

# Leading Edge Innovations LLC

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## Leading Edge Innovations' Advanced Technology Enhances Physical Properties and Increases SPF in Organic and Inorganic Sunscreen Formulations vs. Control Formulations.

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## PRODUCT/SERVICE BACKGROUND INFORMATION

Leading Edge Innovations (LEI) is a premiere formulator of skin care cosmetics, personal care and OTC products, helping brands meet the needs of an ever-evolving beauty market.

Leading Edge Innovations' exclusive **MicroSperse® Technology** process is a unique and proprietary formulating technology which results in outstanding products with superior aesthetics. LEI's technology virtually eliminates the need for traditional surface-active agents that often disrupt the skin's fragile barrier properties. Many LEI customer partners have won best in category awards products that were born in the laboratories of the Leading Edge Innovations Technical Center in Branchburg, New Jersey, USA.

**MicroSperse® Technology** provides an innovative alternative to conventional surfactant-based methods of making oil-in-water emulsions. The novel physical interactions of the **MicroSperse® Technology** high-pressure, high-shear process replace chemical emulsifiers that often result in irritation, dryness and degradation of formula actives which can affect efficacy. This innovation is profound for products targeting consumers with compromised skin, sensitive skin, acne and other dermatological challenges. In addition to imparting enhanced efficacy and higher SPF values, this innovation is ideal for formulations that have an innate irritation potential by reducing or removing the need for traditional emulsifiers, reducing the amount of preservative required and eliminating the need for alcohol containing ingredients (such as generally insoluble botanicals). **MicroSperse® Technology**'s particle size reduction is dramatic, from 1/10th to 1/50th the size, when compared to those produced by conventional emulsification techniques – making it ideal for cosmetics, personal care and OTC topical drug product platforms.

The **MicroSperse® Technology** is a registered trademark belonging to Leading Edge Innovations. It's novel collection of benefits are as follows:

- Virtually eliminates the need for traditional chemical emulsifiers and surfactants
- Increases product quality, efficacy and stability
- Enables a limitless number of product forms
- Reduces use of preservatives
- Does not cause degradation of active ingredients
- Enhances skin's natural barrier properties

- Delivers an aesthetically superior feel
- Significantly reduces skin irritation
- Complies with all federal guidelines and regulations
- Employs natural and environmentally sustainable materials
- Results in a lower carbon footprint

**MicroSperse® Technology** is highly versatile and applicable in every personal care category including but not limited to cleansing, treatment, skin care, sun care, hair care, make-up, foot care and wound care. The end product of this technology is a dispersion of hydrophobic material, oil or oil soluble material, , where the hydrophobic material is reduced into a highly uniform distribution of very small droplets within an aqueous-continuous phase. The resulting Dispersion of hydrophobic material has different attributes than when the same hydrophobic material is used in an emulsion. Without the interference of a traditional emulsifier, the hydrophobic material within the Dispersion retains more of its native properties. The Dispersions of different hydrophobic mixtures can be effortlessly combined in any ratio to create virtually unlimited aesthetic experiences and a luxurious feel which is consumer appealing. Product aesthetics are significantly improved over standard emulsified products. This aspect is why many customers have launched award-winning products utilizing **MicroSperse® Technology**. LEI has many off-the-shelf solutions ready for market, but collaboration projects for unique prototypes are the company's specialty.

### WHAT IS THE COMPANY INTRODUCING TO THE MARKET/INDUSTRY?

Leading Edge Innovations is launching a complete line of commercially available reef-friendly, derm-friendly high SPF mineral suncreens which are powered by LEI's **MicroSperse® Technology**. This launch includes several generations of stability-tested and SPF tested products for face and body including a Hawaii compliant variant, a USVI compliant version and twelve base sunscreens using organic and inorganic sunscreen actives to yield SPF30 to SPF50. LEI's **MicroSperse® Technology** creates luxurious feeling, cost-effective formulas to help brands target mass market, masstige and prestige consumer segments. These innovations are for everyday use as well as periods of intense sun exposure. Formulas can be customized under the guidance of LEI's expertise.

