SUNSPHERES™ Hollow Sphere Technology
An SPF Booster for More Aesthetically Pleasing Formulations

Features, Benefits and Applications

SUNSPHERES SPF Booster is a styrene/acrylates copolymer manufactured via emulsion polymerization. The hollow spheres in a sunscreen raise the UV protection over the whole UVA/UVB spectrum and work equally well with organic and inorganic sunscreen actives. SUNSPHERES polymer is also compatible with a broad range of cosmetic ingredients, including emollients and skin conditioners.

The ability of SUNSPHERES to boost the efficacy of UVA/UVB filters of formulations allows the formulator to use significantly less active to deliver the same level of SPF. As a result, potential irritation caused by the actives is reduced, and the formulator is able to create more aesthetically pleasing products.

CTFA / INCI Name:
Styrene / Acrylates Copolymer

Features

- Boosts UV protection over the whole UVA/UVB spectrum
- Invisible to the eye
- Not noticeable to touch
- Free flowing powder
- Compatible with organic and inorganic UV actives
- Compatible with all commonly used ingredients in suncare products
- Compatible in water resistant formulas
- Suitable for the formulation of inverse (W/O) emulsions
- Can be processed cold
- Easy to formulate
- Supported by comprehensive environmental, health and safety data

Benefits

- Allows reduced amount of UV actives
- Excellent for aesthetically pleasing formulations
- Potential reduction in irritation caused by actives
- Useful for wide variety of cosmetic products
- Excellent for water resistant formulations
- Non-irritating, non-toxic, non-photosensitizing

Applications

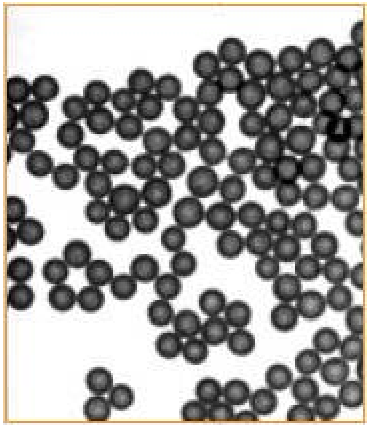
- UVA/UVB sunscreens
- Sunscreens with inorganic and/or organic actives
- Water resistant sunscreens
- Cosmetic products containing sunscreen active:
  – Makeup creams and lotions
  – Hand and face creams and lotions
  – Alpha-Hydroxy acid creams and lotions
  – Medicated and moisturizing creams
  – Leave-on cosmetic products

SUNSPHERES Polymer Technology

The SUNSPHERES polymer is a styrene/acrylates copolymer with a hollow sphere morphology prepared via controlled emulsion polymerization. The polymer spheres, with an external size of approximately 325 nm are in the form of dry, hollow beads.

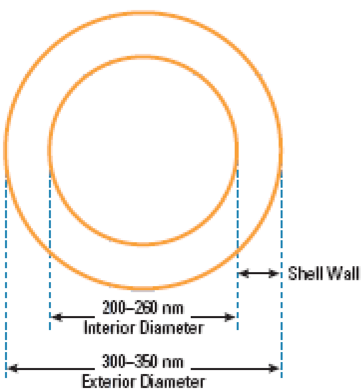
The hollow centers of the polymer particles can be seen (Figure 1) in the transmission electron micrograph of only the dried polymer. These air-filled hollow centers are key to the polymer's mode of action and resulting performance enhancement in personal care applications. The relatively uniform distribution of the particle size can also be observed.

Figure 1: Transmission Electron Micrograph of Dried Polymer Particles



The exterior size of the particle has an influence on the visibility (opacity) of the polymer in a formulation. With an external size of approximately 325 nm, the particle is nearly invisible and cannot be felt during the rubout of the sunscreen or application of cosmetic products. The interior size is maximized to allow for the most efficient scattering of light, while still leaving the shell wall thick enough to allow for particle integrity to remain intact. Figure 2 shows a model of the polymer spheres, indicating the range of sizes of the external and internal walls.

Figure 2: SUNSPHERES Hollow Sphere Model

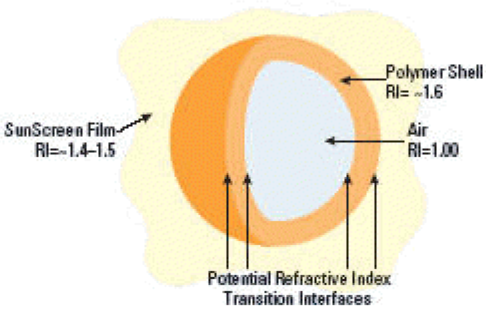


The air void in the polymeric spheres plays a critical role in the performance of the polymer. The air in the voided sphere has a refractive index of 1.0. The refractive index of the polymer shell is approximately 1.6. In a sunscreen formulation, the refractive index of the dried film is typically 1.4 to 1.5. See Figure 3.

