SALVONA®
ENCAPSULATION TECHNOLOGIES

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April 20, 2026

Subject: Safety (Suitability for Pregnancy Use) Statement for SalSphere® Even Skin, 8894-04

To Whom It May Concern,

We, at Salvona LLC d/b/a Advanced Beauty Labs, hereby certify that to the best of our knowledge and based on information provided by our raw material suppliers, the product SalSphere® Even Skin, 8894-04 contains Salicylic Acid, which is officially classified as Reproductive Toxicity Category 2 (H361: Suspected of damaging fertility or the unborn child) under OSHA-aligned GHS (Globally Harmonized System) classifications and European regulation (CLP).

Salicylic Acid is the only ingredient in this product classified with this specific hazard. Please note that while our product's Safety Data Sheet (SDS) carries the H361 hazard statement, this is because our product is a concentrated raw material intended for professional use and further dilution. According to GHS and CLP guidelines, at a finished product usage level containing < 3% Salicylic Acid, the final mixture does not typically trigger an H361 classification. It remains the sole responsibility of the final product manufacturer to conduct proper safety assessments to ensure that their specific finished product is safe for its intended use and complies with all regional regulatory requirements.

Please find below publicly available scientific consensus regarding the safety of topical Salicylic Acid use during pregnancy:

1. The ACOG Consensus (Clinical Authority)

The American College of Obstetricians and Gynecologists (ACOG)—the leading authority on pregnancy care in the US—specifically lists topical Salicylic Acid as a safe option for treating acne during pregnancy.

- Safety Threshold: They generally categorize over-the-counter (OTC) topical products (which are limited to 2% by the FDA) as safe because systemic absorption is minimal.
- Reference: *ACOG Practice Bulletin No. 124: Acne Treatment During Pregnancy.*

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2. SCCS Final Opinion (EU Regulatory Authority)

The Scientific Committee on Consumer Safety (SCCS), which advises the European Commission, conducted an extensive safety assessment (SCCS/1601/18 and updated in SCCS/1646/22).

- Conclusion: They concluded that Salicylic Acid is safe for use in cosmetic products at a maximum concentration of 2.0% in leave-on products (excluding body lotions in some contexts) and 3.0% in rinse-off products.
- The Findings: The study emphasizes that while high *oral* doses of salicylates (like aspirin) show toxicity in animal models, the *topical* application at these levels results in negligible systemic exposure, posing no significant risk to human health or pregnancy.

3. Summary of Systemic Absorption

Toxicological studies show that only approximately 3% to 6% of topically applied Salicylic Acid is absorbed systemically. This is a trace amount compared to the oral doses that originally triggered the Category 2 Reproductive Toxicant classification in laboratory settings.

> **Manufacturer's Recommendation:** While the science supports safety up to 2%, we recommend that pregnant individuals consult their physician to confirm that a high-strength (2%) leave-on treatment is appropriate for their specific skin health and pregnancy stage.

As part of our commitment to producing safe, high-quality, and compliant personal care products, we actively work with our suppliers to ensure transparency and avoid the inclusion of materials that may be of concern to consumers and regulatory bodies.

Should you require any additional documentation or have further questions, please feel free to contact us directly.

Sincerely,



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