PERSONAL CARE

Solaveil™ CT Dispersions

Effortless Elegance in UV Protection

Solaveil Clarus titanium dioxide dispersions offer effective and safe sun protection combined with ease of use and optimised aesthetic properties. Solaveil CT dispersions contain the latest generation of TiO_2 for UV protection, which, when incorporated into a cosmetic emulsion, provides transparency on skin which is equivalent to that offered by organic sunscreens. The key to Solaveil Clarus' total transparency is tightly controlled particle size distribution that eliminates whitening but maintains SPF efficacy. In addition, the dispersion form of the products makes them very easy to use, reducing the time and effort required for formulation development and minimising mixing time and energy in manufacturing. This unique combination of efficacy, simplicity and aesthetics makes Solaveil CT dispersions appropriate for both sun care and daily wear formulations.

Contents

Product Range

Oil-based Dispersions

Trade Name	Solids content (% w/w)	Approx. TiO_2 Content (% w/w)	INCI Names of Ingredients
Solaveil™ CT-100	45	33	C12-15 Alkyl Benzoate, Titanium Dioxide, Aluminum Stearate, Polyhydroxystearic Acid, Alumina
Solaveil™ CT-200	50	37	Titanium Dioxide, Isohexadecane, Triethylhexanoin, Aluminum Stearate, Polyhydroxystearic Acid, Alumina
Solaveil™ CT-300	45	33	Caprylic/Capric Triglyceride, Titanium Dioxide, Polyhydroxystearic Acid, Aluminum Stearate, Alumina
Solaveil™ CT-434	45	33	Titanium Dioxide, Cyclomethicone, Propylene Glycol Isostearate, Aluminum Stearate, Polyhydroxystearic Acid, Alumina

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Aqueous Dispersions

Trade Name	Solids content (% w/w)	Approx. TiO_2 Content (% w/w)	INCI Names of Ingredients
Solaveil™ CT-10W	40	30	Water (Aqua), Titanium Dioxide, Oleth-10, Isodeceth-6, Aluminum Stearate, Alumina, Simethicone, Propylene Glycol, Diazolidinyl Urea, Methylparaben, Propylparaben
Solaveil™ CT-12W	40	30	Water (Aqua), Titanium Dioxide, Oleth-10, Isodeceth-6, Aluminum Stearate, Alumina, Simethicone, Phenoxyethanol
Solaveil™ CT-30W	40	29	Water (Aqua), Titanium Dioxide, Alumina, Sodium Polyacrylate, Silica, Phenoxyethanol, Sodium Citrate

Features & Benefits

Features	Benefits
Homogeneous dispersions	Easy to process, no dust handling or pre-dispersion facilities required Dispersed form optimises UV efficacy
Liquid ingredients	Pre-dispersion easy to incorporate into formulation
Based on inorganic physical sunscreen	Reflect, scatter and absorb UV light generating higher SPF from single active
Mild/safe non-irritant	Ideal for all sun care applications, particularly sensitive skin and baby
Does not degrade/oxidise	Provides long-lasting UV protection
Narrow particle size distribution	Optimised transparency on skin
Choice of oil or water carriers	Formulation flexibility

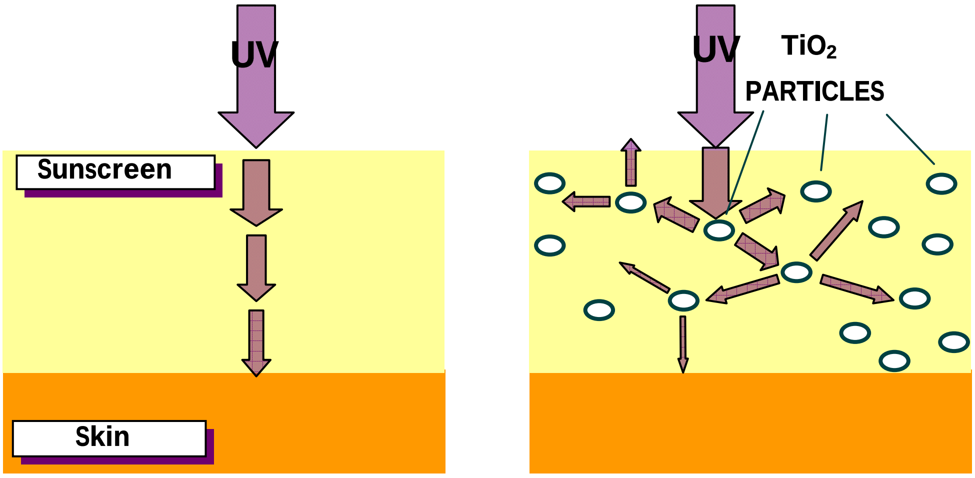
Applications

- Sun Care
- Skin Care
- Colour Cosmetics

Mode of Action

Organic (or "chemical") sunscreens work by absorption of UV light. Physical sunscreens, by contrast, attenuate UV by two mechanisms: absorption and scattering (see Fig.1).