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 SUNSPHERES 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 SUNSPHERES 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.

Figure 3: Light Refraction via SUNSPHERES Hollow Sphere Technology



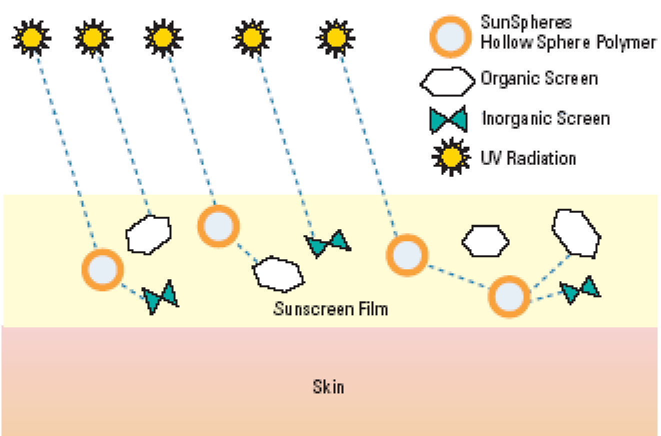
With the addition of SUNSPHERES polymer to an emulsion sunscreen more scattering sites are added as shown in Figure 4. Results have shown that the inclusion of 5% SUNSPHERES powder almost doubles the apparent thickness of the film when Beer's Law is applied to the absorption.

It is important to note that the polymer itself does not absorb UV radiation and therefore is not an "active" sunscreen agent. Rather, the SUNSPHERES are efficient scattering centers that optimize the absorption of organic and inorganic sunscreens in the film by increasing the probability that UV radiation will contact the UV active ingredients that are present.

SUNSPHERES is not a UV absorber on its own:

To confirm that the polymer itself is not an active ingredient, the spheres were formulated into a sunscreen base without any UV active ingredient. The product was then measured *in vivo* according to the final tentative monograph. With 5% SUNSPHERES powder in the formulation, but no UV active ingredient, the SPF was < 2.0, which according to the monograph, confirms that the polymer is not an active ingredient.

Figure 4: Model for UV Scattering by the SUNSPHERES Hollow Sphere Polymer within a Sunscreen Film



Physical and Chemical Characteristics

Typical Properties

These properties are typical but do not constitute specifications.

Appearance	White powder
Solids, %	98%
Moisture, % by weight	Less than 3%
Bulk density (g/cc)	0.22-0.32
Residuals Total acrylates Styrene	 < 100 ppm < 100 ppm

Recommended Use Levels

Generally, the UV absorption capacity of a formulation will increase with increasing concentrations of SUNSPHERES. However, in some circumstances, an optimum is observed, and as such, we recommend that during formulation development, different levels of SUNSPHERES be screened to ensure that if a maximum is not attained, which can detract from optimum performance.

We recommend a use level ranging from 1% to 5% of SUNSPHERES powder in your formulation.

SUNSPHERES Polymer Behavior Profile

Performance in Typical Sunscreen Formulations

To test the efficacy of SUNSPHERES as SPF boosters in personal care applications, two different sunscreen formulas were prepared and evaluated *in vivo* and *in vitro*. Formulation A (see table below) is a relatively simple formulation containing low-oil and utilizing an anionic emulsion system. The expected SPF of this formulation would be about 8 (see table on following page). 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 SUNSPHERES product. They were chosen based on their proven stability under the desired testing conditions.

Sunscreen Formulation A with 6% Octylmethoxycinnamate and 1% Oxybenzone

Phase	Ingredients	Control % w/w	Test % w/w
A	Water, DI	80.72	75.17
A	ACULYN 33 Polymer	3.33	3.33
A	Glycerin	1.00	1.00
A	Tetrasodium EDTA	0.10	0.10
A	SUNSPHERES powder	0.00	5.55
B	Octyl methoxycinnamate	6.00	6.00
B	Oxybenzone	1.00	1.00
B	C12-15 alkyl lactate	2.00	2.00
B	PVP/eicosene copolymer	1.50	1.50
B	Cyclomethicone	2.00	2.00
B	Stearic acid	1.50	1.50
C	Triethanolamine, 99%	0.85	0.85

Both screening formulations (and their non-SUNSPHERES containing controls) were tested for static SPF using the (statistically more rigorous) *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 that contained SUNSPHERES powder had a level of 5% SUNSPHERES solids. Physical stability was monitored weekly for three months, or until failure was confirmed.

