Manufactured Nanomaterials and Sunscreens:

Top Reasons for Precaution

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What are Manufactured Nanomaterials?

'Manufactured nanomaterials' are particles made to have extremely small dimensions in order to leverage the unique physical properties that chemicals can exhibit at the nanoscale. One nanometer (nm) is one thousandth of a micrometer (m), one millionth of a millimeter (mm) and one billionth of a meter (m). Put more simply, 1 nm is roughly 100,000 times smaller than the width of a human hair. Nanoparticles of titanium dioxide and zinc oxide now used in some sunscreens can measure 20-30nm in size or even smaller in at least one dimension. The physical and chemical properties of these and other nanoscale materials, such as reactivity, persistence, or bioavailability, can differ significantly from their larger scale counterparts. However, changes in properties like these can often result in unpredictable changes in toxicity that as yet are not well-understood.

Nanomaterials are already being used (unlabelled) in hundreds of consumer products including sunscreens and cosmetics

Our review of consumer products has found that nanomaterials have entered a wide variety of personal care products on the market, including deodorant, soap, toothpaste, shampoo, hair conditioner, sunscreen, anti-wrinkle cream, moisturizer, foundation, face powder, lipstick, blush, eye shadow, nail polish, perfume and after-shave lotion. Nanoscale titanium dioxide and zinc oxide are widely used in sunscreens. The Australian Therapeutic Goods Administration estimated in 2006 that 70% of titanium dioxide sunscreens and 30% of zinc sunscreens sold in Australia contain manufactured nanomaterials.[1] The extent of U.S. use is unknown since large-scale surveys have not been done and no labeling is required. However, nanoscale zinc oxide and titanium dioxide were detected in all but one of the six US-marketed mineral-based sunscreen products tested by Consumer Reports in 2008 and all 10 mineral-based sunscreens tested in 2007.

"Sunscreen manufacturers are adding nanomaterials to sunscreens ostensibly to make sun-blocking ingredients like titanium oxide and zinc oxide rub on 'cosmetically clear' instead of white."

Why are sunscreen manufacturers using nanomaterials?

Sunscreen manufacturers are adding nanomaterials to sunscreens ostensibly to make sun-blocking ingredients like titanium dioxide and zinc oxide rub on "cosmetically clear" instead of white. These nanomaterials are being added without appropriate labeling or reliable safety information, so the public has no way of making informed purchasing choices.

Here are the top reasons why we have concerns about manufactured nanomaterials in products like sunscreens:

1. **Nanomaterials are different from other conventionally-sized compounds**
   Materials manufactured at the nanoscale can exhibit different physical, biological, and chemical properties than bulk materials (e.g. stable compounds can become highly reactive; relatively benign substances can become more toxic). One reason for these fundamentally different properties is that quantum physics governs at the nanoscale. But just as the size and chemical characteristics of manufactured nanomaterials can give them exciting properties for manufacturers, those same new properties—tiny size, vastly increased surface area to volume ratio, high reactivity—can also create unique and unpredictable human health and environmental risks. Compared with their normal-scale counterparts, the small size of nanomaterials can increase their ability to penetrate biological tissues and their large surface area-to-mass ratio can increase their potential reactivity.

2. **In the body, nanomaterials have much greater access to vulnerable organs and tissues.**
   Although very few nanomaterials have been adequately tested, from the limited data available, it's clear that many can be more bioavailable than larger compounds. Their small size can make them more amenable to entering the lungs, if inhaled, passing through cell membranes, and in some cases penetrating the skin. When ingested, some nanomaterials may pass through the gut wall and circulate through our blood.[2] Once in the blood stream, many seem to have unlimited access to tissues and organs, including the brain and even the developing fetus, where they may disrupt normal cell activity.[3] Animal studies suggest that some nanomaterials once in the body, can cause inflammation, damage brain cells and cause pre-cancerous lesions. Ultrafine air pollution, much of which is nano-sized, is associated with reduced lung function and increased likelihood of asthma, respiratory disease, and deaths from lung and heart disease.