Because of these different mechanisms, physical sunscreens attenuate UV over a broad wavelength range, and this is one of the key advantages of these materials. The UV/visible absorption spectra of the Solaveil CT dispersions are shown in Figure 2 (since the same grade of TiO_2 is used in each oil-based dispersion, these all give similar optical properties; water-based dispersions give a slightly different spectrum). Note the very low extinction coefficients in the visible part of the spectrum, hence the improved transparency on skin.



Organic sunscreen
UV light is absorbed as it passes through the film

Inorganic sunscreen
UV light is scattered and absorbed by TiO_2 particles

Figure: 1 Mode of action: organic sunscreens vs. inorganic sunscreens

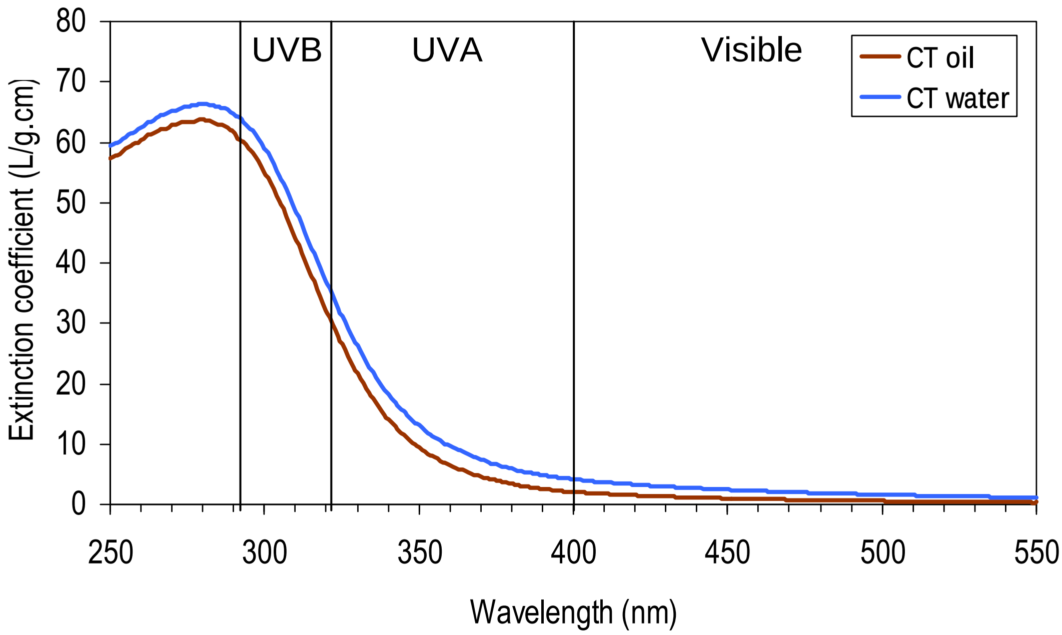


Figure : 2 UV/visible spectra for Solaveil CT dispersions

Long lasting UV protection

Whereas some organic filters can break down in the presence of UV light, inorganic sunscreens such as Solaveil CT dispersions are photostable and will not degrade or oxidise, maintaining SPF for as long as the particles remain on the skin.

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Mild and safe

TiO_2 is well-known as a safe material, with a very low potential for skin irritation, making Solaveil CT dispersions a great choice for formulators working on products for any skin type including babies, children and sensitive skin.

Particle size

Measurement of particle sizes in the sub-micron range is problematical. Results can vary enormously depending upon the measurement technique, which should therefore always be quoted alongside any measurements.

Some techniques, for example x-ray diffraction, measure the Primary Particle Size, or Crystal Size, of the material. This represents the size of the crystals, the smallest fundamental building blocks of a particulate material. These building blocks indicate the primary crystal habit of the particles but individual crystals are difficult to isolate. In use, they are always aggregated to some degree to form larger particles. Many particle size measurement techniques measure the size of these aggregates (the Secondary Particle Size). This is actually the more useful measurement as it more closely represents the size of the particles in use, which dictates the optical properties of the material.

UV-attenuating grades of TiO_2 are typically composed of crystals which have a shortest dimension of 10-20 nm. The secondary particle size is typically in the range 30-150 nm (equivalent sphere diameter). Some particle size techniques have limited sensitivity in this range and therefore tend to overestimate the size of the particles.

The particles in Solaveil CT dispersions are composed of acicular crystals, with a shortest dimension of 10-15nm and an aspect ratio of 3-4 (as measured from electron micrographs). For measurement of secondary particle size, we have found that the most reliable technique is the Brookhaven X-ray disc centrifuge. Figure 3 shows the particle size distribution, as measured by this method, for the particles used in Solaveil CT dispersions.

