

UNCOMPLIKATED MAKEUP SETTING SPF 50- avobenzene, homosalate, octisalate, octocrylene, oxybenzone aerosol, spray
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.

ACTIVE INGREDIENTS

AVOBENZONE 3.00%
HOMOSALATE 10.00%
OCTISALATE 5.00%
OCTOCRYLENE 10.00%
OXYBENZONE 5.00%

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

WHEN USING THIS PRODUCT, KEEP OUT OF EYES.

RINSE WITH WARM 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.

- SHAKE WELL PRIOR TO USE.
- AVOID SPRAYING ON OR AROUND EYE AREA. CLOSE MOUTH.
- HOLD CAN 8-10" FROM FACE AND SPRAY IN A CLOCKWISE DIRECTION.
- DO NOT APPLY IN WINDY CONDITIONS.
- USE IN A WELL-VENTILATED AREA.
- APPLY LIBERALLY 15 MINUTES BEFORE SUN EXPOSURE.
- USE A WATER RESISTANT SUNSCREEN IF SWIMMING OR SWEATING.
- REAPPLY 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 VALUE 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-SLEEVED SHIRTS, PANTS, HATS, AND SUNGLASSES.

- CHILDREN UNDER 6 MONTHS: ASK A DOCTOR.

OTHER INFORMATION

- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN.
- YOU MAY REPORT A SERIOUS ADVERSE REACTION FROM USING THIS PRODUCT TO 1-800-984-KATE ON WEEKDAYS 9 A.M.-5 P.M. PST.

INACTIVE INGREDIENTS

ALCOHOL DENAT., ISOBUTANE, PROPANE, ISODODECANE, ETHYLHEXYL METHOXYCRYLENE, PVP, METHYL DIHYDROABIETATE, HYDROLYZED HYALURONIC ACID, RHODIOLA ROSEA ROOT EXTRACT, KATER/AQUA/EAU, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, SILICA SILYLATE, PENTYLENE GLYCOL



UNCOMPLIKATED MAKEUP SETTING SPF 50			
avobenzone, homosalate, octisalate, octocrylene, oxybenzone aerosol, spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43479-208
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	3 g in 100 g

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ISOBUTANE (UNII: BXR49TP611)	
PROPANE (UNII: T75W9911L6)	
ISODODECANE (UNII: A8289P68Y2)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
HYALURONIC ACID (UNII: S270N0TRQY)	
RHODIOLA ROSEA ROOT (UNII: 3S5ITS5ULN)	
WATER (UNII: 059QF0K00R)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
SILICA, TRIMETHYLSILYL CAPPED (UNII: VU10KU4B9S)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43479-208-41	96 g in 1 CAN; Type 0: Not a Combination Product	11/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/18/2018	

Labeler - KATE SOMERVILLE SKINCARE LLC (615155533)

Establishment

Name	Address	ID/FEI	Business Operations
KIK Piedmont LLC		884802658	manufacture(43479-208)

Revised: 2/2019

KATE SOMERVILLE SKINCARE LLC