3. **Increasing evidence that some nanomaterials can pass through the skin**
   Though studies to date suggest nanoscale mineral compounds in sunscreen may not fully penetrate intact skin, government agencies worldwide are still investigating this route of exposure. Scientific studies with other experimental nanomaterials have shown that some skin penetration can occur under various conditions,

such as[4] if skin is flexed[5] (as during exercise), or if other ingredients are present which enhance penetration[6] (as may be found in certain cosmetics). Damaged skin can take up particles 70 times bigger than a nanoparticle,[7] suggesting that skin penetration by nanomaterials is likely to occur in people with eczema or acne. Recent research has shown that skin penetration is also more likely in sun burnt skin.[8] We do not yet know if common nanoscale ingredients would more likely penetrate thinner skin – e.g. in elderly people or babies or whether deep penetration would always be necessary to elicit any possible toxic effects that may occur.

4. **Senior scientists have called for mandatory premarket safety tests for nanomaterials before they are used in products**
   The United Kingdom's Royal Society, the world's oldest scientific institution, has recommended that given the evidence of potentially serious and unpredictable health risks, nanomaterials should be treated as new chemicals[9] and subject to new safety assessments before being allowed in consumer products.[10] Yet, none of the nano-cosmetics or nano-sunscreens on the market are subject to a premarket safety assessment by the U.S. Food and Drug Administration (FDA) that would require special tests for effects unique to nanoscale ingredients, before being put on the shelves.[11] While agencies in the U.S. have hesitantly acknowledged the possible dangers posed by manufactured nanomaterials, the European Union has taken action to protect the public. New rules passed in Europe on March 2009 will require some nanomaterials in cosmetics and sunscreens to be labeled on the ingredients list; the regulation will also require increased safety testing for cosmetics containing nanomaterials.[12]

5. **Potential next generation harm from nanomaterials**
   Two recent studies by Japanese researchers show the transfer of nanoparticles of titanium dioxide from pregnant mice to their offspring, following intravenous injection. One study shows brain damage, nerve system damage and reduced sperm production in male offspring,[13] while another shows offspring suffer altered gene expression related to brain development[14]. A study by US researchers has also found that pregnant mice exposed to titanium dioxide nanoparticles via inhalation also transfer these to offspring.[15] This resulted in "minor neurobehavioral alterations" in offspring. These results are concerning because titanium dioxide is one of the most widely used nanomaterials, found in cosmetics, sunscreens, food packaging, paints, wall coatings, dirt repellant coatings for windows, car coatings, etc.

6. **Workers and the Environment**

   A product which is potentially harmful to consumers can also have equal or even greater negative consequences for the environment and for those who actually create the product. Workers who manufacture, research, package, handle, transport, use and dispose of nanomaterials all potentially face nano-exposure. There is a limited number of peer-reviewed scientific studies on the health and environmental impacts of nanomaterials. However, there is preliminary scientific evidence that shows nano-ingredients in sunscreens could possibly harm both workers and the environment.

   Workers handling nanomaterials are likely to be exposed at much higher levels than the general public, and on a more consistent basis. There are currently no established safe levels of exposure to nanomaterials and no reliable systems and equipment to protect workers from harmful levels of exposure.[16] Some inhalation and instillation studies have shown that titanium dioxide nanomaterials can cause lung inflammation and injury, or cytotoxicity in test rodents.[17] This suggests that if workplace exposure is high, titanium dioxide nanomaterials could be hazardous for workers' health.

   Moreover, once released into the environment, many nanomaterials may persist and accumulate as pollutants in air, soil or water. For example, a 2006 study demonstrated that some forms of titanium dioxide nanomaterials (popular ingredients in nanosunscreens) are toxic to algae and water fleas, especially after exposure to UV light.[18] Algae and water fleas are a vital part of aquatic environments and are often used by regulators as indicators of ecosystem health.