It can be seen that the particle size distribution is very narrow (standard deviation about 1.2). The geometric mean is typically 30-40 nm with the mode (peak of the distribution) being somewhat less at 24-33 nm. Cumulative distribution curves reveal that 100% of particles are less than 200nm. It is this tight control of particle size distribution which enables the Solaveil CT products to be completely transparent on skin while maintaining high SPF efficacy.

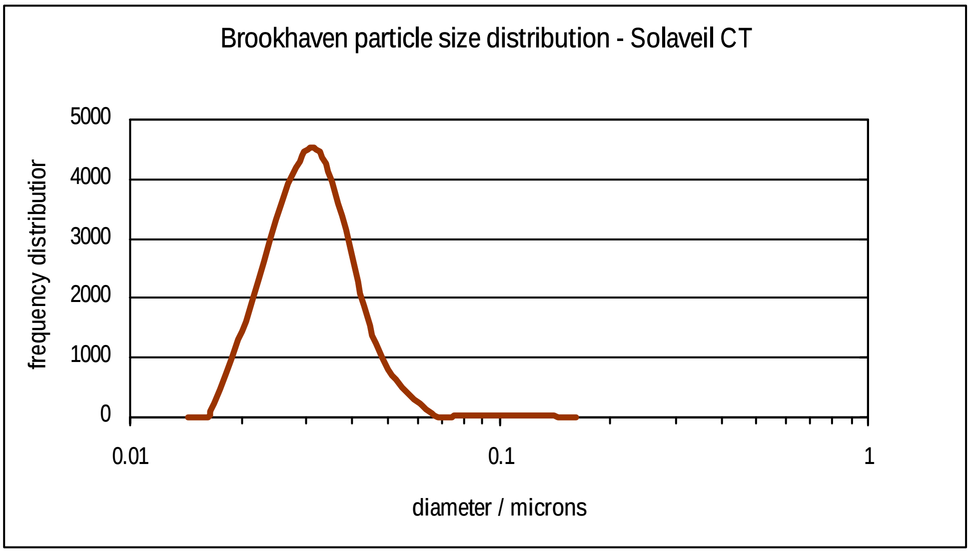

Figure: 3 Particle size distribution for Solaveil CT TiO_2

Efficacy

SPF Efficacy

Figure 4 shows measured SPF values for formulations which contain only Solaveil CT dispersions as active ingredients. As is well known, the SPF of a sunscreen product depends a great deal on the formulation, so it is not possible to give definitive rules to say that a certain percentage of an active ingredient will give a certain SPF. However, from data such as that shown in Figure 4, we can derive the following guideline: every 1% solids provides approximately 2-3 SPF units.

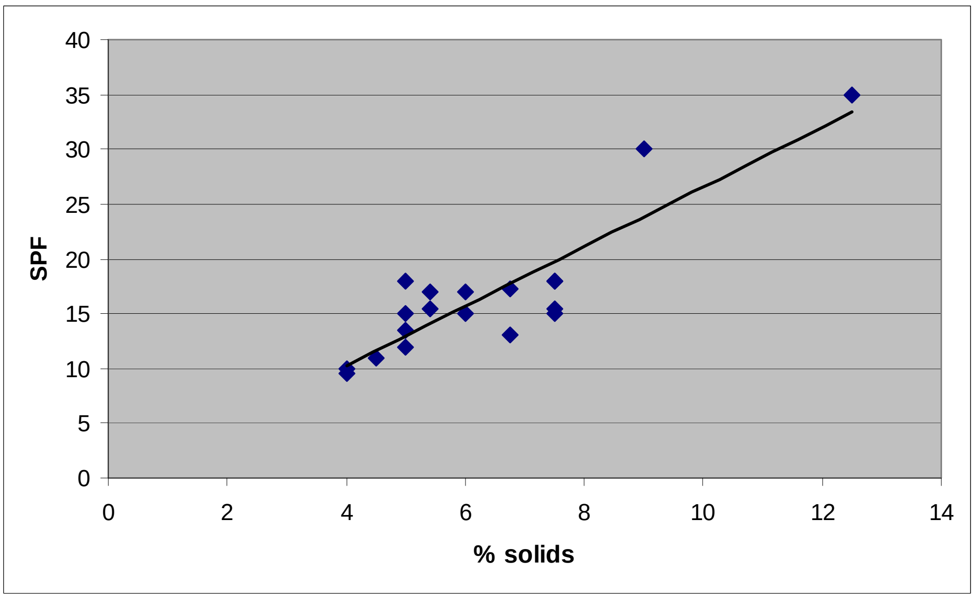

Figure: 4 SPF vs. % solids for formulations based on Solaveil CT dispersions as sole active

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UVA / Broad Spectrum Efficacy

For formulations containing Solaveil CT dispersions as the sole active, typical values for various UVA / broad spectrum performance parameters are as follows:-

- UVA/UVB ratio: 0.40 – 0.50 (Boots 2-star)
- UVA-I/UV ratio: 0.45 – 0.55 (2-star according to proposed FDA system)
- Critical wavelength: 365 – 369 nm
- Ratio of UVA protection factor to SPF: ~0.25

Therefore, formulations containing Solaveil CT dispersions as the sole active usually do not meet the required ratio of UVA protection factor to SPF, as specified in the September 2006 EU guidelines on efficacy and labelling of sunscreen products. To achieve this ratio, or to achieve a higher "star rating" according to the Boots or proposed FDA systems, we recommend combining the Solaveil CT dispersion with a UVA filter such as zinc oxide.

