

### Product Overview - 4900C

## SalSphere<sup>®</sup> Benzoyl Peroxide (SS BPO)

A stable and targeted delivery system of benzoyl peroxide for the treatment of acne.

BPO is an FDA-approved acne treatment to clear pores and eradicate P. acnes bacteria. However, it is also difficult to formulate with due to its poor water solubility and high instability. Additionally, while it is a proven antibacterial agent with clinical success, it often results in dryness and discomfort.

One of the major obstacles in enhancing the efficacy of BPO and minimizing the potential for skin irritation is its large particle size (Figure 2A). This characteristic hinders its ability to penetrate the hair follicles and kill P. acnes bacteria. SS BPO is designed to enhance the acne treatment and tackle these issues.





UNIQUE FEATURES

#### **1** READY FOR FORMULATION

Improved stability and encapsulation provides a safe, quick, and easy way to formulate acne solutions.

#### 2 TARGETED DELIVERY

SalSphere<sup>®</sup> technology is designed to deliver BPO where it is needed most in the hair follicles.

#### **3** GENTLE, SLOW RELEASE

With controlled release technology, SS BPO is gentle on the skin. The Repeat Insult Patch Test (RIPT) for SS BPO shows that it is a non-primary irritant, making it suitable for sensitive skin.



Figure 2: Free BPO (A) and SS BPO (B) dispersed into identical lotion bases (5% BPO) at 42°C. Photographs taken at 100x magnification to show the particle sizes.

#### HOW THE TECHNOLOGY HELPS YOU

SS BPO is a sub-micron encapsulation system of benzoyol peroxide (Figure 1, 3). The small particle size of the technology is designed to facilitate the targeted delivery of benzoyl peroxide into the follicles. Upon application of the product, the sub-micron spheres adhere to the pimples, where they will dissolve and slowly release BPO directly into the hair follicles.

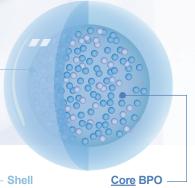


Figure 1: The sub-micron structure of SS BPO, with the BPO infused within the core.



SS BPO raw







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EFFECTIVE	Sample	P. acnes Kill Rate (	P. acnes Kill Rate (%)		
AGAINST	SalSphere <sup>®</sup> BPO Cream	82.22	82.22		
P. ACNES	Traditional BPO Cream	76.09			
	Table 1: An in-vivo bacterial kill study was perfor   within an 8-hour time frame. P. acnes kill rates or	d to determine the ability of SS BPO to kill P. acnes bacteria compared to free BPO an 8-hour period (n=18).			
ENHANCED DEPOSITION: RINSE-OFF	SalSphere® technology provides enhanced deposition of BPO onto the skin from rinse-off products, a critical feature in prolonging treatment and increasing efficacy. Deposition of SS BPO was compare to market competitors in a rinse-off application (Figure 3).	Ad A A A A A A A A A A A A A A A A A A	Bonderee Bon	BPO resides on the skin strating that the time release	
IMPROVED STABILITY AND SHELF LIFE	SalSphere® technology protects BP thus extending its potency, shelf life and stability (Figure 6). SalSphere® BPO 10% National Brand BPO 10%	BD Concentration BD Concentra			
	Days in Accelerated Stability (42°C)   Figure 5: Effect of SalSphere® encapsulation on BPO content in a lotion compared				
PARTICLE SIZE	SalSphere® BPO to free BPO (10%) in a lotion at 42°C.				
		TECHNICAL	Appearance@20°C	Opaque liquid	
	<b>S</b> <b>S</b> <b>S</b> <b>S</b> <b>S</b> <b>S</b> <b>S</b> <b>S</b> <b>S</b> <b>S</b>		Applications	Creams, lotions, spot treatments, and facial cleansers	
	Particle Diameter (µm)		Color	White to off-white	
	Figure 3: Particle size distribution analysis perfo on Beckman Coulter LS13320 Laser Diffraction		Odor	Characteristic	
	Particle Size Analyzer using a liquid diffraction m	odule.	pH (1 % solution)	4.5 ± 1.5	
FORMULATION	Ingredients (W/W	%)	BPO Assay (HPLC) (Wt.%)	≥ 24.0	
	SalSphere <sup>®</sup> 20		Shelf Life (months)	36	
	Benzoyl Peroxide		Usage Level (wt%)	10-40	
	Salvona Pre-Mix B79Preservative1		Storage (°C)	Closed container at 12-32°	