The *in vitro* tests were made based on a modified test protocol that resulted in significantly reduced inter- and intra-sample 'noise' than the standard 3M Transpore Tape method. Instead of the 3M Transpore Tape substrate, films were drawn-down onto quartz glass slides using a Byrd applicator.

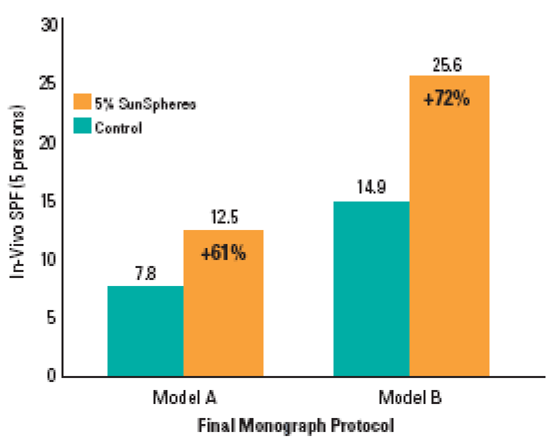
Because the skin-mimicking 'topography' provided by the 3M Transpore Tape method was not present in the modified procedure, high Optometrics SPF readings were obtained. To compensate for the elevated readings, test results were compared and reported on the basis of 'percent boost over control without polymer.'

Sunscreen Formulation B with 7.5% Octylmethoxycinnamate, 2% Oxybenzone and 3% Octyl Salicylate

Phase	Ingredients	Control % w/w	Test % w/w
A	Water, DI	71.70	66.15
A	PVM/MA decadiene crosspolymer	0.50	0.50
A	Butyl glycol	3.00	3.00
A	SUNSPHERES powder	0	5.55
B	PEG-20 Stearate	1.50	1.50
B	Glyceryl stearate & laureth-23	2.00	2.00
B	Octyldodecyl neopentanoate	1.00	1.00
B	Octyl palmitate	2.00	2.00
B	Glyceryl dilaurate	0.50	0.50
B	Octyl methoxycinnamate	7.50	7.50
B	Oxybenzone	2.00	2.00
B	Octyl salicylate	3.00	3.00
C	Sodium hydroxide 10%	1.30	1.30
C	Glyceryl polymethacrylate & propylene glycol	3.00	3.00
C	Glyceryl polymethacrylate & propylene glycol & PVM/MA copolymer	0.50	0.50
D	Diazolidinyl urea & iodopropynyl butylcarbamate	0.30	0.30
D	Methylparaben	0.20	0.20

As shown in the graph below, even in these non-optimized systems, 5% solids of the SUNSPHERES polymer clearly boosts SPF by 60 to 72% at both room temperature and 45°C for the length of the three month evaluation.

Screening Formulations: *In Vivo* Results



Both screening formulations gave similar results when evaluated for stability at room temperature and 45°C for three months. *In vitro* determinations were made with an Optometric™ SPF Analyzer with an integrating sphere. As shown in the table below, the formulation containing the SUNSPHERES polymer exhibited a significant boost *in vitro*, and retained the boost at both room temperature and 45°C for the length of the three-month evaluation.

Proven Stability *In Vitro* Under Accelerated Conditions

Length of Storage	% SPF Boost over control	
	Storage at RT	Storage at 45°C
Inital	135	135
2 Weeks	145	156
3 Weeks	160	143
4 Weeks	152	160
8 Weeks	158	145
12 Weeks	170	130

Performance in Water-Resistant Sunscreen Formulations

SUNSPHERES hollow spheres have also been proven to have minimal to no effect on the performance of water-resistant formulations. The water resistant sunscreen formulation (shown below) selected for these studies was based on a lamellar gel system that has been proven through testing to be very water-resistant. The control with no polymer spheres and the formulation containing SUNSPHERES (5% solids) were tested using the same *in vivo* protocol defined in the Final OTC Monograph.

