoyant moussant médicamenteux contre l'acné possède une texture fouettée unique et contient 3 % de soufre pour aider à traiter et à prévenir les imperfections tout en désincrustant les pores obstrués. Il contient aussi des extraits de miel et de son de riz qui aident à apaiser la peau sujette à l'acné, et des extraits d'avoine naturelle qui aident à éliminer l'excès de sébum. Utilisé régulièrement, ce nettoyant quotidien doux et efficace dévoile un teint visiblement plus clair et réduit l'apparence des pores sans dessécher la peau.

Utiliser en combinaison avec les traitements anti-acné EradiKate® ou EradiKate® To-Go, et avec le masque hebdomadaire EradiKate® pour obtenir des résultats optimaux.

EradiKate® Daily<sup>o</sup>  
Foaming Cleanser

Acne Treatment  
Traitement anti-acné

e 120 mL | 4 Fl. Oz.



## ERADIKATE DAILY FOAMING CLEANSER ACNE TREATMENT

sulfur gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43479-110
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	3 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
COCO GLUCOSIDE (UNII: ICS790225B)	

CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)
COCONUT ALCOHOL (UNII: 13F4MW8Y9K)
GLYCERETH-18 ETHYLHEXANOATE (UNII: IWS58C6V2Y)
GLYCERETH-18 (UNII: SA5E43C17C)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
HONEY (UNII: Y9H1V576FH)
ORYZA SATIVA WHOLE (UNII: 84IVV0906Z)
AVENA SATIVA WHOLE (UNII: 5P8D0Z74RG)
OLIGOPEPTIDE-10 (UNII: Q46328TRNK)
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)
DOCOSANOL (UNII: 9G1OE216XY)
GLYCERIN (UNII: PDC6A3C0OX)
XANTHAN GUM (UNII: TTV12P4NEE)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
EDETATE DISODIUM (UNII: 7FLD91C86K)
DISODIUM CARBOXYETHYL SILICONATE (UNII: 4U4C79679G)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43479-110-51	1 in 1 BOX	10/12/2018	
1	NDC:43479-110-13	120 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:43479-110-12	50 mL in 1 TUBE; Type 0: Not a Combination Product	10/12/2018	
3	NDC:43479-110-11	30 mL in 1 TUBE; Type 0: Not a Combination Product	10/12/2018	
4	NDC:43479-110-14	240 mL in 1 TUBE; Type 0: Not a Combination Product	10/12/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/12/2018	

**Labeler** - Kate Somerville Skincare, LLC (615155533)