ACTIVE INGREDIENT
ZinCLEAR
100% MINERAL PHYSICAL

Guide Formulations

ARTG ID – 304043 (Astivita)

ZinXation SPF50 with ZinClear-XP65 COCO dispersion

Phase	Trade Name	INCI Name	Function	% w/w
A	Water	Aqua	Solvent	27.46
	Glycerin	Glycerol	Humectant	11.00
	ICB3000	Maltodextrin	Polymer	1.00
	Amphisol A	Cetyl Phosphate	Emulsifier	0.50
	Sodium Chloride	Sodium Chloride	Salt	0.50
	EDTA Salt	EDTA Disodium Salt	Chelant	0.10
B	Vegelight 124 LC	Coconut Alkanes (and) Coco-Caprylate/Caprate	Emollient	7.00
	Jojoba Oil	Simmondsia Chinensis (Jojoba) Seed Oil	Emollient	5.50
	PGPR	Polyglyceryl-3 Polyricinoleate	Emulsifier	5.00
	Candelilla Wax	Euphorbia Cerifera	Wax	2.50
	Pelemol PHS-8	Polyhydroxystearic Acid	Dispersant	1.00
	ZinClear-XP65 COCO	Zinc Oxide, Coco-Caprylate/Caprate, Polyglyceryl-3 Polyricinoleate, Isostearic Acid	Active Dispersion	***38.44***
				100.00

Procedure:

1. Premix phase A and heat to 60°C.
2. Premix phase B sequentially and heat to 60 – 70°C.
3. Maintain heat on both phases, stirring until uniform.
4. Add phase A slowly to phase B while stirring
5. Homogenise until uniform
6. Begin to cool to 30°C.

Note: This formulation is provided as a sample formulation guide only. No liability on the part of Antaria Pty Ltd for any third party use of this formulation is implied. Any user of these formulations will be responsible for all appropriate testing to confirm that this formulation meets any requirements whether statutory or contractual, including, but not exclusively, SPF and product stability.

ZinXation SPF50 with ZinClear XP Powder

Phase	Trade Name	INCI Name	Function	% w/w
A	Purified Water	Aqua	Solvent	27.46
	Glycerin	Glycerol	Humectant	11.00
	ICB3000	Maltodextrin	Polymer	1.00
	Amphisol A	Cetyl Phosphate	Emulsifier	0.50
	NaCl	Sodium Chloride	Salt	0.50
	EDTA Salt	EDTA Disodium Salt	Chelant	0.10
B	Vegelight 124 LC	Coconut Alkanes (and) Coco-Caprylate/Caprate	Emollient	7.00
	Jojoba Oil	Simmondsia Chinensis (Jojoba) Seed Oil	Emollient	5.50
	PGPR	Polyglyceryl-3 Polyricinoleate	Emulsifier	6.35
	Candelilla Wax	Euphorbia Cerifera	Wax	2.50
	Pelemol PHS-8	Polyhydroxystearic Acid	Dispersant	1.00
	Lanol	Coco-Caprylate/Caprate	Emollient	11.53
	Prisorine 3505	Isostearic Acid	Dispersant	0.58
	ZinClear XP	Zinc Oxide	Active	***24.99***
				100.00

Procedure:

1. Premix phase A and heat to 60°C.
2. Premix phase B sequentially and heat to 60 – 70°C.
3. Maintain heat on both phases, stirring until uniform.
4. Add phase A slowly to phase B while stirring
5. Homogenise until uniform
6. Begin to cool to 30°C.

