SunSpheresTM SPF Boosters

Hollow sphere technology for more aesthetically pleasing formulations at higher SPF



SunSpheres™ SPF Boosters are built on a unique hollow sphere technology that enables greater SPF efficiency* in sun care and daily wear SPF products. The hollow spheres raise the UV protection over the whole UVA/UVB spectrum, working equally well with organic and inorganic actives. SunSpheres™ SPF Boosters ease of use, wide compatibility, cost effectiveness and favorable aesthetic properties make them a desirable ingredient for SPF containing formulations.

A cost-effective solution: use less UV actives

The ability of SunSpheres™ SPF Boosters to raise the efficacy of UVA/UVB filters in formulations allows the formulator to use significantly less UV actives to deliver the same level of SPF, or to deliver a higher SPF for a given level of UV actives. As an extra benefit, potential irritation caused by these actives is reduced, and the formulator is able to create more aesthetically-pleasing products.

Product line summary

Product	Product INCI/CFTA name Form		Average % polymer solids
SunSpheres™ Powder	Styrene/Acrylates Copolymer	Free flowing powder, contains 10% fatty acid ethoxylate	90.0%
SunSpheres™ PGL Polymer	Styrene/Acrylates Copolymer	Aqueous emulsion, no preservative contains low molecular weight glycol	25.5%
SunSpheres™ LCG Polymer	Styrene/Acrylates Copolymer	Aqueous emulsion, contains chloromethylisothiazolone and methylisothiazolone	27.0%

^{*}SunSpheres™ SPF Boosters are not UV active ingredients



Features and benefits

Feature	Benefit
Increases the efficiency of UV filters, both organic and inorganic	Reduces the amount of UV filters needed to provide target protection levels, which can improve formulation feel and lower the risk of skin or eye irritation
Increases UVA absorbance	Helps provide more complete UV protection
Available in powder and liquid formulations	Provides flexibility for different production needs
Suitable for a wide range of formulations (O/W, W/O, W/Si, low viscosity pumps, creams and lotions, stick formulations)	Allows use across multiple formats for beach and daily wear
Predictable performance, 11 to 15% boost in SPF per 1% Solids of SunSpheres™ Polymer	Helps formulator select the level of SunSpheres™ Polymer needed to obtain protection objectives

Physical and chemical characteristics

Typical Properties	SunSpheres™ Powder	SunSpheres™ PGL Polymer	SunSpheres™ LCG Polymer (Not available in Europe)
Appearance	White powder	Milky, white liquid	Milky, white liquid
Active, percent	88 – 90	24.5-26.5	26 – 28
Solvent	Not applicable	Water	Water
pH (1% dispersion in water)	10.0 – 11.0	6.5-7.5	6.5 – 7.5
Bulk density	0.22 - 0.32	Not applicable	Not applicable
Viscosity	Not applicable	< 100 cps (Brookfield, LVT#2, 60 rpm)	< 100 cps (Brookfield, LVT#2, 60 rpm)
Residuals Total acrylates Styrene	< 100 ppm < 35 ppm	< 100 ppm < 35 ppm	< 100 ppm < 35 ppm

 $^{^{\}star}$ The values presented in this chart should not be considered as product specifications.



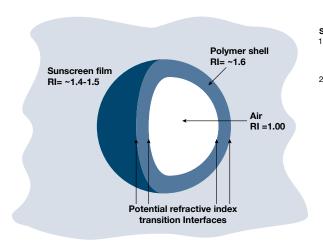
Applications

SunSpheres[™] SPF Boosters can be used in a wide range of sun care and daily wear SPF products containing UV active ingredients.

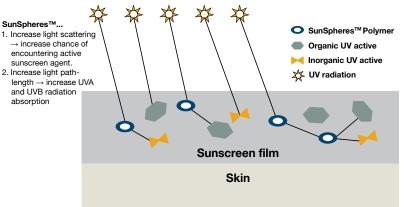
- · Organic and inorganic UVA and UVB actives
- · Oil-in-Water, Water-in-Oil and Water-in-Silicone systems
- Cold- and hot-processable systems
- · Low viscosity spray systems
- · Crème and lotion formulations
- · Stick formulations, lip balms
- Makeup (Foundation, BB Creams, etc.)

