

Rade Dudurovic
Non-Executive Chairman
Antaria Limited
3 Brodie Hall Drive
Bentley WA 6102

3rd August 2012

Dear Mr Dudurovic,

Response to Antaria letter – July 11, 2012

We are deeply concerned by your response on the 11th July 2012 and statement to the ASX on July 25th, 2012.

Our responses to the six comments from your letter are addressed in-text below:

1. *“We reject the assertions made in your correspondence which allege that we mislead the public regarding ZinClear IM.”*

Since ZinClear IM was launched in 2007, Antaria Limited have made several statements to the Australian Stock Exchange (ASX), shareholders and sunscreen brands (e.g. Invisible Zinc, October 2010) claiming that ZinClear IM is “non-nano”.

To understand what the claim “non-nano” means, we look to definitions for what “nano” means. Here in Australia, NICNAS have defined nanomaterials to include aggregates of nanoparticles since 2006 and more formally since 2010. This important aspect of the NICNAS nanomaterial definition is mirrored by the International Organisation for Standardization (ISO), agreed upon by 32 member countries.

Since 2010, more than ten different Australian sunscreen brands have provided ZinClear IM certificates of analysis to Friends of the Earth for the explicit purpose of listing these sunscreen brands as nano-free. By describing the ZinClear IM as “particles [greater than] > 1um” and “NOT classified as a nanomaterial” to these brands, we assert that Antaria Limited are responsible for misleading these sunscreen brands and subsequently the Australian public.

We believe a reasonable approach is to now inform sunscreen brands and the public that Antaria’s view of the available evidence is selective and does not fairly represent the available evidence, nor represent ZinClear IM accurately as a nanomaterial.

2. *“In particular, we confirm that the zinc oxide in our ZinClear IM dispersion is of a non-Nano particle size. This is based on measurement of the diameter of the particle using internationally accepted methods.”*

On 24th February 2012, the patent US 2010/0310871 A1 was confirmed by the Antaria employee Dr. John Robinson to be the basis of the ZinClear IM product.

As we explained in our letters on the 21st May, 2012, the ZinClear IM product – as described by the patent US 2010/0310871 A1 - should be classified as a nanomaterial, according to both NICNAS and ISO (ISO/TS 80004-1:2010) definitions. This understanding is confirmed by the National Measurement Institute (NMI) report (June 28, 2012), commissioned by Friends of the Earth and sent to Antaria on July 6, 2012.

The patent (US 2010/0310871 A1) describes the ZinClear IM aggregates as composed of primary crystallites approximately 15-20 nanometres in size. In simple terms, this means that nanoparticles form the basis of the ZinClear IM product.

Furthermore, the patent (US 2010/0310871 A1) characterises the ZinClear IM “heat treated powder....using techniques well known to those skilled in the art...” [0065]. A summary of these results (Table 1) from this patent is inserted below:

TABLE 1

Summary of ZnO powder characteristics		
Property	Technique	Result
Average aggregate size (volume average)	Laser Scattering	4.1 microns (volume distribution)
Average aggregate size (number average)	Laser Scattering	1.1 microns (number distribution)
Aggregate Structure	SEM	Aggregates of 15-20 nm primary
Primary crystallite size	XRD	14 nm
Specific surface area	BET	49.8 m ² /gram
Skeletal density/closed pore volume	Pycnometry	2.6% (0.0047 cm ³ /gram)
Average open pore size (volume average)	Gas adsorption	37.3 nm.
Open pore volume	Gas adsorption	0.65 cm ³ /gram
Total Pore Volume	Calculation	0.655 cm ³ /gram

These results clearly describe ZinClear IM as a nanomaterial according to the Scanning Electron Microscopy (SEM), X-ray diffraction (XRD) and Barrett-Joyner-Helenda (Gas adsorption) techniques.

From this table, we can see that the only analytical method which might suggest the ZinClear IM aggregates to be “non-nano”, would be the Malvern Mastersizer laser scattering measurements (1.1-4.1 micrometres).

By only representing the Malvern Mastersizer (laser scattering) measurements to sunscreen brands and the stockmarket, Antaria continue to be ‘selective’ in their choice of measurement technique. We believe it is unfair, if not misleading to sunscreen brands, manufacturers and the public to not mention results from these other techniques.

3. *“As you would know, the Australian Therapeutic Goods Administration as well as other international regulators, such as the United States Food and Drug Administration, have repeatedly confirmed that zinc oxides such as ZinClear IM are safe for use in sunscreens.”*

Nanomaterials are typically used in consumer products for their new physico-chemical properties (such as transparency). In addition to new desirable or useful properties, nanomaterials also present some undesirable and potentially harmful properties (such as potent free radical generation). High-level scientific bodies such as the UK Royal Society (2004) have claimed that there is enough evidence to warrant a precautionary approach, and believe that nano-forms of existing chemicals should be treated as new chemicals for regulatory purposes and as such undergo new safety assessments and be labelled differently from bulk forms. Accordingly, the European Union is introducing mandatory safety testing and labelling of nanomaterials from July 11, 2013.