Transparency

Delivering true transparency on skin

The key benefit of Solaveil CT dispersions is much improved transparency on skin, when compared to conventional fine particle grades of titanium dioxide. This improved transparency is achieved by a combination of the closely-controlled particle size distribution, and optimised dispersion of the particles, enabling whitening to be reduced without compromising SPF efficacy.

Transparency can be measured either in-vitro or in-vivo:

- In-vitro
  - The whiteness of a black card (L_s) is measured using a colormeter (Minolta CR-300)
  - The sunscreen formulation is applied to the card using a 'K' Bar, giving a thin film of the sunscreen on the card
  - After 10 minutes the whiteness of the sunscreen and substrate (L_f) is measured
  - The "whitening index", ΔL, is calculated as $\Delta L = L_f - L_s$
- In-vivo
  - Similar to in-vitro, but with sample applied on skin (forearm), by spreading with a gloved finger

Figures 5 and 6 show in-vitro and in-vivo whitening index values for formulations containing Solaveil CT-100, and the same formulations made with Tioveil 50 FIN.

The in-vivo data (Figure 6) are plotted as "relative whitening index", which is the difference in whitening between the test formulation and an equivalent formulation based on organic sunscreens.

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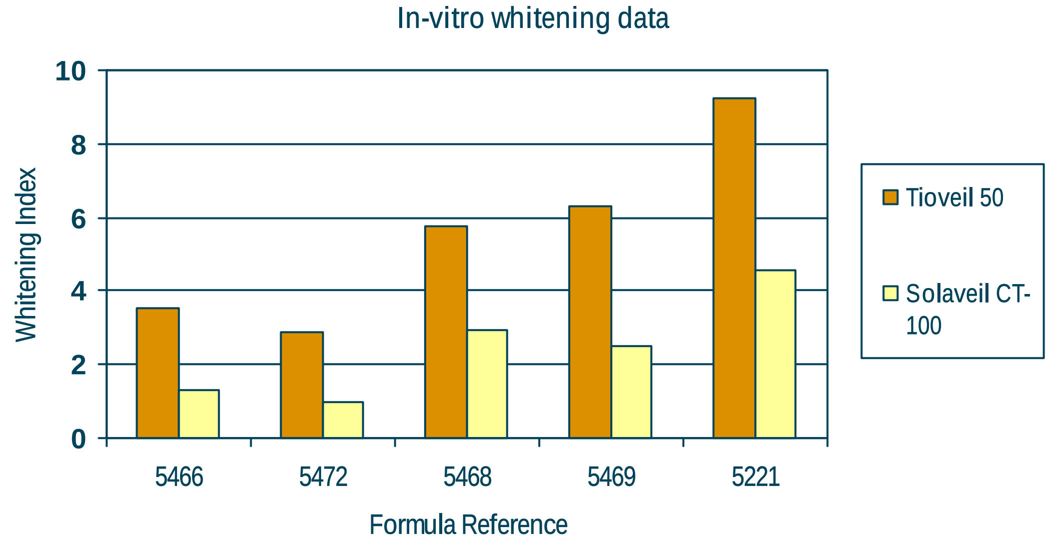

Figure: 5 Whitening index for formulations prepared with Tioveil 50 and Solaveil CT-100