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ZinXation SPF47 with ZinClear XP Powder

Phase	Trade Name	INCI Name	Function	% w/w
A	Purified Water	Aqua	Solvent	27.00
	Glycerin	Glycerol	Humectant	10.50
	ICB3000	Maltodextrin	Polymer	1.00
	Amphisol A	Cetyl Phosphate	Emulsifier	0.50
	NaCl	Sodium Chloride	Salt	0.50
	EDTA Salt	EDTA Disodium Salt	Chelant	0.10
B	Vegelight 124 LC	Coconut Alkanes (and) Coco-Caprylate/Caprate	Emollient	7.20
	Jojoba Oil	Simmondsia Chinensis (Jojoba) Seed Oil	Emollient	5.70
	PGPR	Polyglyceryl-3 Polyricinoleate	Emulsifier	6.50
	Candelilla Wax	Euphorbia Cerifera	Wax	2.60
	Pelemol PHS-8	Polyhydroxystearic Acid	Dispersant	1.00
	Hinokitiol	β-Thujaplicin	Active	0.50
	Crodamol OP	Ethylhexyl Palmitate	Emollient	11.40
	Prisorine 3505	Isostearic Acid	Dispersant	0.50
	ZinClear XP	Zinc Oxide	Active	***25.00***
				100.00

Procedure:

1. Premix phase A and heat to 60°C.
2. Premix phase B sequentially and heat to 60 – 70°C.
3. Maintain heat on both phases, stirring until uniform.
4. Add phase A slowly to phase B while stirring
5. Homogenise until uniform
6. Begin to cool to 30°C.

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SPF Test Result Table — ISO 24444 SPF Test Method- 2010

Client: **Advance Nanotek Ltd**

Test Condition: Static Testing

Product: **ZinXation 100**

Appendix A Report p1
UV Source: **XE**

EP3035CW2.5HS Report Reference Number: **20558**

	Subj Code	Skin Type	ITA	Sex	Age	Exposure Date	Applied By	Read By	MED /hr	MEDus** secs	MEDus** mJ	MEDps secs	SPFi	SPFn'	s(n')	c(n')	CIn' [%] (100cn'/SPFn')	Conclusion: c(n')<Cn'	P2 Ref MEDr	P2 Ref SPF
1	92481	II	55	m	27	28/1 /21	S. M	H. F	115	17	16.9	816	48.0						286	16.8
2	92621	II	46	F	31	2/2 /21	H. L	H. F	110	20	19.0	900	45.0						290	14.5
3	92654	II	46	F	32	3/2 /21	S. M	H. F	110	20	19.0	986	49.3						300	15.0
4	92423	III	37	F	28	30/4 /21	H. L	H. F	128	24	26.6	1104	46.0						348	14.5
5	92167	II	44	F	31	5/5 /21	S. M	H. F	117	21	21.2	1129	53.8						315	15.0
6	92659	II	52	M	48	17/5 /21	A. W	H. F	125	23	24.9	1176	51.1						395	17.2
7	92438	I	61	F	27	28/5 /21	S. M	H. F	115	17	16.9	750	44.1						282	16.6
8	92466	II	48	M	56	4/6 /21	S. M	H. F	114	24	23.7	1100	45.8						370	15.4
9	92612	III	36	M	46	4/6 /21	H. L	H. F	125	27	29.2	1200	44.4						420	15.6
10	92242	III	37	M	32	7/6 /21	H. L	H. F	126	26	28.3	1248	48.0	47.6	3.1	2.24	4.71	COMPLIES	390	15.0
11																				
12																				
13																				
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16																				
17																				
18																				
19																				
20																				

Study Dates From: 28 Jan 2021 To: 8 Jun 2021 — s= **3.1** c=**2.24** CI%=**4.71** n=**10**

FINAL — Product Mean SPF= **47.6** — 95% CI: **45.3** to **49.7**

Signoff Clinical Manager: Holly Huang Feng B.Sc. (Eng) Dip. Appl.Sc
Signoff Study Director: Jennifer Wan BSc (Hons) MASM
This report has been electronically signed

Ref Std Mean: 15.6 Range: 14.5 – 17.2

20558 DESOP - 010 V1.8

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Formulating with ZinClear XP™ powder and 100% Vegan Organic plus ZinClear XP™ Dispersions