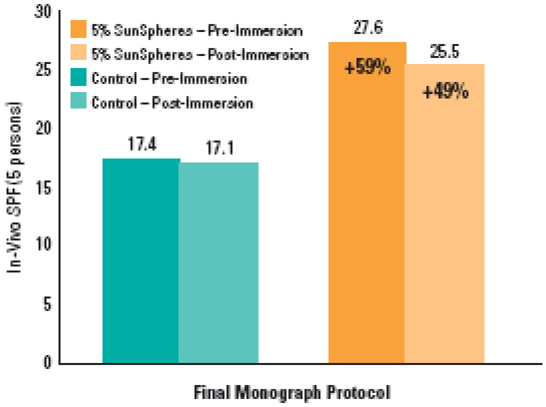
Water-Resistant Sunscreen Formulation

Phase	Ingredients	Control % w/w	Test % w/w
A	Water, DI	67.85	62.3
A	Magnesium aluminum silicate	1.00	1.00
A	Carboxymethyl cellulose	0.50	0.50
A	Disodium EDTA	0.10	0.10
A	Butyl glycol	3.00	3.00
A	Glyceryl polymethacrylate & propylene glycol & PVM/MA copolymer	0.75	0.75
A	SUNSPHERES powder	0.0	5.55
B	Glyceryl stearate & behenyl alcohol & palmitic acid & stearic acid & lecithin & lauryl alcohol & myristyl alcohol & cetyl alcohol	4.00	4.00
B	PVP/eicosene copolymer	1.00	1.00
B	Octyl palmitate	2.00	2.00
B	Octyl methoxycinnamate	7.50	7.50
B	Oxybenzone	2.00	2.00
B	Octyl salicylate	3.00	3.00
B	Tridecyl neopentanoate	3.00	3.00
B	Glyceryl dilaurate	0.50	0.50
B	Phenyl trimethicone	0.30	0.30
B	Cyclomethicone	3.00	3.00
C	Diazolidinyl urea & iodopropynyl butylcarbamate	0.30	0.30
C	Methylparaben	0.20	0.20

The test was conducted as specified in the FDA protocol for determination of water-resistance. The control, as expected, was determined to have an SPF of 17.4 prior to immersion and 17.1 post-immersion. The sunscreen formulation containing SUNSPHERES polymer gave a pre-immersion SPF of 27.6 (59% boost over control) and a post-immersion result of 25.5, a 49% boost over the post-immersion control.

This experiment provides additional data that the SUNSPHERES hollow spheres significantly boost the SPF of sunscreen formulations above their baseline performance, and additionally do not interfere with or disrupt the formation or adherence of a water-resistant film. It is highly probable that systems designed to maximize the performance of the SUNSPHERES polymer will obtain better results than those obtained in these evaluations.

Water-Resistant Screening Formulation: *In Vivo* Results



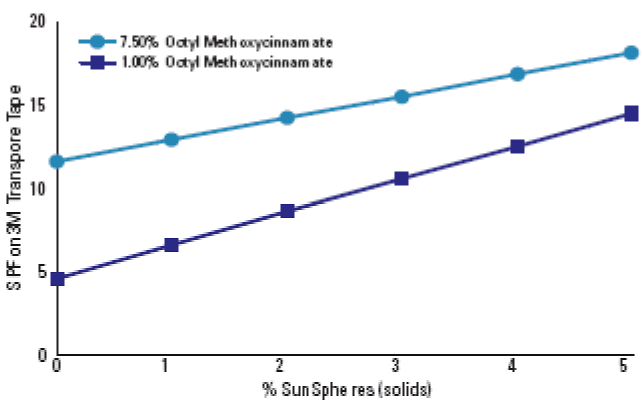
Performance with Various UV Actives

The performance of SUNSPHERES varies with different UV actives. Conditions such as concentration, solubility and the presence of other ingredients in a formula may impact the boost in SPF values. Understanding the performance relationship(s) for each combination of sunscreen actives should result in opportunities to optimize formula performance and maximize potential cost savings.

The ability of the SUNSPHERES hollow sphere particles to provide enhancement of SPF values in formulations containing various active ingredients was determined utilizing Design-Expert software. The SPF was measured using *in vitro* experiments on the Optometrics 290 using 3M Transpore Tape with a typical spreading rate of 2 $\mu l/cm^2$.