How it works

Light refraction via hollow sphere technology



Basic concept of SunSpheres™ SPF Booster



Model for UV Scattering by the SunSpheres™ Polymer Within a Sunscreen Film

As radiation passes through material of one refractive index into a material of another refractive index, it is bent, or scattered. The presence of a large number of the SunSpheresTM Polymers in a formulation will therefore cause increased (and hence more efficient) scattering of radiation. A rough calculation demonstrates that because of the particle size and density of the SunSpheresTM product, there are about 10 to 20 trillion particles (scattering centers) per weight percent of solid polymer product added to a formulation.

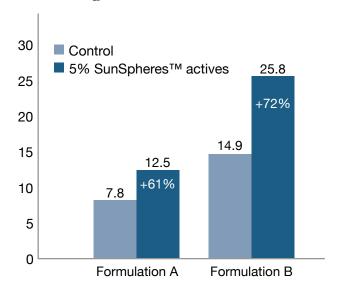
Having this large a number of particles in a sunscreen film or other cosmetic product (which concentrates 4 to 5 times as the film dries allows for efficient scattering of UV radiation through the film, thereby increasing the path-length. According to Beer's Law, the absorbance of the UV radiation is thus increased when an active ingredient is present, which leads to increases in the Sun Protection Factor (SPF) value of the formulation.

Proven performance

To test the efficacy of SunSpheres™ SPF Boosters in personal care applications, two different sunscreen formulas were prepared and evaluated in vivo. As shown in the graph below, even in these non-optimized systems, 5% solids of the SunSpheres™ SPF Booster clearly increased SPF by 60 to 70 percent.

Physical stability was also monitored weekly for three months, yielding a stable product and a stable boost.

Screening formulations: in vivo results



Formulation A is a relatively simple formulation containing low oil and utilizing an anionic emulsion system. The expected SPF of this formulation is 8. Sunscreen Formulation B is a more complex formulation with a nonionic emulsifier and an expected SPF of approximately 15. Neither of these formulas was designed to optimize the performance of the SunSpheresTM SPF Booster. They were chosen based on their proven stability under the desired testing conditions.

Both screening formulations were tested for static SPF using the in vivo protocol specified in the Food and Drug Administration's (FDA's) Final OTC Monograph (21 CFR Parts 310, 352, 700 and 740, May 21, 1999). Each sunscreen contained 5% solids SunSpheres™ SPF Booster.

Sunscreen Formulation A with 6% Ethylhexyl methoxycinnamate and 1% Benzophenone 3

Phase	Ingredients	Control %w/w	Test %w/w
	Water, DI	80.72	62.22
	ACULYN™ 33 Rheology Modifier	3.33	3.33
Α	Glycerin	1.00	1.00
	Tetrasodium EDTA	0.10	0.10
	SunSpheres™ LCG Polymer	0.00	18.50
	Ethylhexyl methoxycinnamate	6.00	6.00
	Benzophenone 3	1.00	1.00
В	C12-15 alkyl lactate	2.00	2.00
Б	PVP/eicosene copolymer	1.50	1.50
	Cyclomethicone	2.00	2.00
	Stearic acid	1.50	1.50
С	Triethanolamine	0.85	0.85

Sunscreen Formulation B with 7.5% Ethylhexyl methoxycinnamate, 2% Benzophenone 3 and 3% Ethylhexyl salicylate

Phase	Ingredients	Control %w/w	Test %w/w
	Water, DI	71.70	53.20
Α	PVM/MA decadiene crosspolymer	0.50	0.50
А	Butylene glycol	3.00	3.00
	SunSpheres™ LCG Polymer	0.00	18.50
	PEG-20 stearate	1.50	1.50
	Glyceryl stearate & laureth-23	2.00	2.00
	Octyldodecyl neopentanoate	1.00	1.00
В	Ethylhexyl palmitate	2.00	2.00
D	Glyceryl dilaurate	0.50	0.50
	Ethylhexyl methoxycinnamate	7.50	7.50
	Benzophenone 3	2.00	2.00
	Ethylhexyl salicylate	3.00	3.00
	Sodium hydroxide, 10%	1.30	1.30
С	Glyceryl polymethacrylate & propylene glycol	3.00	3.00
	Glyceryl polymethacrylate & propylene glycol & PVM/MA copolymer	0.50	0.50
D	Diazolidinyl urea & iodopropynyl butylcarbamate	0.30	0.30
	Methylparaben	0.20	0.20