- For maintaining percentage of ZinClear XP™ when formulating with 100% Vegan Organic plus ZinClear XP™ Dispersions, for every 1 wt% ZinClear-XP65 COCO Dispersion, substitute in 1.1 – 1.3 wt% of 100% Vegan Organic plus ZinClear XP™ dispersion (dependant on the choice of 100% Vegan Organic plus ZinClear XP™ Dispersion).
- For a SPF50 25 wt% ZinClear XP™ formulation, use 43 – 50 wt% of 100% Vegan Organic plus ZinClear XP™ Dispersion (dependant on the choice of 100% Vegan Organic plus ZinClear XP™ Dispersion).
- Guide: To formulating SPF50 water-in-oil sunscreen using ZinClear XP™ Powder
    - Add all the water phase ingredients (Phase A) together and mix at 60°C until evenly distributed and solubilised.
    - Separately, add ZinClear XP™ Powder with additional oil phase ingredients (Phase B) together and mix at 60 – 70°C allowing wax to melt. Mix until ingredients are evenly distributed and solubilised.
    - Maintaining temperature, add Phase A to Phase B and mix until homogenised.
- Guide: To formulating SPF50 water-in-oil sunscreen using 100% Vegan Organic plus ZinClear XP™ Dispersions
    - Add all the water phase ingredients (Phase A) together and mix at 60°C until evenly distributed and solubilised.
    - Separately, add 100% Vegan Organic plus ZinClear XP™ Dispersion with additional oil phase ingredients (Phase B) together and mix at 60 – 70°C allowing wax to melt. Mix until ingredients are evenly distributed and solubilised.
    - Maintaining temperature, add Phase A to Phase B and mix until homogenised.

Formulating with ZinClear

ZinClear® products are being used to formulate elegant sunscreens with broad spectrum (UVA and UVB absorption) coverage, and high SPF. ZinClear® dispersions allow the formulation of very safe, mineral based sunscreens, which do not require the use of “chemical” UV absorbers, but still provide high SPF, high transparency, and low whitening effect on the skin.

ZinClear® XP dispersions are ideal for the following applications:

- Broad Spectrum UV protection (UVB, UVA-I, UVA-II)
- Mild sun care for sensitive skin types or sensitive areas (face, neck)
- Children’s sunscreens suitable for young skin at risk of sensitisation
- UV protection for daily use products
    - Daily protection from UVA Damage
    - Daily protection from Skin Ageing
    - Daily protection from Skin Darkening
    - Daily protection form Skin Pigmentation
- As an SPF booster and UVA absorber for sun care using “chemical” absorbers or TiO_2

ZinClear XP™ Powder

ZinClear XP™ powder is provided as a homogenous dry powder of uncoated micron-sized zinc oxide particles. It is supplied as a powder to give formulators the option to incorporate zinc oxide into different phases and use different dispersing agents.

ZinClear XP™ powder must be dispersed evenly to achieve good SPF protection. For this, Antaria highly recommends the combination of organic Isostearic Acid (wetting agent) and organic Polyglycerol-3 Polyricinoleate (dispersing agent) when formulating with ZinClear XP™ powder. It is important to note

that a number of different grades of these organic ingredients are available, with different particle sizes and therefore different chemical and physical properties. Antaria recommends that some experimentation will be necessary using different grades of organic raw materials to determine the optimum grade and concentration to use in specific formulation systems.

New 100% Vegan Organic plus ZinClear XP™ Dispersions

Antaria is leading the way by becoming the first company in the world to divert away from traditional ingredients used in its manufacture of current dispersions, to formulating 100% Organic and Vegan products using natural ingredients. Organic materials are derived from natural plants with no chemical pesticides, artificial fertilisers, ionizing radiation and synthetic chemicals that deeply moisturises the skin with natural texture, providing excellent broad-spectrum protection against UVA and UVB.

