# SACHEU SPOT ERASER- benzoyl peroxide lotion Sacheu Beauty 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.

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#### Sacheu Spot Eraser

**Drug Facts** 

# **Active Ingredients**

Benzoyl Peroxide (2.5%)

### Purpose

Acne Medication

#### Uses

• For the treatment of acne

## Warnings

**For external use only. Do not use** if you have very sensitive skin or are sensitive to benzoyl peroxide.

**When using this product** skin irritation and 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. Avoid unnecessary sun exposure and use a sunscreen. Avoid contact with the eyes, lips, and mouth. Avoid contact with hair and dyed fabrics, which may be bleached by this product. Skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Stop use and ask a doctor if irritation becomes severe.

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

### Directions

- Clean the skin thoroughly before applying this product
- Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with on 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.
- If going outside, apply sunscreen after using this product. If irritation or sensitivity

develops, stop use of both products and ask a doctor.

# Inactive Ingredients

Water (Aqua), Kaolin, Bentonite, Propylene Glycol, Hydroxyethyl Behenamidopropyl Dimonium Chloride, Butyrospermum Parkii (Shea) Butter Extract, Magnesium Aluminum Silicate, Euphorbia Cerifera (Candelilla) Wax, Xanthan Gum, Allantoin, Bisabolol, Caprylyl Glycol, Sodium Citrate, Phenoxyethanol, Ethylhexylglycerin.

imported/distributed by Gloss Brands Europe with offices at Keizersgracht 391a, Amsterdam, 1016EJ, Noord Holland, The Netherlands.

imported/ distributed by Gloss Brands LLC with offices at 3381 Robertson Place, Los Angeles, CA, 90034, USA.