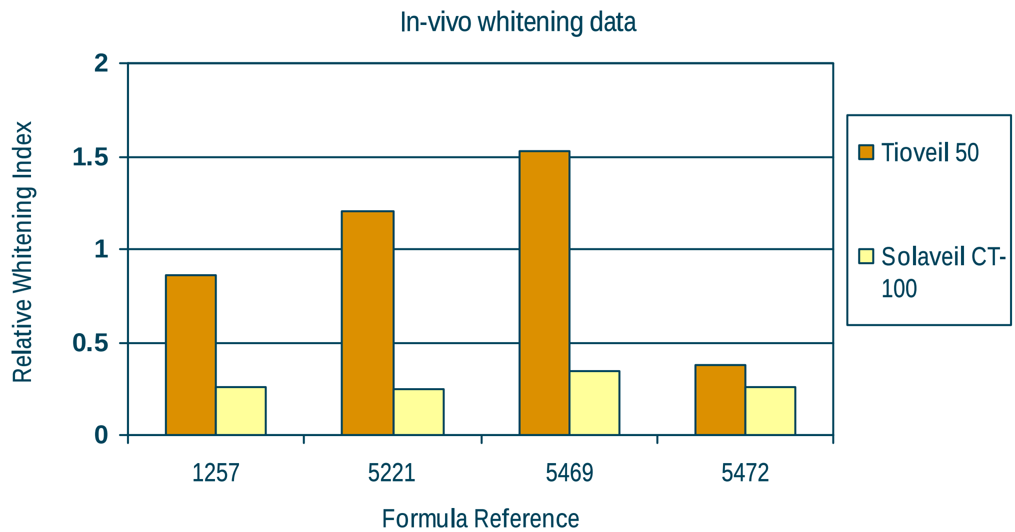

Figure: 6 In-vivo whitening data for formulations prepared with Tioveil 50 and Solaveil CT-100

It is clear that Solaveil CT-100 gives much lower levels of whitening than Tioveil 50 (which, in turn, gives less whitening than most conventional sunscreen grades of TiO_2). More importantly, the *in-vivo* relative whitening indices for the Solaveil CT-100 formulations are all <0.5; such a difference in whitening cannot be detected by eye. In other words, formulations based on Solaveil CT-100 are visibly as transparent on skin as equivalent formulations based on organic sunscreens.

Figure 7 shows whitening data for Solaveil CT-200, compared to Tioveil 50 MOTG and also against competitor TiO_2 dispersions and powders. Once again, the Solaveil product gives the lowest whitening. There is one powder product which also gives very low whitening, but, as can be seen from Figure 8, this powder also has poor SPF efficacy, whereas Solaveil CT-200 combines excellent transparency with high SPF.

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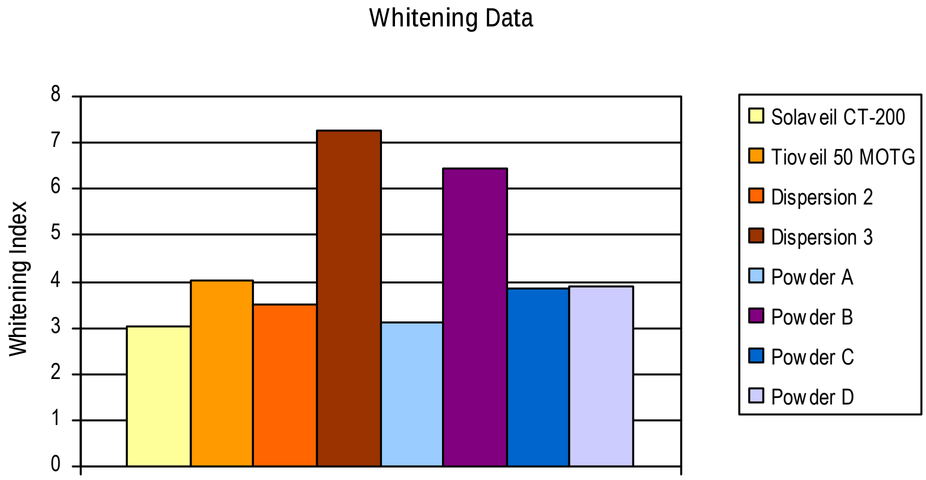

Figure: 7 Whitening data for formulations containing Solaveil CT-200 and competitor materials

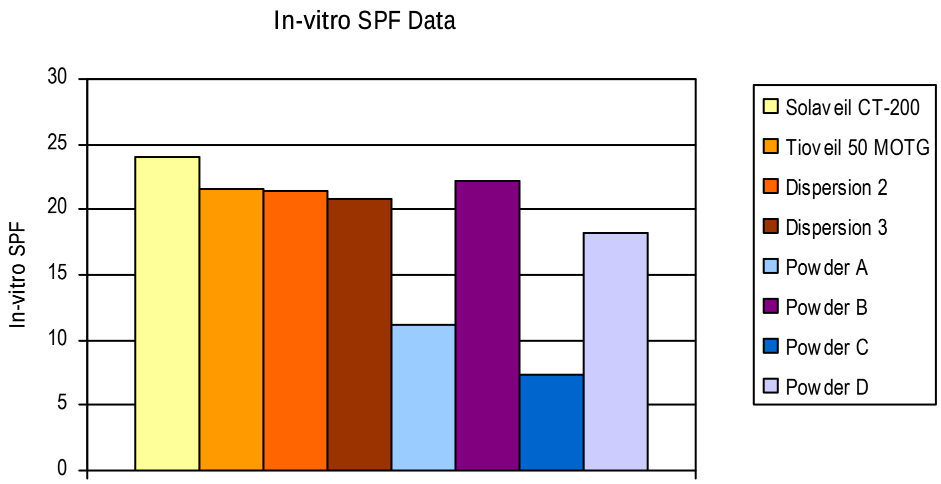

Figure: 8 In-vitro SPF data for formulations containing Solaveil CT-200 and competitor materials

Figures 9 and 10 show in-vitro SPF and whitening data for two formulations containing Solaveil CT-10W, compared to the same formulations made with other aqueous TiO_2 dispersions. Once again, the Solaveil Clarus product gives much less whitening compared with the other dispersions, while maintaining high SPF efficacy.