Compatibility with sunscreen and cosmetic ingredients

The SunSpheres™ Polymer has been evaluated with a variety of typical cosmetic ingredients. Based on the results of these studies, SunSpheres SPF Boosters have broad compatibility with ingredients used for personal care products, including organic and inorganic sunscreen actives, silicones, oils, esters, anionic and nonionic emulsifiers, thickeners, and water resistance polymers. There are, however, a few exceptions. In general, cationic ingredients should be avoided because the polymeric shell of the SunSpheres™ Polymer has a slight anionic charge that could interact with cationics. Associative rheology modifiers/thickeners should be tested individually for viscosity effects. Extraordinary viscosity increases have been observed with some associative thickeners. Adipates are known to be aggressive plasticizers for many polymers, and therefore it is recommended that SunSpheres™ SPF Boosters not be used in formulations containing these ingredients.

Formulation guidelines

Recommended use level:

1.0 - 5.0%, solids basis

For SunSpheres™ PGL Polymer and SunSpheres™ LCG Polymer

 Add the SunSpheres[™] PGL Polymer or SunSpheres[™] LCG Polymer into the water phase prior to emulsification and continue with formulating

For SunSpheres™ Powder:

- Add SunSpheres[™] Powder into the water phase, and, after addition of the oil phase, homogenize while hot (65°C) or
- Add SunSpheres[™] Powder into the water phase, 1% of an emollient from the formulation (isopropyl myristate,isopropyl palmitate, or similar) and homogenize either while hot (65°C), or during the emulsification step, or
- If the SunSpheres[™] Powder is going to be used in an anhydrous product (e.g. stick, lip balm), add a small amount of a more polar oil, and homogenize. In some cases, a small amount of water (<0.5%) may help.



Formulation guidelines continued

Cold-processed formulations

SunSpheresTM PGL Polymer is recommended for cold-processed formulations since it is a low viscosity emulsion and can be easily incorporated into formulations. SunSpheresTM PGL Polymer and SunSpheresTM LCG Polymer should be incorporated and dispersed in the aqueous phase after dissolution of any water-soluble solids and prior to emulsification.

Heat-processed formulations

Both SunSpheres[™] PGL Polymer, SunSpheres[™] LCG Polymer and SunSpheres[™] Powder are recommended for heat-processed formulations. SunSpheres[™] PGL Polymer and SunSpheres[™] LCG Polymer can be incorporated into a formulation during the cool down stage of the emulsion, as long as the viscosity of the product is not too high (> 30,000 cps). SunSpheres[™] Powder is best incorporated either in the aqueous phase or the oil phase prior to forming the emulsion. Formulations with SunSpheres[™] Powder should include homogenization during processing and the addition of heat. Heating to 50°C facilitates processing.

Homogenization

SunSpheres[™] Powder, as supplied, is in the form of agglomerates, with a mean particle size of about 100 µ. The agglomerates must be broken down in the final formulation to liberate the primary SunSpheres[™] SPF Booster particles. If this step is not performed, the expected SPF performance boost will not be achieved, and a granular appearance will be observed in the formulation causing the emulsion to feel "gritty" when applied to the skin. To break down the agglomerates, a high shear process, such as, homogenization is recommended.

High and low viscosity emulsions

For low viscosity emulsions (<1000 cps), it is recommended that both SunSpheres[™] PGL Polymer, and SunSpheres[™] LCG Polymer and SunSpheres[™] Powder be incorporated at the end of the processing, i.e., at point of biocide addition using homogenization to fully disperse. Very viscous formulations will require extended mixing to ensure uniform dispersion of the SunSpheres[™] PGL Polymer, SunSpheres[™] LCG Polymer and SunSpheres[™] Powder.

High level of silicones and SunSpheres™ Powder

When formulating with high levels of silicones, it is best to blend SunSpheres[™] Powder into an oil phase containing aliphatic oils to avoid flocculation. SunSpheres[™] Powder can be either added to the water phase or dispersed in the non-silicone organic phase prior to preparing the emulsion, and then post adding the silicones.

