Nano-ingredients in sunscreen
The need for regulation

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Executive Summary

Australia has the highest rate of skin cancer in the world. Using sunscreen, along with protective clothing, a broad-brimmed hat, sunglasses and staying out of the sun in the middle of the day, is important to help reduce the risk of developing skin cancer. However, Friends of the Earth is concerned that some nano-ingredients in sunscreens may be doing more harm than good.

We are concerned about the use of manufactured nanomaterials in sunscreen because:

- Peer-reviewed study has demonstrated that some nanomaterials used in commercial sunscreens sold in Australia behave as extreme photocatalysts, aggressively producing free radicals that can damage DNA and skin cells
- If nanomaterials are absorbed into our skin, they could make sun damage worse
- We do not yet know the extent to which nanomaterials in sunscreens penetrate intact, healthy skin, although it seems likely they will be taken up through damaged skin
- Despite having a toxicological profile that is very different from the same chemical composition in larger particle form, nano-ingredients in sunscreens are not subject to new safety assessment or separate listing on the Australian Register of Therapeutic Goods (ARTG). That is, if a substance has been approved for use in bulk form, its nano-form faces no new assessment, despite exhibiting novel behaviours. This leaves nanomaterials subject to far less scrutiny than any other potential new active ingredient for sunscreen
- Nano-ingredients in sunscreens are not subject to mandatory labelling. This is especially a problem for people with skin conditions such as eczema that may make them more vulnerable to skin penetration by nanomaterials
- Nano-ingredients are not necessary to manufacture effective sunscreens; there is no need to put their commercial use ahead of appropriate safety assessment

Friends of the Earth is calling for nano-forms of zinc oxide and titanium dioxide to be treated as new chemicals for the purposes of listing on the ARTG or for other regulatory purposes. This would trigger an assessment of their safety that is specific to the nano-form, and a listing on product labels that is also specific to the nano-form. This is in line with recommendations from senior scientific bodies internationally, and new laws introduced in the European Union.

We recognise the significant technical challenges and scientific uncertainties plaguing efforts to regulate nanomaterials. Until risk assessment for nanomaterials is validated, and fit-for-purpose detection methods are developed, we do not support the commercial sale of nano-sunscreens.

By Georgia Miller and Louise Sales
Friends of the Earth Australia
nano.foe.org.au

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The health concerns regarding nano-ingredients in sunscreen

There are growing concerns around the health and environmental risks of using nano-ingredients in sunscreen. Alarmingly little research has been conducted into the potential health risks. However, from the research that has been performed, we know that surface area plays a key role in the toxicity of nanomaterials. As we reduce the size of particles, the larger relative surface area increases the potential for free radical production which can damage proteins and DNA. The leader of CSIRO's Nanosafety group warned in 2008 that in a worst-case scenario, nano-ingredients in sunscreens could cause skin cancer.[1] More recently, dermatologists have called for mandatory labelling of nano-ingredients so that vulnerable sections of the population can avoid them.[2]

Some nano-sunscreens act as photocatalysts

It has long been established that nano-ingredients used in sunscreens can produce free radicals, especially when exposed to UV light[3]. Some nano-ingredients used in sunscreens are aggressive producers of free radicals. Barker and Branch found that contact with several commercially available nano-sunscreens resulted in pre-painted roofs breaking down 100 times faster. They described the process as "An aggressive, photocatalytically initiated, free-radical degradation mechanism"[4]. While this study did not examine the interaction of nano-sunscreens with human skin, it did demonstrate a potential toxicity mechanism that was of great concern to the scientific community. A subsequent modelling study conducted by the CSIRO suggested that there is a very narrow size range of titanium dioxide nanoparticles where transparency is acceptable, SPF is effective and free radical production is low[5]. This may mean that rather than offering effective sun protection, some nanoparticles in sunscreens may actually make sun damage worse.

What are nanomaterials?