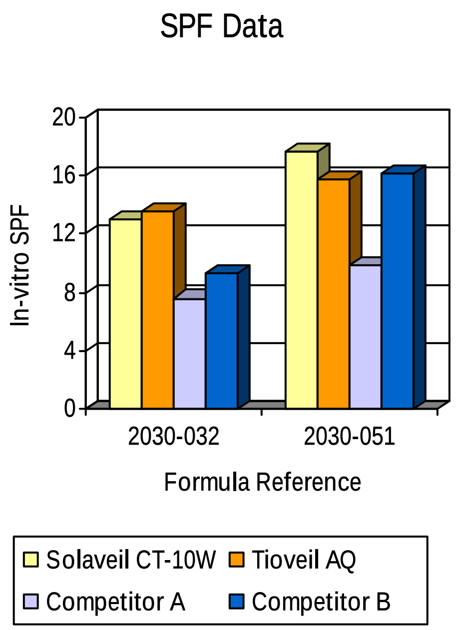

Figure: 9 In-vitro SPF data for formulations based on Solaveil CT-10W and other dispersions

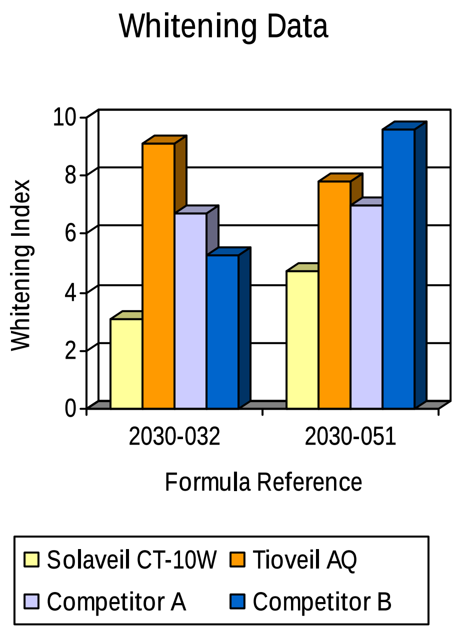

Figure: 10 Whitening data for formulations based on Solaveil CT-10W and aqueous TiO_2 other aqueous TiO_2 dispersions

Formulating Guidelines

Solaveil CT dispersions should be incorporated into the appropriate phase of the emulsion (i.e. water-based dispersions in the water phase, oil dispersions in the oil phase), with stirring. In cases where the Solaveil CT dispersion is in the external phase, it can also be incorporated as a separate phase after emulsification.

Formulating with Solaveil CT Oil Dispersions

Solaveil Clarus oil-based dispersions can be incorporated into either the internal phase of an oil-in-water emulsion, or the external phase of a water-in-oil system. They have been designed to be compatible with a wide range of different oil phase ingredients and therefore good dispersion can be maintained with a many different emollients.

W/O Emulsions

This type of emulsion has previously been shown to be a very efficient vehicle for sunscreen actives, and is particularly suitable for oil-based dispersions of TiO_2. The main principles of formulating W/O emulsions with Solaveil Clarus are similar to guidelines for working with “first-generation” Tioveil oil dispersions and Tioveil 50 dispersions, since these principles arise from the physical properties of an inorganic particulate in a W/O emulsion. These key principles are:-

- Determine the optimum phase volume fraction for stability, by adjusting the concentrations of emollient oils.
- Use low concentrations of emulsifiers, for optimum stability and aesthetics
- Addition of waxes or other rheological additives improves SPF

Other tips for optimising W/O formulations containing Solaveil CT oil dispersions are:-