7. **Nanomaterials in sunscreens and cosmetics could theoretically cause skin damage over time.**

   Scientific studies in laboratory animals and cell systems have shown that certain nanoscale materials of titanium dioxide and zinc oxide compounds commonly used in sunscreens and cosmetics can produce free radicals,[19] damage DNA[20] and cause cell toxicity,[21] especially when exposed to UV light.[22] Such findings raise concerns about the potential for these compounds to cause skin damage over time if such effects persist when these ingredients are used in product formulations.

8. **Consumers can get highly effective transparent protection from harmful rays of the sun with products made without nanoscale chemical ingredients.**

   Adding nanomaterials means adding an unnecessary potential risk to our health and to the environment, with no significant gain.

In 2007 Consumer Reports tested sunscreens containing nanomaterials and found no correlation between nanomaterial content and sun protection.[23] Consumer Reports testing found neither nanoscale zinc nor titanium oxides provide a clear performance advantage over other active ingredients (though it's not clear whether non-mineral, carbon-based formulations, are all nano-free). For example, most products containing avobenzone were at least very good at blocking UVA, but one was just good. Likewise, most products containing nanoscale zinc oxide provided at least very good protection against UVA, but one was only fair. In any case, sunscreens developed without nanomaterials have been shown to be effective at blocking the harmful rays of the sun. While questions do exist about safety of some other chemicals in sunscreens, nanoscale ingredients bring a whole new range of serious health concerns that need to be assessed.

Options for consumers

Apart from nanomaterials, some other sunscreen ingredients, such as oxybenzone, a hormone disruptor[24], also pose health concerns and require further safety testing. However, consumers need to know that engineered nanocale zinc and titanium oxides are not the only choice and are not necessarily the most effective or safest choice for sun protection.

Besides several different carbon-based active ingredients, consumers can also look for larger-scale, more opaque metal-oxide based sunscreens, although without mandatory labeling these may be very hard to find (at least in the U.S.).

What Industry and Government must do

- *Test and Require Approval for these products before commercialization*
  Because of their capacity to have fundamentally different properties, nano-ingredients in sunscreens should be classified as new chemicals, they should be regulated as new products and new ingredients that require premarket safety tests. Regulators and industry should not assume the safety of nanomaterials based on testing of larger particles of the same chemical composition. Governments should review industry data and approve the safety of these substances before commercialization is permitted.

- *Transparency and Labeling*
  Industry should make information on nanomaterial ingredients in its products available to the public. The fundamental right of

consumers to make informed purchasing choices is compromised by the lack of transparency regarding the use of nanomaterials in nano-formulated sunscreens and other products and the limited disclosure of information regarding safety. At a minimum, consumers need a list of ingredients, including any nano-scale ingredients in the products they buy and use on themselves and their families. In addition, to that, however, nano-ingredient labeling is necessary for health professionals and others in order to assess causation and provide traceability in the event that adverse health or environmental effects occur.

- *Support Much More Vigorous EHS Research*
  Publically available, peer-reviewed, and independent study of human health and environmental impacts is urgently needed to protect public health and the environment and provide the basis for adequate regulatory oversight of nanomaterials. Crucially, the lack of data or evidence of specific harm should not be a proxy for reasonable certainty of safety.

- *Look at the whole lifecycle*
  Because of their presence in all environmental media, nanomaterials affect every area of environmental concern. Environmental impacts can occur at any stage of a nanomaterials' lifecycle—R&D, manufacturing, transportation, product use, recycling, disposal, or some time after disposal—and a nanomaterial lifecycle framework helps assess how various statutory frameworks apply and where regulatory gaps exist.[25] To address all possible exposures and environmental impacts adequately, a nanomaterial's complete lifecycle must be considered.