The word nanomaterial is an umbrella term for objects of all different shapes and sizes with one or more dimensions (length, width or height) or surface structures on the nano-scale. The nano-scale is the range from 1 - 100 nanometres – with one nanometre being one millionth of a millimetre. Importantly, the term nanomaterial also includes aggregates and agglomerates (clumps) of nanoparticles.

The properties of matter change at the nano-scale, as the laws of classical physics give way to quantum effects. The properties of nanomaterials can therefore be quite different from those of larger particles of the same substance. Altered properties can include colour, solubility, material strength, electrical conductivity and magnetic behaviour. Nanomaterials also have a greater surface area relative to volume. This makes them much more chemically reactive than larger particles.

Why are nano-ingredients used in sunscreen?

Two increasingly popular sunscreen ingredients are the metal oxides – zinc oxide (ZnO) and titanium dioxide (TiO2). The traditional larger bulk forms of these chemicals leave a white residue on the skin, but once the size of these particles is reduced down towards the nano-scale they start to become transparent. Clumps of nanoparticles (agglomerates or aggregates) are also sometimes used for their transparency.

Existing skin penetration studies are inadequate

A literature review by the Therapeutic Goods Administration in 2009 found that most studies to date have found no or limited skin penetration by nano-ingredients. However, serious limitations in these studies prevent us concluding that skin absorption does not occur. The European Union's high level Scientific Committee on Consumer Products has warned that existing research into skin penetration by nano-ingredients is inadequate and that further studies "taking into account abnormal skin conditions and the possible impact of mechanical effects on skin penetration need to be undertaken."[6]

Many existing skin penetration studies are deficient because they:

- **Are overwhelmingly short term, often 24 hours,**
- **Are mostly based on excised skin *in vitro*,** where there is no movement or blood circulation,
- **Fail to consider the role of skin condition** (eg eczema, acne, sunburn, children with thinner skin) and,
- **Do not assess the role of penetration enhancers,** despite the prevalence of these substances in sunscreens, cosmetics and workplaces.

Recent peer-reviewed literature reviews have emphasised that these deficiencies limit the relevance of earlier skin penetration studies to 'real life' scenarios and prevent any reliable conclusion about skin penetration by nano-ingredients.[7] Gulson et al emphasise that they first identified radio isotope labelled zinc in blood at the end of the second day of their longer term study, after 4 applications of sunscreen.[8] More long-term studies are clearly needed to assess the extent to which nano-ingredients penetrate the skin and to determine their fate if they do.

Peer-reviewed studies now demonstrate that skin penetration can occur

A study published after the TGA's most recent literature review found small amounts of zinc from sunscreen in the blood and urine of human trial participants[9]. The study used live human volunteers and was carried out over 5 days, with follow up testing for at least six days. The study was not able to show whether the zinc was absorbed in particle or ionic form, so this requires further research. Another limitation of the study was the poor control used (the 'bulk' zinc control had an average particle size of 110 nm and many particles smaller than 100 nm, meaning that there could not be effective comparison between nano and 'non-nano' zinc uptake). Nonetheless, this study shows that skin uptake of ingredients from sunscreen applied to intact skin does occur in some form. The results of a separate pilot study conducted as a prelude to this study have been published very recently; they also showed that small amounts of zinc from sunscreen were detectable in blood and urine[10].

Several other peer-reviewed studies have shown skin penetration by other types of nanomaterials. Quantum dots and fullerenes can penetrate skin[11], especially if skin is flexed[12] (as during exercise) or exposed to 'penetration enhancers' which can be found in some cosmetics.[13] A 2003 study by the United States National Institute for Occupational Safety and Health[14] found that when accompanied by repetitive skin flexing, inert fluorospheres 1000 nm in size could reach living cells in the dermis. Particles were also found to be concentrated under torn skin, suggesting that compromised skin is more vulnerable to penetration.

Labelling is needed for at risk groups

Dermatologists and toxicologists have issued public warnings that people with damaged skin, young children (whose skin is thinner), and people who use sunscreens very regularly are at greater risk of exposure to nanomaterials and should avoid using nano-sunscreens.[15]

Europe and New Zealand move to regulate nano-ingredients in sunscreen

High level scientific calls for nano-specific regulation have resulted in Europe and New Zealand moving to regulate nano-ingredients in sunscreen.