- Phase Volume Fraction can also affect SPF efficacy. This is a rheological effect; IPR in W/O emulsions affects rheological behaviour and hence can affect SPF. Of course, as mentioned above, the IPR must also be such that the emulsion remains stable. At high IPR, W/O emulsions can be made with a very light skin feel, suitable for daily use skin care products. Experimental work has shown that with judicious choice of emulsifier (see below), W/O emulsions containing Solaveil Clarus are stable at IPR's of up to 83%.
- Emulsifier Type: The best stability, SPF and transparency results are achieved with polymeric emulsifiers such as Arlacel™ P135 (PEG-30 Dipolyhydroxystearate), Prisorine™ 3700 (Polyglyceryl-3 Diisostearate) or Arlacel 1690 (Sorbitan Isostearate (and) Polyglyceryl-3 Ricinoleate).
- For formulation of low viscosity W/O emulsions with Solaveil CT dispersions, Prisorine 3700 or Arlacel 1690 are recommended.
- Emulsifier Content: Arlacel P135 is a highly efficient emulsifier, and for emulsions with a high internal phase ratio, 1% of this emulsifier can be sufficient to give stable emulsions. At a level of 2%, Arlacel P135 gives good stability over a wide range of phase volume ratios. With other emulsifiers at least 3% is usually required for stability.
- Rheological Additives: Waxes and other rheological additives can substantially boost SPF efficacy in W/O sunscreen emulsions, due to improvements in the recovery and film-forming properties of the emulsions on skin after spreading. The same applies with Solaveil Clarus dispersions; beeswax, ozokerite, candelilla and castor wax all give improvements in SPF.
- The optimum wax content varies according to phase volume fraction, solids content, emulsifier type and emulsifier content. Generally, the lower the viscosity of the base emulsion (i.e. without wax), the higher the optimum wax content. This is because if the base emulsion has a low viscosity, a higher level of wax can be incorporated before it starts to have an adverse effect on spreadability.

O/W Emulsions

In terms of analysing the mechanisms by which different parameters influence SPF efficacy and whitening, O/W emulsions are more complex to study than W/O systems, because evaporation of water begins as soon as the product is first applied to the skin, and the physical and chemical composition of the emulsion is constantly changing during rub-in. Often it is only possible to determine empirically which factors influence the results.

The formulator has a very wide choice of emulsifier types and emulsion systems available for O/W emulsions. In order to get a comprehensive picture of the behaviour of Solaveil Clarus, a number of different systems have been studied, including:-

- "Conventional nonionic" systems, such as blends of sorbitan esters with ethoxylated sorbitan esters
- "Liquid crystal" systems, which make use of lamellar liquid crystalline structures to stabilise the emulsion
- "Combined" systems, which make use of both nonionic and anionic surfactants
- Anionic emulsifier systems

Generally, the best results are achieved with the first three types of system, i.e. those based on nonionic or combined nonionic / anionic emulsifier systems.

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Other formulating tips for Solaveil CT dispersions in O/W emulsions are:-

- Effect of Emollients: The emollients used in the formulations have little influence on SPF, demonstrating again that the dispersions are compatible with a wide range of oils.
- Lipid Thickeners: Fatty alcohols, fatty acids, and fatty acid esters such as glyceryl stearate are commonly used to build structure in O/W emulsions and are sometimes referred to as "lipid thickeners". These materials have significant effects on emulsion rheology and as such might be expected to influence SPF and transparency. In studies with Solaveil Clarus dispersions, it was found that SPF could be boosted by addition of an appropriate lipid thickener, without significantly affecting whitening.
- Hydrocolloids: Various types of hydrocolloid have been evaluated with Solaveil CT dispersions in different formula systems. The only general comment that can be made is that use of a hydrocolloid is usually advantageous in terms of emulsion stability; the influence of the different thickeners on SPF and whitening varied according to the formula system, although silicate types (e.g. Veegum Ultra) gave good results in all the systems studied.
- Polymers: It is recommended to include a film-forming polymer such as SolPerForm™ 100 to boost the SPF efficacy of O/W emulsions containing oil-based sunscreen actives. Other film-formers can be used but SolPerForm 100 provides an SPF boosting effect in a wide range of formulations, without any negative impact on skin feel.

Formulating with Solaveil CT Water Dispersions

Solaveil CT-10W and Solaveil CT-12W contain hydrophobically-coated TiO_2, with non-ionic dispersing agents to maintain the stability of the dispersion. Solaveil CT-30W, by contrast, contains hydrophilic TiO_2, with a polyelectrolyte to stabilise the dispersion. Therefore the formulation behaviour of Solaveil CT-30W differs from that shown by Solaveil CT-10W and CT-12W.

O/W emulsions

As with the Solaveil CT oil dispersions, the water-based dispersions Solaveil CT-10W and Solaveil CT-12W have also been evaluated in various different types of O/W emulsion systems. Once again, the best results are achieved with nonionic or combined anionic/nonionic systems. A particularly versatile emulsifier combination for use with Solaveil CT-10W or CT-12W is Arlacel™ 165 (glyceryl stearate (and) PEG-100 stearate) combined with Arlatone™ MAP-160K (potassium cetyl phosphate). This system is useful for making sprayable sunscreen formulations, or if a higher viscosity is desired, this can be achieved by increasing the content of Arlacel™ 165.

In purely nonionic systems, the HLB of the emulsifier system is also important. Generally, the best results are achieved with an overall HLB value of less than 10. However, the optimum HLB value in any given system varies according to the composition of the oil phase.

The emulsifier combination Brij™ 72 (steareth-2) and Brij™ 721 (steareth-21) was used to study the effects of varying emulsifier HLB with different emollients, when Solaveil CT-10W is used as the active. The overall HLB of this emulsifier system can be varied by changing the proportions of the two components.