### HOW WILL THIS NEW PRODUCT/SERVICE IMPACT THE INDUSTRY (BENEFITS)?

**MicroSperse® Technology** boosts SPF and enhances sun care performance. Helping brands achieve compliant products in the face of changing regulatory while delivering efficacy and superior aesthetics is a a key aspect of LEI's offering. Furthermore, traditional products use chemical emulsifiers to allow the water and oil phases to come together. These emulsifiers change the properties of both the oil and the water to allow them to coexist. Since emulsifiers change the properties of the oils in the product, they will also change the properties of the natural oils that make up the skin's barrier when applied topically. Ultimately, they can cause the skin to become more porous. This lets more water out of the skin making it dry. In addition to water loss, porous skin let's unwanted materials in the cream or lotion (or from the environment) migrate into the skin which can cause irritation and elicit allergic responses. Current formulating practices may in fact decrease the performance efficacy of important physiological active ingredients. This is because many of these active ingredients are susceptible to the harsh prolonged heating conditions needed

for manufacturing, especially when exposed to air, where oxygen can degrade the integrity of the chemical bonds rendering them valueless. Further, the emulsifier by definition changes the nature of the hydrophobic materials so that they do not manifest the true potential of the active or they change the penetration rate of the active reducing its availability at the site of the skin where they are needed the most.

Leading Edge Innovations has developed a technique for combining high levels of oils (and other hydrophobic materials) and water without the need for traditional chemical emulsifiers and other chemical stabilizing agents. In fact, elegant, high performing final formulations can be made with fewer than 10 ingredients. LEI's process uses physics to make small particles (Typically 150-300nm) of the hydrophobic materials. The process imparts a small negative charge on the particles and the small droplets repel one another like two negative ends of a magnet and spread throughout water phase to make a "Dispersion" not an emulsion. As a result, they are very stable. This process is powered by air and utilizes a cold process to preserve the integrity of the oils, the active materials that are added, and the environment. These dispersed oils have totally different aesthetic and performance properties than the same oils when they are emulsified. Hydrophobic actives are exposed to the process for less than a milli-second so they are not subjected to extended degrading conditions. Further, the absence of traditional emulsifiers maintains the integrity of the active ingredient in its pure biologically-active state. Additionally, therapeutic agents can be placed in one of the many novel delivery systems that have been developed for pharmaceuticals. Most of these delivery systems are unstable in the presence of surface-active agents, but they maintain their integrity in formulas prepared with MicroSperse® Technology. Greater efficacy without irritation can be achieved by chaperoning the active into the skin while keeping unwanted agents in the base from entering. Efficacy is improved while irritation is minimized.

The MicroSperse® Technology is particularly relevant for sunscreens. The SPF value of sunscreens made using both the chemical and physical UV filters is enhanced by the small particle size increasing the surface area of the UV filters by a factor of over 320 times the surface area of an emulsified particle. The lack of traditional emulsifier permits the application of a uniform film that maximizes the UV protection by increasing the concentration of UV filters in a more continuous film and by retaining the sunscreen at the surface of the skin where it can enhance efficacy against UVB and UVA radiation. The MicroSperse® Technology process permits the generation of high SPF values with lower levels of certain UV filters such as TiO<sub>2</sub>. ZnO and the organic UV filters. Additionally, the absence of a strong emulsifying agent creates a hydrophobic film that is often resistant to removal by water. The hydrophobicity of the film possesses a high interfacial tension between the UV filter and water making the sunscreen difficult to remove from the skin. Further, the aesthetic properties are improved because the process makes the UV filters feel lighter, less oily, and without perceptible whitening and residue. The improved aesthetics makes the product consumer appealing and helps with the application of the functional level of sunscreen, all resulting in greater overall customer compliance and skin health. LEI is open to collaboration with customers and brands to help improve their products through better aesthetics, improved efficacy and enhance the prospect of improved skin health.