Non-aqueous formulations and SunSpheres™ Powder

SunSpheres™ Powder is especially recommended for non-aqueous products, such as, sunscreen sticks and lip balms.



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The following formulations are provided as starting recommendations for a variety of sunscreen and daily wear product types.

Sunscreen formulation with 5% Titanium Dioxide						
Phase	Ingredients	Control % w/w	Test % w/w			
	Water, DI	74.50	63.39			
Α	Glycerin	2.00	2.00			
	Tetrasodium EDTA	0.10	0.10			
	Titanium dioxide & isononyl isononano- ate & polyglyceryl-6 polyricinoleate & stearic acid & aluminum hydroxide	10.00	10.00			
	Stearyl alcohol & ceteareth-20	1.00	1.00			
	PEG-20 stearate	0.50	0.50			
В	C12-15 alkyl benzoate	3.00	3.00			
	Ethylhexl palmitate	3.00	3.00			
	Sorbitan oleate	1.00	1.00			
	Dimethicone	1.00	1.00			
	Stearic acid	1.50	1.50			
С	Triethanolamine	0.40	0.40			
D	ACULYN™ 44 Rheology Modifier	2.00	2.00			
D	SunSpheres™ LCG Polymer	0.00	11.11			

Procedure:

- Combine the ingredients of phase A and with mixing, heat to 75°C.
- 2. Combine the ingredients of phase B separately and heat to 75°C with mixing.
- 3. Add phase B to phase A with homogenization at 75-80°C.
- 4. Switch to sweep mixing. Add phase C.
- 5. Begin to cool with mixing.
- 6. Add phase D individually with mixing.
- 7. Cool to room temperature with continual mixing.

An in vivo SPF test was conducted as specified in the Food and Drug Administration's (FDA) Final OTC Monograph (21 CFR Parts 310, 352, 700, and 740, May 21, 1999 protocol on a five person panel. The control formulation yielded an in vivo SPF value of 11, while the formulation with SunSpheres™ LCG Polymer had an in vivo SPF of 17. This is a 35% boost for 3% solids of the polymer.

Water-resistant sunscreen formulation						
Phase	Ingredients	Control % w/w	Test % w/w			
	Water, DI	67.85	49.35			
	Magnesium aluminum silicate	1.00	1.00			
	Carboxymethyl cellulose	0.50	0.50			
Α	Butylene glycol	3.00	3.00			
	Disodium EDTA	0.10	0.10			
	Glyceryl polymethacrylate & propylene glycol & PVM/MA copolymer	0.75	0.75			
	Glyceryl stearate & behenyl alcohol & palmitic acid & stearic acid & lecithin & lauryl alcohol & myristyl alcohol & cetyl alcohol	4.00	4.00			
	PVP/eicosene copolymer	1.00	1.00			
	Ethylhexyl palmitate	2.00	2.00			
_	Ethylhexyl methoxycinnamate	7.50	7.50			
В	Ethylhexl salicylate	3.00	3.00			
	Benzophenone 3	2.00	2.00			
	Tridecyl neopentanoate	3.00	3.00			
	Glyceryl dilaurate	0.50	0.50			
	Phenyl trimethicone	0.30	0.30			
	Cyclomethicone	3.00	3.00			
С	Diazolidinyl urea & lodopropynyl butylcarbamate	0.30	0.30			
	Methylparaben	0.20	0.20			
D	SunSpheres™ LCG Polymer	0.00	18.50			

Procedure:

- Combine the ingredients of phase A and with mixing, heat to 75°C.
- Combine the ingredients of phase B separately and heat to 75°C with mixing.
- 3. Add phase B to phase A with homogenization at 75-80°C.
- 4. Switch to sweep mixing and begin to cool.
- 5. At 45°C add phase C individually with mixing.
- 6. Add phase D with mixing.
- 7. Cool to room temperature with continual mixing.