The Australian (TGA) and US (FDA) regulators of sunscreens have repeatedly confirmed that products containing zinc oxide are safe, in response to growing concerns around the use of nano-scale zinc oxide in sunscreens. However, the TGA and FDA have not scientifically assessed nano-forms of zinc oxide, separately from bulk forms of the same chemical.

By referring to the TGA and FDA above, Antaria are demonstrating their support for the claims that zinc oxides of all sizes are safe for use in sunscreens. However, in providing a background for the patent (US 2010/0310871 A1) protecting the invention of ZinClear IM, Antaria provide a rationale for developing ZinClear IM particles “...that are of a sufficiently large size that do not raise concerns about product safety or stability...”.

The patent also states “Recently, concerns have been raised regarding potential negative health consequences of transdermal penetration of nano size inorganic particles....Irrespective of whether or the extent to which these concerns are substantiated, there has been and remains an as yet unmet need for topical photoprotective compositions that minimize or, preferably, do not contain organic sunscreen filters and/or nano-sized physical sunscreen blocking agents.”

However, it appears to us the issue here is one of truth and accuracy in labelling. A recent government polling demonstrates that a large proportion of the Australian public are concerned about the use of untested nano-ingredients in sunscreens, as evidenced by mainstream Australian media coverage of these concerns in recent years. This is also demonstrated by the growing numbers of sunscreen brands asking Antaria for certificates of analysis to provide to Friends of the Earth in preparation of our Safe Sunscreen Guide.

4. *“It is impossible for us to comment on the nature of the composition of third-party end-product sunscreen formulations of which ZinClear IM is only one ingredient.”*

The key issue here is the zinc oxide ingredient manufactured and sold by Antaria Limited – namely ZinClear IM – and how this has been represented as “non-nano” to the stockmarket, shareholders and sunscreen brand customers. Your statement implies - but does not demonstrate - that there is some aspect of the manufacturing process of “end product sunscreen formulations” that may create nanomaterials. The position is, as explained above, manufacturers have used Antaria’s ZinClear IM and have provided us with Antaria’s certificates of analysis. Those manufacturers have not provided any other certificates – indicating there is no other source of zinc oxide in their products.

5. *“We deny liability for any loss claimed to have been suffered by Friends of the Earth Australia (FOE) as a result of actions taken by FOE and others for which we are not responsible.”*

The Friends of the Earth Safe Sunscreen Guide relies on and incorporates information from those sunscreen brands that use ZinClear IM as a means of informing the general public as to which sunscreen brands contain nanomaterials and which do not. More than 50,000 copies of the guide had been printed but had to be destroyed and all further distribution halted in late February 2012, once Friends of the Earth understood that ZinClear IM is a nanomaterial. Preparation of this particular guide began in early October, 2011 and materials were promoted and updated consistently until late February 2012.

On the basis of Antaria’s representations, many sunscreen brands using Antaria’s product (‘Antaria’s Clients’) have claimed their sunscreens contain no nanomaterials on the basis of Antaria’s representations. These claims, and supporting certificates of analysis, were forwarded to Friends of the Earth Australia by Antaria’s clients, in response to our annual survey regarding the use of nanomaterials in Australian sunscreens. Antaria clients provided signed statements to Friends of the Earth that their products were free of both nanoparticles and the aggregates and agglomerates of nanoparticles. Relying on this information, in our annual Safe Sunscreen Guide, Friends of the Earth incorrectly listed as nano-free ten brands supplied by Antaria Limited.

As a result of the inaccuracies caused by Antaria’s misleading and deceptive conduct, Friends of the Earth Australia has suffered serious reputational loss. The inaccuracies in our guide have been the focus of the National Measurement Institute presentation and subsequent discussion at the ICONN (International Conference On Nanoscience & Nanotechnology) conference in February 2012, media coverage and government commentary. It has been suggested by many commentators that the inaccuracies result from our error, rather than stemming from false statements provided to sunscreen brands by Antaria.

6. *“We have repeatedly offered to meet with you and members of FOE personally in order to understand and discuss your concerns, but you have not taken up our offers.”*

A Friends of the Earth (FoE) representative personally met with Antaria’s General Manager of Research and Development twice in Perth in February 2012 and was unable to resolve the differences between NMI findings that products with ZinClear IM contained nanomaterials and the limited measurement data presented by Antaria (e.g. laser light scattering).

Between February 13 and 15, FoE sent three emails to the Antaria General Manager of Research and Development, strongly suggesting Antaria seek independent testing of ZinClear IM and work closely with the NMI to resolve these differences. On February 24, Antaria’s General Manager of Research and Development replied to one of my emails, confirming the patent which described the basis for the ZinClear IM invention. The patent specifies the nano-structure of ZinClear IM.

However, Antaria has – to date – failed to reply to any other requests sent in these emails, nor have Antaria has provided Friends of the Earth with results from independent testing or given

any indication that the company is working with the NMI to resolve the differences clearly identified in February.

Formal letters were sent by Friends of the Earth to Antaria on May 21 and July 6, seeking further clarification and restorative actions.

To date, Antaria has failed to provide any evidence that ZinClear IM is not a nanomaterial nor provide any independent testing to suggest that the NMI research or (June 28) report are factually incorrect.

Regards,

A handwritten signature in black ink, appearing to read 'G. Crocetti', is positioned above the typed name and contact information.

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