In 2004 senior scientists in the United Kingdom's Royal Society and Royal Academy of Engineering produced a detailed report into nanotechnology. They emphasised that the toxicity of nanomaterials cannot be predicted from the known properties of larger particles of the same chemical composition. That is, nanomaterials exhibit novel bioavailability, solubility, reactivity and toxicity: they behave as new chemicals.

Given the novel behaviour of nanomaterials, the UK Royal Society recommended that:

- For regulatory purposes **nanomaterials should be treated as new chemicals**[16]
- **Nanomaterials should be subject to new safety assessments** before being allowed in consumer products[17]
- **Nano-ingredients in consumer products should be labelled**[18]

After an extensive investigation, the European Union's Scientific Committee on Consumer Products concluded that "review of the safety of the insoluble nanomaterials presently used in sunscreens is required". The committee recommended a case-by-case risk assessment of all nanomaterials used in sunscreens and cosmetics[19].

The European Parliament has subsequently passed laws that will require manufactured nanomaterials in sunscreens and cosmetics to go through nano-specific safety testing before they can be sold, and to be listed on product labels[20]. These laws come into effect in July 2013.

New Zealand will also require the mandatory labelling of nano-ingredients in sunscreen and cosmetics from 2015.

The Australian regulatory response

Australia's regulators have taken contradictory approaches on the need to regulate manufactured nanomaterials.

In 2007, a Federal Government commissioned review of Australia's regulation of nanotechnology (the "Monash review") identified the failure to treat nano-forms of existing substances as new chemicals as an important regulatory gap[21].

In 2008 the NSW Parliamentary Inquiry into Nanotechnology also recommended that nano-forms of existing chemicals be assessed by regulators as new chemicals[22]. Further, it recommended mandatory labelling of nanomaterials used in sunscreens and cosmetics.

The Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) - the regulator for industrial chemicals, cosmetics and secondary sunscreens - introduced new regulatory measures for nano-forms of new chemicals in January 2011. NICNAS will begin consultation to underpin reform of regulations relating to nano-forms of existing substances within the next year. That is, in the near term, secondary sunscreens will face nano-specific regulation by NICNAS.

In contrast, the Therapeutic Goods Administration (TGA), regulator of primary sunscreens, has rejected calls for nano-specific regulation and labelling of the products it has responsibility for. The TGA's approach has been questioned by legal and medical academics who suggest that the potential for health harm warrants a precautionary approach to regulation of nanomaterials in sunscreens[23].

There is widespread public support for nano-specific safety assessment and mandatory labelling

A survey of nearly 1300 people commissioned by Friends of the Earth and carried out by The Australia Institute found very strong support for both mandatory labelling of nano-ingredients and safety testing of these ingredients before their use in commercial products[24]:

- 85% of Australians want companies to be required to label sunscreens and cosmetics which contain nano-ingredients, and
- 92% of Australians believe sunscreen and cosmetics manufacturers should have to conduct safety tests on nano-ingredients before using them in products

ACCORD, the national body representing the sunscreens and cosmetics sector, has also called for mandatory labelling of nano-ingredients in sunscreens and cosmetics to bring Australia into line with new European standards, and to maintain consumer confidence. ACCORD has called the Australian government's refusal to label nano-ingredients in sunscreens and cosmetics "out of touch"[25].

Other community, union and consumer groups that support both mandatory labelling of nano-ingredients in sunscreens and the regulation of nanomaterials as new chemicals (i.e. nano-specific safety assessment before commercial use) include:

- Australian Council of Trade Unions
- Choice (the Australian Consumers Association)
- Consumers Federation of Australia
- Public Health Association of Australia
- The Australia Institute

Mandatory labelling is necessary to support informed choice, to allow post marketing surveillance of any potential health effects, and to enable people who may be at greater risk of skin penetration by nanomaterials to use a non-nano sunscreen.

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