SunSpheres[™] hollow spheres have minimal-to-no effect on the water resistance of water-resistant formulations. The test was conducted as specified in the Food and Drug Administration's (FDA) Final OTC Monograph (21 CFR Parts 310, 352, 700, and 740, May 21, 1999 protocol for determination of water resistance on a five person panel. The control, as expected, was determined to have an in vivo SPF of 17.4 prior to immersion and an in vivo SPF of 17.1 post-immersion. The sunscreen formulation containing SunSpheres[™] LCG Polymer gave a pre-immersion in vivo SPF of 27.6 (59% boost over control) and a post-immersion in vivo SPF result of 25.5, a 49% boost over the post-immersion control.

Water-in-oil	l sunscreen f	formulatio	n containin	g Zinc Oxid	le and
Titanium Di	oxide				

Phase	Ingredients	Control % w/w	Test % w/w
	Polyglyceryl-4 isostearate & cetyl PEG/ PPG 10/1 dimethicone & hexyl laurate	5.00	5.00
A	Dipentaerythrityl hexacaprylate /hexacaprate & tridecyl trimellitate & tridecyl stearate & neopentyl glycol dicaprylate/dicaprate	11.00	11.00
	Cyclomethicone	7.50	7.50
	Cetyl dimethicone	3.00	3.00
	Methyl glucose distearate	0.50	0.50
	Diethylhexyl malate	2.00	2.00
В	Zinc oxide	6.00	6.00
С	Titanium dioxide	6.00	6.00
D	SunSpheres™ Powder	0.00	5.00
F	Water, DI	55.70	50.70
E	ACULYN™ 44 Rheology Modifier	2.50	2.50
F	Sodium chloride	0.50	0.50
0	NEOLONE 950 Preservative	0.10	0.10
G	Methylparaben	0.20	0.20

Procedure:

- 1. Combine the ingredients of phase A and with mixing, heat to 75°C.
- 2. Add phase B to phase A with homogenization at 75-80°C.
- 3. Add phase C to phase A/B with homogenization at 75-80°C.
- 4. Add phase D to phase A/B/C with homogenization at 75-80°C. Homogenize for 7-10 minutes.
- 5. Switch to sweep mixing and begin to cool.
- 6. Premix phase E. Add phase F to phase E.
- 7. Add phase E/F to A/B/C/D with mixing.
- 8. Begin to cool to 45°C. Add phase G with mixing.
- 9. Cool to room temperature with continual mixing.

An in vivo SPF test was conducted as specified in the Food and Drug Administration's (FDA) Final OTC Monograph (21 CFR Parts 310, 352, 700, and 740, May 21, 1999 protocol on a five person panel. The control formulation yielded an in vivo SPF value of 21.4, while the formulation with SunSpheres™ Powder had an in vivo SPF of 32.8. This is a 53% boost for 4.5% solids of the polymer.

Nonaqueous sunscreen stick formulation						
Phase	Ingredients	Control % w/w	Test % w/w			
	Mineral oil	38.00	34.67			
	Ozokerite	18.00	18.00			
	Paraffin	14.00	14.00			
Α	Octocrylene	8.00	8.00			
A	Ethylhexyl methoxycinnamate	7.50	7.50			
	Benzophenone 3	5.50	5.50			
	Ethylhexyl salicylate	2.00	2.00			
	Euphorbia Cerifera (Candelilla) Wax	5.00	5.00			
В	Zinc oxide	2.00	2.00			
	SunSpheres™ Powder	0.00	3.33			

Procedure:

- Combine the ingredients of phase A and with mixing, heat to 90°C.
- 2. At 90°C, add the zinc oxide and SunSpheres $^{\text{TM}}$ Powder.
- 3. Homogenize for 7-10 minutes.
- 4. Pour into molds and cool quickly.

An in vivo SPF test was conducted as specified in the Food and Drug Administration's (FDA) Final OTC Monograph (21 CFR Parts 310, 352, 700, and 740, May 21, 1999 protocol on a five person panel. The control formulation yielded an in vivo SPF value of 45.6, while the formulation with SunSpheres™ Powder had an in vivo SPF of 57.3. This is a 26% boost for 3% solids of the polymer.

An in vivo test for water resistance was also measured on a twenty person panel with this formulation. The in vivo SPF was measured at 55.5 post-immersion.