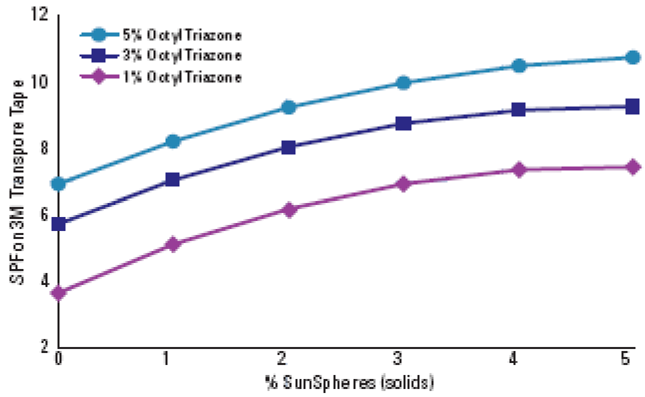
Below is a graph of results determined using a formulation containing only the globally approved UVB active octyl methoxycinnamate. The graph shows that 1.00% of octyl methoxycinnamate (OMC) in the formulation with 4% SUNSPHERES powder gives an SPF of slightly over 12, which is better than 7.5% OMC alone in the same formulation.

SUNSPHERES Performance with Octyl Methoxycinnamate (OMC)



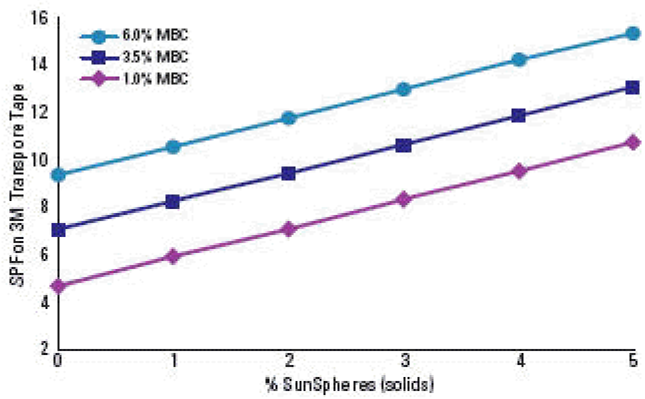
Similar tests were performed with octyl triazone, a UVB active ingredient approved for use outside the United States. In this case, diminishing returns were observed in formulations with higher levels of SUNSPHERES polymer. However, 3% of SUNSPHERES powder with 1% octyl triazone performs equivalently with 5% of just the octyl triazone in the same base formula.

SUNSPHERES Performance with Octyl Triazone



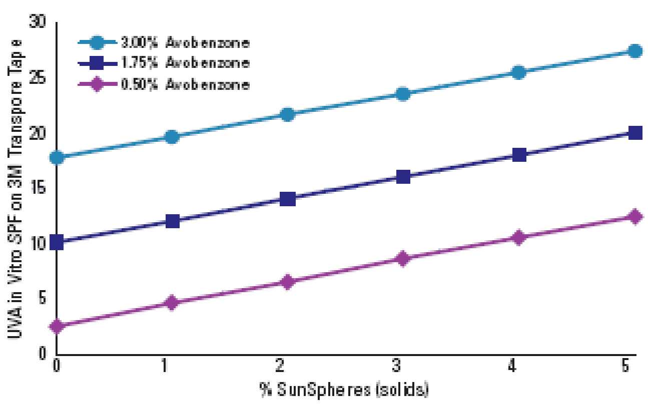
With methylbenzylidene camphor (MBC), another UVB active ingredient approved for use outside the United States, a relationship similar to the OMC holds true with the SUNSPHERES. The graph shows that equivalent performance is possible from systems containing either 6% MBC or a combination of 1% MBC with 3.5% SUNSPHERES powder.

SUNSPEHRES Performance with MethylBenzylidene Camphor



For avobenzone, which is used for UVA protection, the SPF of formulations containing SUNSPHERES powder was determined as a UVA performance score, read directly from the Optometrics 290. The linear relationship holds true for the UVA value, and 0.50% avobenzone with 4% of the SUNSPHERES powder will outperform 1.75% of the avobenzone in the same base for UVA determination. The data also demonstrates that the SUNSPHERES polymer functions equally well with UVA active ingredients.

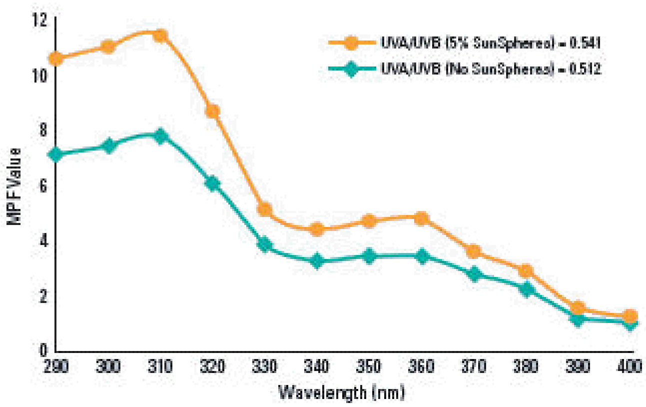
SUNSPHERES Performance with Avobenzone



This fact becomes apparent in the results obtained from a complete scan using the Optometrics 290. The absorption spectrum output is uniformly increased across the entire scan from 290 to 400 nm. In this experiment, 5.5% SUNSPHERES powder were added to a control formula containing 5% octyl methoxycinnamate and 2% avobenzone. Scans from the test and control formulas were similar, except in magnitude.