A trend emerges when the required HLB and polarity of the oil phase are taken into account. Arlamol™ PS15E (PPG-15 stearyl ether) is a highly polar oil, and has a relatively low required HLB value of 7. With this oil, the emulsions show significant flocculation if the emulsifier HLB value is greater than 9. By contrast, isohexadecane is a non-polar oil with a required HLB of 12. In this case, agglomeration is observed if the HLB is below 8, but viable emulsions are still formed up to an HLB value of at least 12 (although at this HLB the emulsions are of very low viscosity and SPF tends to be low as a result). Ethylhexyl stearate and isopropyl myristate are both of medium polarity, but their required HLB values are somewhat different (7.5 and 11.5 respectively). With these oils, viable emulsions are formed across the full range of HLB. In other words, with a medium polar oil phase, the required HLB of the oil phase is less important and there is greater flexibility in choosing the emulsifier mix.

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Other tips for O/W emulsions containing Solaveil CT-10W and 12W are:-

- Lipid Thickeners: In studies with Solaveil CT-10W, it was found that SPF could be boosted by addition of an appropriate lipid thickener. However, an excess of lipid thickener can result in a formulation which is too viscous, and with decreased SPF. The optimum concentration of lipid thickener varies between formula systems, and needs to be determined experimentally.
- Hydrocolloids: Various types of hydrocolloid have been evaluated with Solaveil CT-10W. Use of a hydrocolloid is usually advantageous in terms of emulsion stability; best results have been achieved with magnesium aluminium silicate (Veegum Ultra), xanthan gum, and starch-based thickeners. Carbomers are not recommended.

When formulating with Solaveil CT-30W, it is recommended to use non-ionic emulsifier systems, as ionic surfactants tend to de-stabilise the dispersion leading to agglomeration, which has an adverse effect on SPF efficacy and whitening. It is also recommended to avoid electrolytes, and to maintain a formulation pH of at least 5.

W/O Emulsions

A novel feature of Solaveil CT-10W and Solaveil CT-12W is that they also show good efficacy in W/O emulsions. This is in contrast to most aqueous TiO_2 dispersions.

Relatively little work has been done on W/O emulsions thus far. The conclusions given below are based on a simple W/O system using Arlacel P135 (PEG-30 dipolyhydroxystearate) as emulsifier.

- Phase Volume Fraction: In formulations containing Solaveil CT-10W, it was observed that if the oil phase content is too low, the result is a highly viscous, gel-like emulsion which can be difficult to spread. A higher oil phase content reduces viscosity and improves spreadability, but if the oil phase is too high, the SPF can be adversely affected due to poor film-forming. The optimum phase volume fraction, providing good spreading and also good SPF, depends on the composition of the oil phase. With a combination of Estol™ 3609 (light spreading, medium-polar emollient) and isohexadecane (fast spreading, non-polar emollient), the optimum oil phase content was around 20%.
- Rheological Additives: As with oil-based dispersions, W/O emulsions containing Solaveil CT-10W also show improvements in SPF with incorporation of waxes, but the improvements tend to be smaller than those observed with oil-based dispersions. Waxes also tend to increase whitening slightly.

Solaveil CT-30W normally gives poor efficacy in W/O systems. This is because an electrolyte is normally incorporated into such emulsions to aid stability, and as noted above, Solaveil CT-30W is not compatible with electrolytes.

Formulating with Organic Sunscreens

Inorganic sunscreens such as Solaveil CT dispersions are often combined with organic UV filters. Such combinations are advantageous because there are often synergistic effects between the different types of UV filter, such that the SPF efficacy of the combinations is greater than would be achieved by using either type by itself. Solaveil CT dispersions can be formulated with all organic sunscreens, and this is usually the most cost-effective way to achieve high SPF values and broad spectrum UVA/UVB protection.

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Certain organic sunscreens, such as butyl methoxydibenzoylmethane and benzophenone-3, can give a yellow colour in formulations with TiO_2 in the oil phase. This does not affect the efficacy of the actives but can be cosmetically undesirable. To avoid this, it is recommended to use Solaveil CT water dispersions (CT-10W or CT-12W) in formulations which contain these organic filters. By incorporating the TiO_2 into the water phase of the emulsion, it can be kept separate from the oil-soluble organic UV filters and any undesired interactions are avoided. (NOTE: In the USA, under the FDA's current proposed rules for sunscreen products, the combination of titanium dioxide and butyl methoxydibenzoylmethane is not permitted).

Regulatory

Titanium dioxide is globally approved for use in sunscreen formulations. In most countries, the maximum allowed concentration in the final product formulation is 25% w/w titanium dioxide; however there is some variation in controls and the appropriate country regulations should be consulted in order to ensure compliance for the final product formulation.

The composition of the Solaveil CT dispersions is declared in full using INCI naming to allow formulation development and marketing to proceed by checking conformance with any applicable regulatory controls.