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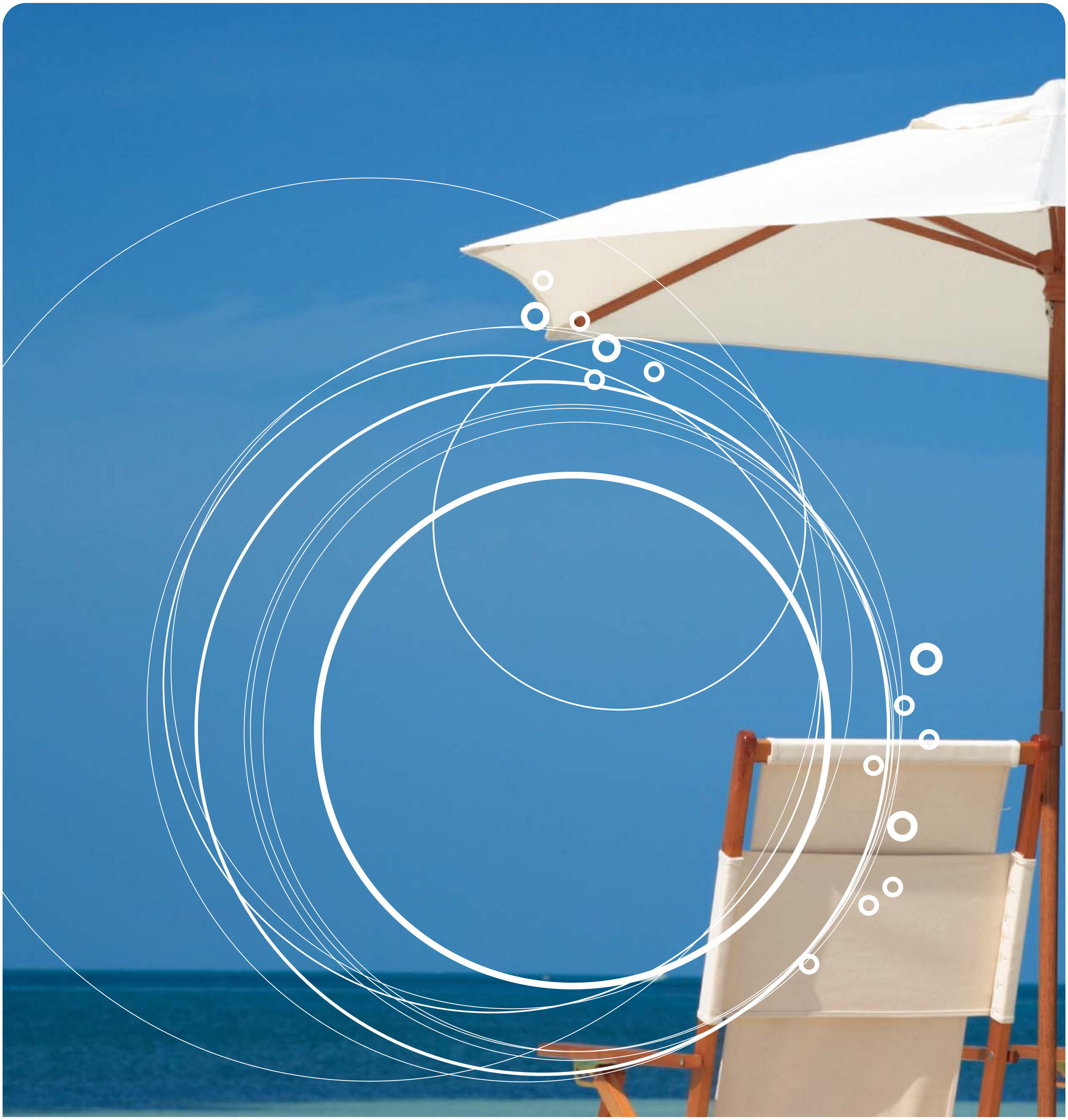

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