The calculated UVA/UVB ratio of the formula with SUNSPHERES polymer is about 6% higher than the control with SUNSPHERES. This data suggests that the SUNSPHERES polymer may be somewhat more effective in the UVA region than in the UVB region. Depending on the protocol used to determine UVA efficacy, the SUNSPHERES polymer may provide a measurable advantage, since the boosting effect from the SUNSPHERES polymer is more likely to have an impact in the *in vivo* Persistent Pigment Darkening (PPD) and Immediate Pigment Darkening (IPD) methods than it is in the *in vitro* Diffey and Critical Wavelength methods.

5% OMC/2% Avobenzone Optometrics Scan



Compatibility with Sunscreen and Other Cosmetic Ingredients

The SUNSPHERES polymer has been evaluated with a variety of typical cosmetic ingredients. Based on the results of these studies, it appears that the SUNSPHERES hollow spheres have broad compatibility with most ingredients used for personal care products with only a few exceptions.

Compatibility with Sunscreen Active Ingredients

Compatibility of the SUNSPHERES polymer with various sunscreen actives has been investigated. With all actives tested, retention of SPF-boosting efficacy was observed for the length of the study, thereby indicating no incompatibilities.

Organic Actives

- Octyl methoxycinnamate
- Octocrylene
- Octyl salicylate
- Phenylbenzimidazole sulfonic acid
- Oxybenzone
- Methylbenzylidene camphor
- Avobenzone
- Octyl triazone

Inorganic Actives

- Titanium dioxide
- Zinc oxide

Compatibility with Emollients

In order to explore the applicability of the SUNSPHERES polymers in cosmetic products other than sunscreens, the hollow spheres were evaluated in combination with a variety of emollients and skin conditioners. All of the products tested, except diisopropyl adipate, were found to be compatible with the SUNSPHERES polymer. Adipates are known to be aggressive plasticizers for many polymers, and therefore it is recommended that SUNSPHERES not be used in formulations containing these ingredients.

Silicones

- Cyclomethicone
- Dimethicone

Oils

- Mineral oil
- Sunflower seed oil

Esters

- C12–15 Alkyl benzoate
- C12–15 Alkyl lactate
- Octyl palmitate
- Isopropyl myristate
- Laureth-2 octanoate
- Isostearyl isostearate
- Octyldodecyl neopentanoate

Compatibility with Other Ingredients

The SUNSPHERES polymer was tested with other cosmetic ingredients including emulsifiers, thickeners and insect repellant. In general, cationic ingredients should be avoided because the polymeric shell of the SUNSPHERES product has a slight anionic charge that could interact with cationics.

Associative thickeners should be tested individually for viscosity effects. Extraordinary viscosity increases have been observed with some associative thickeners.

Emulsifiers

- Anionic
- Nonionic

Thickeners

- Gums
- Stabileze™
- Carbomers
- ACULYN™ Rheology Modifiers

Insect Repellant

- DEET

Formulating with ACULYN Rheology Modifiers and SUNSPHERES Powder

Surfactant-Free Emulsions

Both ACULYN rheology modifiers and SUNSPHERES polymer can be combined and formulated into non-surfactant containing emulsions in which the surfactant emulsifiers have been replaced by these polymers.

Being a small particle both hydrophobic and hydrophilic functions, SUNSPHERES particles are capable of forming pickering emulsions, and as such, they can also contribute to the overall stability of sunscreen formulations. Stabilisation of both O/W and W/O emulsions prepared with traditional surfactants or with polymeric emulsifiers have been observed when incorporating SUNSPHERES powder into sunscreen formulations.

For the ACULYN rheology modifiers, the presence of hydrophobes groups grafted onto the acrylic polymeric chain provides ACULYN 22 or ACULYN 28 with excellent emulsification properties. The use of ACULYN 22 or ACULYN 28 gives rise to extremely stable emulsions. An added advantage of such emulsions can be found in the preparation of water resistant sunscreens, as the use of low levels of polymers in place of the traditional surfactants leads to formulations which have a lower tendency to re-disperse in water.

