

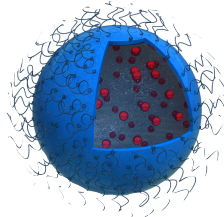
# SalSphere™ Salicylic Acid 30

PID #8248

U.S. Patent #6979440

## Effective Acne Treatment from a Clear Application

**SalSphere™ Salicylic Acid 30** is a time release delivery system designed to treat acne from a clear rinse-off application, such as facial wash and clear gels. The technology allows for the utilization of a pre-manufactured blend of Salicylic Acid (SA) that is able to be suspended in a clear base.

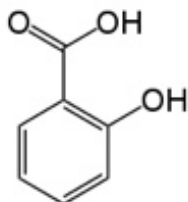


**Fig. 1:** Structure of SalSphere™ Salicylic Acid 30.

Salicylic Acid is a white crystalline powder, or needle-shaped crystals, with a benzene ring and two neighboring functional groups. SA is poorly soluble in water (0.2 g/100 ml at 20°C), but is soluble in acetone, ether, alcohol, and other organic solvents.

Despite its poor solubility, SA is widely used as a medication for acne because of its ability to clear out clogged pores.

The first challenge for use in a commercial application, then, is dissolving SA into a water-based, anti-acne emulsion. A secondary challenge that exists for all acids used in personal care, is how to delivering the acid to the skin in an effective form without causing irritation. The traditional solution has been to titrate a formulation with a base such as NaOH. The resulting reaction of the NaOH and SA, however, forms a salt that is minimally effective in treating acne.



**SalSphere™ Salicylic Acid 30** addresses both of these issues by employing a unique delivery system designed to slowly release the SA over time from small vesicles called sub-micron spheres. These tiny, hydrophobic spheres encase the SA and suspend it in an aqueous medium via a cationic outer shell. Once applied to skin, the cationic charge anchors the sphere while the hydrophobic matrix gradually breaks down and releases the SA, in a controlled manner, over time.

### Clear Products: Suspending Salicylic Acid

**SalSphere™ Salicylic Acid 30** is a water-based product that is easily incorporated into an aqueous face wash or gel. This feature eliminates the need to dissolve the SA in organic solvents, alcohol, or surfactants that can harm the skin and cause additional irritation to skin that is already inflamed.



(A)

(B)

**Fig. 2:** SalSphere™ Salicylic Acid 30 is clear as a raw material (A) and also in a facial cleanser at 2% SA (B). 100% of the particles have a diameter of <0.1 micron.

### Applications:

-Recommended mostly for rinse-off products, body wash, shampoos used as cleansers, smoothing, anti-aging, acne (OTC).

### INCI names:

Cocamidopropyl Dimethylamine (and) Salicylic Acid (and) Water (and) Polysorbate 80 (and) Phenoxyethanol (and) Ethylhexylglycerin (and) Carthamus Tinctorius (Safflower) Seed Oil (and) Olea Europaea (Olive) Fruit Oil

### Product Specification:

**Appearance:** Emulsion

**Color:** Pale Yellow to Brown

**Odor:** Odorless

**Payload:** 30% (Assay, HPLC)

**pH @ 1 wt% SA in water:** 4.0 +/- 0.5

**Solid (%):** 90-97

**Storage:** Closed container, room temp.

**Shelf Life:** 12 Months (Closed @ 25°C)

**Solubility:** miscible in water



Version 4.19.11



### Guide Formula for Cleanser

	Ingredients	INCI	wt %
A.	DI Water	DI Water	61.64
	SalSphere™ SA 30	Cocamidopropyl Dimethylamine (and) Salicylic Acid (and) Water (and) Polysorbate 80 (and) Glyceryl Stearate (and) Phenoxyethanol (and) Ethylhexylglycerin (and) Carthamus Tinctorius (Safflower) Seed Oil (and) Olea Europaea (olive) Fruit Oil	6.66
B.	Mackadet EQ-163	Sodium C14-16 Olefin Sulfonate (and) Cocamidopropyl Betaine (and) Cocamide DEA (and) Sodium Laureth Sulfate (and) DMDM Hydantoin	30.00
	Mackstat DM	DMDM Hydantoin	0.40
	AE Protek	Phenoxyethanol/ Ethylhexylglycerin	1.00
C.	Sodium Chloride	Sodium Chloride	0.30
			100

#### Instructions:

1. Combine Phase A and mix well
2. Combine B and add to A while mixing. Control foaming by regulating the speed.
3. Add Sodium Chloride to adjust viscosity.
4. Some Foaming may result after mixing. This is a temporary state that will disappear within 1 hour.

### Skin-friendly pH: Slow release of SA

The structure of SalSphere™ Salicylic Acid 30 provides a slow release of Salicylic Acid, in its most potent form, over time. Delivering the Acid in this controlled form allows the skin to re-balance its pH a short time after coming in contact with the acid. The result is a skin pH that does not drop into a range that could cause irritation (figure 4).

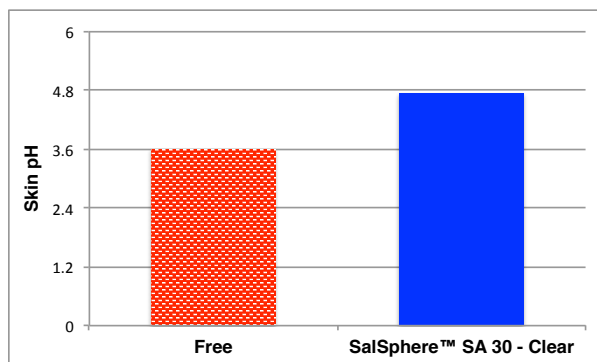
#### Skin Study: pH Post Application

Skin pH is typically used as a criteria to predict the possible irritation capacity of a product. A pH of 4.5 is considered to be safe for sensitive skin.

Volunteers washed their forearms with two different cleansers. The cleanser used on one arm contained a commercial formula using Free (non-encapsulated) Salicylic Acid, while the cleanser on the other arm contained SalSphere™ Salicylic Acid 30 technology. The pH of the skin was tested with a skin pH meter (figure 3), and the results appear below (figure 4).



**Fig. 3:** Skin pH was measured using Hanna, HI99181 Skin pH meter following application and rinse-off of the washes on the forearms.



**Fig. 4:** Skin pH post treatment with encapsulation technology is 4.7, compared to 3.5 when washed with free Salicylic Acid. SalSphere™ Salicylic Acid 30 is a skin-friendly solution.