Antaria has added to its dispersions, a range of 100% Vegan Organic plus ZinClear XP™ dispersions to provide customers with an option to make end products using completely organic and vegan ingredients, i.e. sunscreens with organic ingredients offer a safe and more environmentally friendlier choice for its customers.

Antaria's use of high grade interchangeable organic oils, such as Sunflower and Coconut oil has produced formulations with high *in-vitro* and *in-vivo* SPF levels. It is important to note that due to varying chemical composition of oils, e.g. fatty acid profile; the percentages of ZinClear XP™ powder activities and loadings may vary slightly for each specific formulation.

Achieving Formulation Stability with 100% Vegan Organic plus ZinClear XP™ Dispersions

A stable formulation is required to achieve high transparency, and broad-spectrum absorption with high SPF. To produce a stable formulation, the following factors need to be considered:

Homogeneity

Antaria recommends that all products in the emollient phase, such as oils, waxes, film formers, emulsifiers and other UV absorbers, are mixed with high energy and at sufficient temperature prior to emulsification to ensure homogeneity is maintained. Through homogeneity, SPF and transparency are intimately linked, which enables transparency to be used as a guide to the level of homogeneity in the formulation.

pH Stability and Control

One of the most important considerations when formulating with zinc oxide is the pH. It will affect the level of zinc ions in the water phase of an emulsion as zinc oxide will become slightly soluble at pH values below 7.5, with a sharp increase below pH 7. The problem with zinc ions present in the aqueous phase is unwanted reactions that can cause thickening and/or emulsion instability. Working at low pH (pH <7) should be avoided if possible. A chelating agent can assist in improving formulation stability.

The pH of the aqueous phase may rise during formulation. Buffering is often performed during formulation using citric acid, lactic acid or other organic acids. Addition of these acids to the aqueous phase before emulsification can help to stabilise the emulsion, but care must be taken to not reduce the pH below 7, as the amount of zinc ions in the aqueous phase could increase.

Unwanted Zn^{2+} ion reactions

Some thickeners and film-formers may result in formulation problems. Most acrylate-type thickeners (e.g. carbomers) are sensitive to zinc ions, forming zinc complexes which disrupt the thickener's efficiency. Non-ionic thickeners such as organic xanthan gum are generally stable.

Other species that may react with zinc ions, such as sodium stearate, should be avoided, especially in lower pH range formulations, as zinc stearate can form. It has been found that NaCl in the aqueous phase can also be used to stabilise the emulsion causing less formulation problems to occur. Non-ionic emulsifiers should be used instead of water-soluble fatty acid salts.

Zinc Oxide Density = Dense material

This is usually only a potential issue in oil-in-water systems. Adding zinc oxide to an oil phase will increase its density, and loadings of greater than 5 wt% zinc oxide may make the oil phase denser than the water phase. At high loadings more emulsifier may be needed to counteract this problem. Another way to overcome this issue is to add polymers to match densities of the oil and water phases, which can overcome any phase separation in the emulsion.

Ensuring Transparency

To optimise the transparency of 100% Vegan Organic plus ZinClear XP™ formulations, it is advised to start with a base emulsion system that will not leave a white film on the skin prior to the addition of 100% Vegan Organic plus ZinClear XP™ dispersion. The transparent property of 100% Vegan Organic plus ZinClear XP™ in non-whitening formulations are best seen after the film has been allowed to dry out on the skin. Whitening of the skin by the base formulation may be caused by the wrong amount and/or type of emulsifier.

Sun Protection Factor (SPF) Performance

The key factor in producing a high SPF sunscreen using 100% Vegan Organic plus ZinClear XP™ dispersion is in getting the formulation correct and stable. This has been covered in the above section of this document. This section below will cover what a formulator can achieve with 100% Vegan Organic plus ZinClear XP™ dispersion.