Sunscreen Sprays

The ACULYN rheology modifiers (ACULYN 22 or ACULYN 28), due to their high degree of pseudoplasticity, can also contribute to the formulation of suncare formulations in spray packages, where shear thinning behaviour is required for effective spray patterns. These rheology modifiers, but in particular ACULYN 28, also contribute significantly to low shear viscosity build, leading to stabilisation of liquid or solid particles in the matrix. SUNSPHERES powder can also be incorporated into spray formulations to give a boost to the UV absorbance, as their small size will enable them to pass through a spray nozzle.

An example of a surfactant-free emulsion is given below. The water resistance of such a formulation can be further improved if desired by the incorporation of classic water resistant additives.

Phase	Ingredients	Control % w/w	Test % w/w	
A	Water	65,55	Water	Diluent
A	Propylene glycol	5,00	Propylene Glycol	Humectant
A	Panthenol	2,00	D-Panthenol	Vitamin
A	Methyl p-hydroxy benzoate	0,2	Methyl parabens	Preservative
A	Methylisothiazolinone	0,1	NEOLONE™ 950	Preservative
B	Acrylates/Steareth-20 Methacrylate Copolymer	2,5	ACULYN 22	Emulsifier HASE
B	Acrylates Copolymer	2,7	ACULYN 33A	Emulsifier ASE
C	Sodium hydroxide	2,0	NaOH 10% solution	Neutralizer
D	Isopropyl palmitate	10,0	Isopropyl palmitate	Emollient
D	Tocopheryl acetate	1,00	dl-a-Tocopheryl Acetate	Vitamin
D	Tocopherol	0,01	dl-a-Tocopherol	Antioxidant
D	Octyl methoxycinnamate	5,00	Parsol MCX	UVB Filter
D	Mineral oil	3,99	Liquid Paraffin	Filming agent
E	Fragrance	0,20	Soul Mate	Fragrance

Physical Characteristics	
Appearance:	White pseudoplastic cream
pH:	adjust to 6.5 to 7
Brookfield LV Viscosity at 12 rpm:	30000

Manufacture:

Combine the ingredients of part A and mix.
Add part B, mix and neutralise with part C.
Add part D (to parts A+B+C) slowly under agitation.
Add part E and mix until uniform.

Formulation and Use Guidelines

The recommended processing guidelines when using SUNSPHERES powder in a formulation are as follows:

1. Use appropriate equipment to handle SUNSPHERES powder, as this is a low density, dusty solid. Avoid inhalation.

2. Incorporate SUNSPHERES Powder either in the aqueous phase or oil phase prior to emulsion formation. Efficient incorporation in the water or oil phase will be dependent on the available equipment. Homogenization for 7-10 minutes was found to be sufficient in most cases, but longer times may be necessary depending on efficiency.

3. The SUNSPHERES powder is in the form of an agglomerate, with a mean particle size of the order of 100 microns. These agglomerates are less dusty than a non-agglomerated equivalent, and are thus less of a hazard from an inhalation or from a dust explosion point of view. However, they must be broken down in the final formulation so as to liberate the primary SUNSPHERES particles. If this step is not performed, the expected performance boost will not be achieved. In addition, a granular appearance will be observed in the formulation, and the emulsion may feel “gritty” to the touch.

4. In order to break down the agglomerates, a high shear process is recommended. This can be performed using a homogenizer. Homogenization can be run on the aqueous dispersion of SUNSPHERES powder before forming the emulsion. This dispersion is facilitated by heating, and we suggest that in this case, a temperature of at least 50°C be used. Due to the high shear, it is possible that foaming may be an issue. In this case, a small part of the non-aqueous phase, such as mineral oils or ester, can be added to the blend to alleviate the problem. If silicones are a component of the formulation, these can also be employed.

5. An alternative means of dispersing the SUNSPHERES powder and breaking down the agglomerates is by dispersing them in water and then recycling the dispersion through a centrifugal pump.

6. If the formulation is a low viscosity emulsion (<1000 cps), incorporation of the SUNSPHERES powder can be at the end of the processing with the preservative. However, uniform dispersion of the powder in very viscous creams may be a problem.

7. When formulating with silicones, it is recommended that the SUNSPHERES powder be blended into an oil phase containing aliphatic oils, but in the absence of silicones, as flocculation of the SUNSPHERES can occur. In such a system, either add the polymer into the water phase, or if dispersed in the organic phase, prepare the emulsion, and post add the silicones.