Skin BFF daily use moisturizer with sunscreen					
Phase	Ingredients	% w/w			
	Deionized water	42.65			
	ACULYN™ 38 Rheology Modifier	3.00			
	Butylene glycol	2.00			
Α	EcoSmooth™ Universal Fluid 75-H-450	0.50			
	SymSave H	0.50			
	SunSpheres™ PGL Polymer	19.60			
	VERSENE™ NA₂ Crystals	0.10			
	Procol CS20D	1.75			
	Arlacel 165	2.00			
	Ritamollient CCT	5.00			
В	Ritamollient TN	5.00			
Ь	Parsol HMS	5.00			
	Parsol EHS	5.00			
	Parsol 1789	3.00			
	Parsol 340	4.00			
С	TEA, 99%	0.40			
D	NEOLONE PH-100 Preservative	0.50			

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- 1. Add Phase A ingredients except SymSave H to main vessel with mixing and begin heating to heat to 70-75°C. At 70°C, add SymSave H to Phase A and mix until dissolved.
- Mix sunscreen ingredients of Phase B together and start heating to 70-75°C. Continue mixing/heating until avobenzone dissolves, then add remainder of Phase B ingredients. Mix at 70-75°C until all ingredients are melted/ dissolved.
- 3. With Phase B @ 70°C add to Phase A (70-75°C) and mix well for 5 min.
- 4. Homogenize @ 10,000 RPM for 3 min. After 2 min, add half of Phase C (TEA) and continue to homogenize.
- Switch back to standard mixing and add the other half of Phase C. When batch reaches 45°C,add Phase D and continue mixing until batch reaches 25°C. Adjust pH to 6.0-7.0 with Phase C if necessary.

Emulsifier free daily wear formulation with sunscreen		
Phase	Ingredients	% w/w
А	Water, DI	66.05
	ACULYN™ 33 Rheology Modifier	2.00
	ACULYN™ 88 Rheology Modifier	3.00
	Propylene glycol	3.00
	Disodium EDTA	0.10
В	Isopropyl isostearate	2.00
	Triethylhexanoin	4.00
	Isopropyl myristate	2.00
	Cyclomethicone	1.00
	PCA dimethicone	1.50
	Tocopheryl acetate	0.10
	Ethylhexyl methoxycinnamate	7.50
	Butyl methoxydibenzoylmethane	3.00
	SunSpheres™ Powder	3.00
С	Sodium hydroxide, 10%	1.15
D	NEOLONE MxP Preservative	0.50
Е	Fragrance	0.10

Procedure:

- Combine the ingredients of phase A and with mixing, heat to 75°C.
- 2. Combine the ingredients of phase B separately and heat to 75°C with mixing.
- 3. Add phase B to phase A with homogenization at 75 80°C.
- 4. Homogenize for 7 10 minutes.
- 5. Switch to sweep mixing.
- 6. Add phase C to phase A/B and begin to cool.
- 7. At 45°C add phase D with mixing.
- 8. Add phase E with mixing.
- 9. Cool to room temperature with continual mixing.

An in vivo test yielded an SPF of 18.8 on a five person panel test. SunSpheres™ technology has also been shown to be effective in providing additional benefits to other cosmetic and personal care formulations containing UV actives in addition to the boost. In this daily wear formulation, which is also emulsifier free due to the use of the ACULYN™ Rheology Modifiers, the SunSpheres™ Powder provides a silky feel on the skin, after the film is allowed to dry.

Regulatory status and storage & handling

In the United States, the SunSpheres™ SPF Booster does not impart SPF at levels up to 6% solids, and is therefore not regulated as a sunscreen active. For SunSpheres™ Polymer sold in the European Union, all REACH relevant components of SunSpheres™ Polymer are REACH pre-registered or registered. In Japan, the use of the SunSpheres™ SPF Boosters are permitted according to the 1998 CLS ingredient code 522011 ("Alkyl Acrylate-Styrene Copolymer Emulsion"). In Australia, the SunSpheres™ Polymer is NICNAS listed. Toxicology information available upon request.

No special conditions are required for the storage of SunSpheres™ Powder, but the material should be kept from humidity. When handling this product, take the usual precautions for dusty materials. SunSpheres™ PGL and LCG polymer should be kept from freezing. The minimum recommended storage temperature for this material is 1°C/34°F. The maximum recommended storage temperature for SunSpheres™ PGL Polymer and SunSpheres™ LCG Polymer is 49°C/120°F.



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