#### **PRINCIPAL DISPLAY PANEL - 15 ml Tube Carton**

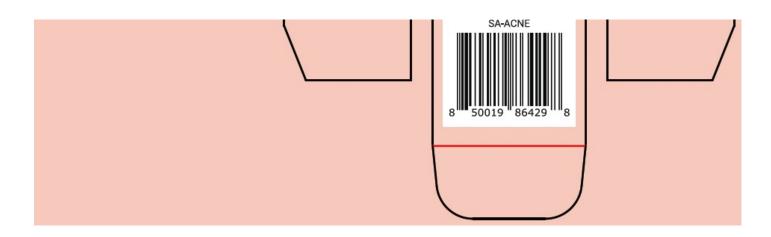
spot eraser

blemish drying lotion

0.5 fl oz / 15 ml

SACHEU

FSC This box is made with FSC Exc Excloard. The tube inside is made with eco-friendly post- consumer recycled materials.			
Spot eraser blemish drying lotion séchante pour les imperfections	Description of the second s	DRUG FACTS Active Ingredients Benzoyl Peroxide 2.5% Purpose Acne Medication Use for the treatment of acne WARNINGS For external use only. Do not use if you have very sensitive skin or are sensitive to benzoyl peroxide. When using this product skin irritation and 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. Avoid unnecessary sun exposure and use a sunscreen. Avoid contact with the eyes, lips, and mouth. Avoid contact with hair and dved fabrics, which may be bleached by this product. Skin irritation may occur, characterized by redness, burning, itching peeling, or possibly swelling, Irritation may be reduced by using the product less frequently or in a lower concentration. Stop use and ask a doctor if irritation becomes severe. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control center right away. DRECTIONS Clean the skin thoroughly before applying this product is swallowed and the secons to the or or the entire affected area with a thin layer one to three times daily. Because excessive dying of the skin may occur, start with one application daily, then gradually increase to two or or three times daily if needed or a directed by a doctor. If bothersome dryness or peeling occurs, reduce application to or orce a day or every other day. If is top use of both product. If initation or sensitivity develops, start with one application to orce a day or every other day. If pothersome dryness or peeling occurs, reduce application to orce a day or every other day. If pothersome dryness or peeling occurs, reduce application to orce a day or every other day. If pothersome dryness or peeling occurs, reduce application to orce a day or every other day. If pothersome dryness or peeling occurs, reduce application to orce a day or every other day. If pothersome dryness or peeling occurs, reduce application to orce a day or or proble day. Bento- nite, Propylene Glycol	FAITS SUR LES MÉDICAMENTS Ingrédients actifs Peroxyde de benzoyle 2,5% Objectif Médicaments contre l'acné Utilisation pour le traitement de l'acné MESE EN GARDE Pourusage externe uniquement. Ne pas utiliser si vous avez la peau très sensible ou si vous êtes sensible au peroxyde de benzoyle. Lors dellutilisation de ce produit, une imitation et une sécheresse de la peau sont plus susceptibles de se produire si vous utilisez un autre médicament topique contre l'acné en même temps. En cas diritation, mutilisez qu'un seul médicament topique contre l'acné en même temps. En cas diritation, mutilisez qu'un seul médicament topique contre l'acné el la fois. Evitez l'exposition inutile au soleil et utilisez un écran solaire. Eviter tout contact avec les yeux, les lèvres et la bouche. Éviter tout contact avec les quex, les lèvres de la bouche. Éviter tout contact avec les du soleil et utilisez un écran solaire. Eviter tout contact avec les du soleil et utilisez un écran solaire. Eviter tout contact avec les de se produites par des rougeurs, des brûlures, des démangeaisons, une desquamation ou éventuelle- ment un gorflement L'irritation peut être réduite en utilisant le produit moins fréquemment ou à une concentration plus faible. Arrêtez l'utilisation et demandez à un médecin si limitation devient grave. Tenir hors de porte des enfants. Si le produit est avalé, obtenir de l'aide médicale ou contacter immédiatement un centre antipoison. DIRECTIONS Nettoyez solis pusement la peau avant d'appliquer ce produit. Couvri toute la zone affectée d'ine fine couche une à frois fois parjour. Comme un dessèche- ment excessif de la peau peut survenir, comme une dessoches ment excessif de la peau peut survenir, comme une sensibilité se développe, anêtez l'utilisation des deux ou trois fois parjour ou tous les deux jours. Si vous sortez, appliquez un écran solaire après avoir utilisé ce produit. Si un eintation ou une sensibilité se développe, anêtez l'utilisation des deux
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benzoyl peroxide lotion						
Product Information						
Product Type HUMAN OTC DRUG Item Code (Source)				NDC:83101-004		
Route of Administration TOPICAL						
Active Ingredient/Active	e Moiety					
Ing	redient Name		Basis o Streng		Strength	
BENZOYL PEROXIDE (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM) BENZOYL PEROXIDE -				ROXIDE	2.5 g in 100 mL	
Inactive Ingredients						
Ingredient Name				Strength		
WATER (UNII: 059QF0KO0R)				65.0188 g in 100 m		
KAOLIN (UNII: 24H4NWX5CO)				19 g in 100 mL		
BENTONITE (UNII: A3N5ZCN45C)				6 g in 100 mL		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					3 g in 100 mL	
HYDROXYETHYL BEHENAMIDOPROPYL DIMONIUM CHLORIDE (UNII: 9CO8OUL4TH)				1.32 g in 100 mL		
SHEA BUTTER (UNII: K49155WL9Y)					0.88 g in 100 mL	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)					0.6 g in 100 mL	
CANDELILLA WAX (UNII: WL0328HX19)					0.55 g in 100 mL	
XANTHAN GUM (UNII: TTV12P4NEE)					0.13 g in 100 mL	
ALLANTOIN (UNII: 344S277G0Z)				0.0003 g in 100 mL		
LEVOMENOL (UNII: 24WE03BX2T)				0.0003 g in 100 mL		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)					0.0003 g in 100 mL	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				0.0003 g in 100 mL		
PHENOXYETHANOL (UNII: HIE492ZZ3T)					0.86 g in 100 mL	
PHENOXYETHANOL (UNII: HIE49	922231)			0.00 g	III 100 IIIL	

# Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
- <b>-</b> -	NDC:83101-004- 01	15 mL in 1 TUBE; Type 0: Not a Combination Product	11/30/2022			
	Marketing Information					
Μ	larketing l	nformation				
Μ	larketing l Marketing Category	nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	Marketing Category	Application Number or Monograph	-	-		

Labeler - Sacheu Beauty Inc. (118824244)

**Registrant -** Product Society LLC (118666329)

Establishment					
Name	Address	ID/FEI	Business Operations		
Product Society LLC		118666329	MANUFACTURE(83101-004), PACK(83101-004), LABEL(83101-004)		

Revised: 12/2022

Sacheu Beauty Inc.