ACULYN Rheology Modifiers

SUNSPHERES Polymer can be used in a formulation with ACULYN Rheology Modifiers used either as stabilizing/thickening agents, or as polymeric emulsifiers. When the SUNSPHERES Polymer is used with an associative rheology modifier, such as ACULYN 22, ACULYN 28, or ACULYN 88, an increase in viscosity will be noted because of the association of the rheology modifier with the spheres, causing more structure in the formulation. In this case less of the associative rheology modifier can be used to achieve a lower viscosity. When the ACULYN Rheology Modifiers are used as polymeric emulsifiers with the SUNSPHERES Polymer, the following procedure should be used:

1. Incorporate the ACULYN rheology modifier into the aqueous phase part of the formulation along with the other water soluble ingredients.

2. Incorporate the SUNSPHERES Polymer either in the aqueous phase or the oil phase.

3. After mixing the oil phase with the aqueous phase, add only half of the total neutralizing agent. Homogenize the emulsion for 7-10 minutes.

4. Add the remaining amount of neutralizing agent and begin to cool the emulsion, or proceed with the process as usual. By following this process of a two step neutralizing procedure a good dispersion of the SUNSPHERES Polymer can be achieved.

Environmental, Health and Safety Record

Acute Toxicity Profile

Test / Species	Results
Oral LD_{50} — rat	>5 g/kg — non-toxic
Dermal LD_{50} — rabbit	>5 g/kg — non-toxic
Eye irritation — rabbit	Non-irritating (US and EEC)
Skin irritation — rabbit	Slightly irritating (US), Non-irritating (EEC)

US — United States classification
EEC — European Economic Community classification

Genetic Toxicity Profile

Test / Species	Results
Ames Test	Non-mutagenic with and without metabolic activation

Human Toxicity Profile

Test / Species	Results
HRIPT	Non-sensistizing and Non-irritating

Environmental Fate

Test	Results
Biodegradation	Not readily biodegraded

Ecotoxicity Profile

Test / Species	Results
Algae EC_{50} — 72 hr	>100 ppm — non-toxic
Daphnia Magna LC_{50} — 48 hr	>100 ppm — non-toxic
Rainbow Trout LC_{50} — 96 hr	>100 ppm — non-toxic

Overall Evaluation

SUNSPHERES polymer is considered non-toxic by single oral and dermal exposure, produces minimal to no irritation to the eyes and skin, is a non-sensitizer and non-irritating to humans, non-mutagenic in the Ames assay, and non-toxic to aquatic organisms. This material is safe and appropriate for use in a broad range of rinse-off and leave-on personal care applications.

Regulatory Status

In the United States, the SUNSPHERES polymer is inert by definition, does not impart SPF at levels up to 6%, and is therefore not regulated as a sunscreen ingredient. In Europe, the SUNSPHERES polymer is acceptable for use in EINECS countries because all monomers are registered.

In Japan, the use of the SUNSPHERES SPF Enhancer polymer should be permitted according to the 1998 CLS ingredient code 522011 (“Alkyl Acrylate-Styrene Copolymer Emulsion”). In Australia, the SUNSPHERES polymer is NICNAS-listed. TGA-listing is being researched.

Storage and Handling

Storage

No special conditions are required for the storage of SUNSPHERES powder, but the material should be kept in the absence of humidity. When handling this product take the usual precautions for dusty materials.

Material Safety Data Sheets

Rohm and Haas Material Safety Data Sheets (MSDS) contain pertinent information that you may need to protect your employees and customers against any known health or safety hazards associated with our products. Under the OSHA Hazard Communication Standard, workers must have access to and understand MSDS on all hazardous substances to which they are exposed. Thus, it is important that you provide appropriate training and information to your employees and make sure they have available to them MSDS on any hazardous products in the workplace.

Upon initial shipment of non-OSHA-hazardous and OSHA-hazardous products (including samples), Rohm and Haas Company sends the appropriate MSDS to the recipient. If you do not have access to one of these MSDS, please contact your local Rohm and Haas representative for a copy. Updated MSDS are sent upon revision to all customers of record. MSDS are also sent annually to all customers receiving products deemed hazardous under the Superfund Amendments and Reauthorization Act (SARA). MSDS should be obtained from suppliers of other materials recommended in this bulletin.

Rohm and Haas Company is a member of the American Chemistry Council (ACC) and is committed to the ACC's Responsible Care® Program.

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