Particle Loading

Formulators aiming for mineral only sunscreens are using between 50 – 60% of 100% Vegan Organic plus ZinClear XP™ dispersion to give SPF 50+ (depending on the formulation). At this loading, if the formulation is good, no whitening of the skin (normally associated with minerals such as titanium dioxide or other currently used micronised zinc oxide products) should be observed. More standard sunscreens have been formulated with very high SPF's using 100% Vegan Organic plus ZinClear XP™ dispersion at lower levels in conjunction with other UV absorbers. Generally, it should be found that 2 wt% of 100% Vegan Organic plus ZinClear XP™ dispersion (~1% ZnO) gives about 1.5 SPF units; some formulations give up to 2 SPF units.

Film formers

As ZinClear™ XP powder does not penetrate the skin like some chemical UV absorbers, forming a consistent film thickness over the contours of the skin is essential to achieving greater SPF efficiency. Antaria has found that the addition of waxes such as organic Candelilla Wax, assist in raising SPF performance.

Antimicrobial Activity

Zinc oxide has some natural antimicrobial properties as can be seen in Table 1. This may allow a reduction in the preservative concentration in the formulation and/or some anti-microbial functionality or claims to be made in the end-user products subject to efficacy testing.

Table 1: Mean Minimal Inhibition Concentration (MIC) for 100% Vegan Organic plus ZinClear XP™ dispersion against a panel of organisms with ten isolates per organism type. Method used agar dilution.

Organism	Isolate numbers	ZnO solution MIC(% ZnO)
C. albicans	10	>4
P. aeruginosa	10	1
S. aureus	10	0.125
E. coli	10	0.5

UVA Performance of 100% Vegan Organic plus ZinClear XP™ Dispersions

UVA/UVB ratio

ZinClear® only formulations will typically have UVA/UVB ratios of between 0.7 – 0.8, which indicate that the formulations give balanced protection against UVA and UVB radiation. The UVA/UVB ratio defines the average absorbance in the UV-A range (320 – 400 nm) in relation to the average absorbance in the UV-B range (290 – 320 nm). The closer the UVA/UVB ratio approaches 1, the better the balance between UVB and UVA protection. For a given SPF, the higher the UVA/UVB ratio, the better the sunscreen will protect against UVA radiation.

EU and Australian UVA Requirements

Current requirements for UVA protection in both Europe and Australia are two-fold:

1. The UVA Protection Factor (UVAPF) must be at least 1/3 of the labelled SPF;
2. The critical wavelength must be at least 370 nm.

The critical wavelength is given as the upper limit of the spectral range from 290 nm onwards, within which 90% of the area under the absorbance curve of the whole UV-range between 290 nm and 400 nm is covered. The higher the critical wavelength of a sunscreen, the better its UVA-performance in relation to its UVB-performance. If that wavelength is 370 nm or greater, the product is considered "broad spectrum," which denotes balanced protection throughout the UVB and UVA ranges.

Formulations based on ZinClear XP™ powder will usually meet and exceed the requirements as seen in *in-vitro* SPF measurements in our laboratories. However, in rare cases the critical wavelength with 100% Vegan Organic plus ZinClear XP™ dispersions may be slightly below 370 nm.

FAQs

I am experiencing whitening and a lower SPF than expected when using ZinClear XP™ powder, what can I do?

- The level of dispersant for the zinc oxide powder is probably too low. Try modifying the dispersant or increasing the level. We recommend the 100% Vegan Organic plus ZinClear XP™ dispersions for easier handling.

I want to increase my SPF but I can't increase my ZnO % (costs / regulation max reached), what can I do to maximise SPF?

- Try increasing the level of thickeners and waxes in your formulation. You can also try using a film former, SPF boosters or increase the stability of your formula by using gelling agents, for example:
    - Brassica Oil Copolymer (cosmos approved)

I observe some 'clumps' in my emulsion when I use ZinClear XP™ powder, what can I do?

- The zinc oxide is probably migrating to the water phase and agglomerates. Try increasing the levels of emulsifiers.