

ACCORD Statement on the use and safety of nanotechnology in cosmetics and sun protection products

Nanotechnology is an innovative range of small-scale technologies which have many useful applications across a large number of industries; including medicine, communication technology and environmental science.

Generally, when the term 'nanotechnology' is used it refers to technologies using materials or particles that are less than 100 nanometres, in any one dimension. One nanometre (nm) is one-billionth of a metre. This is the general accepted definition which is also employed by Australian government regulatory agencies, including the industrial chemicals regulator, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), and the medicines regulator, the Therapeutic Goods Administration (TGA).

Nanotechnology and nanomaterials are not widely used in the cosmetics and personal care products routinely available for Australians to purchase and use. Of the very limited number or quantity of nanomaterials commercially available in Australia, primary usage is in paints and surface coatings, water treatment products, printing products and as sunscreen ingredients¹. This includes new generation sun protection products which contain nanoparticle zinc oxide or titanium dioxide. These have been available on the Australian market for a number of years.

The Australian cosmetics product industry places the highest regard on the safety and environmental performance of its products. Our industry's products and the ingredients they contain are regulated and subject to stringent safety testing and evaluation.

Cosmetic product ingredients are regulated for safety by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and, in the case of sun protection products with SPF15+ or higher, the Federal Health Department's Therapeutic Goods Administration (TGA). These Australian government agencies independently assess the safety of product ingredients and have a watching brief to review any new safety reports, studies or theoretical concerns.

The TGA has undertaken ongoing reviews of the use of sun protection products containing nanoparticle zinc oxide and titanium dioxide commencing in 2006. In its August 2009 publication of its most recent review TGA concluded these products posed no "tangible safety risks"²:

"In early 2009, the Therapeutic Goods Administration (TGA) conducted an updated [review of the scientific literature](#) in relation to the use of nanoparticulate zinc oxide and titanium dioxide in sunscreens. The TGA review concluded that:

- *The potential for titanium dioxide and zinc oxide nanoparticles in sunscreens to cause adverse effects depends primarily upon the ability of the nanoparticles to reach viable skin cells; and*
- *To date, the current weight of evidence suggests that **titanium dioxide and zinc oxide nanoparticles do not reach viable skin cells; rather, they remain on the surface of the skin and in the outer layer of the skin that is composed of non-viable cells.***

The TGA is continuing to monitor the emerging scientific literature to ensure appropriate action is taken should any tangible safety concerns be identified."

It is important to remember that nanoparticles are not new.

Sunscreen ingredients at particle sizes less than 100 nanometres have been around for years. For example, TGA concluded in its 2006 review that:

"At the present time around 70% of sunscreens with titanium dioxide and 30% of sunscreens with zinc oxide have these materials in nanoparticle form. Titanium dioxide has been used in this way since at least 1990 and zinc oxide since 1999."

¹ From the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) call for information published in January 2007 - http://www.nicnas.gov.au/Publications/Information_Sheets/General_Information_Sheets/NIS_Call_for_info_Nanomaterials.pdf

² See <http://www.tga.gov.au/npmeds/sunscreen-zotd.htm#labels> and <http://www.tga.gov.au/npmeds/sunscreen-zotd.pdf>

Theoretical health concerns have also been raised for nanoemulsions in some skin care products. Emulsions containing very small materials are not uncommon in either nature or general food and household products. For example, milk is an emulsion made up of oil droplets just above the nano-size range.

Skin care nanoemulsions generally contain well characterised ingredients that are already in use in 'traditional' cosmetic formulations. These ingredients are chosen specifically for their mildness, protective effects on human skin and also because they are approved for use by Australian regulations.

As noted by the European Commission's Scientific Committee on Consumer Products³ nanoemulsions also break down to their constituent ingredients once applied to the skin or hair:

*"Ordinary cosmetic emulsions have droplet sizes between 100 and 100,000 nm. **Nanoemulsions contain the same type of ingredients as the former** but their droplet dimensions may be as low as 10 nm. Given this small droplet size, nanoemulsions are transparent and have particular rheological properties that so far have not been obtained by other formulation methods. Because of these properties, nanoemulsions are used in a number of cosmetics. **Generally, when applied to skin or hair, nanoemulsions are not stable and break down into their constituent ingredients.**"*

ACCORD recognises that new technologies such as nanotechnology can attract public concern regarding safety implications. Our industry also recognises that, on occasion, reforms will be needed to improve the capacity of existing regulations to deal with new technologies. **On the whole, there are checks and balances within Australia's strong, independent, science-based regulatory system to deal with nanotechnology safety.** These would, for example, prevent the large scale introduction of novel nano-ingredients, like carbon fullerenes. Such ingredients require extensive independent safety assessment by Australian regulators before they could be legally sold in Australia.

However, some tweaking to improve the existing regulatory system will still be needed. Good progress has been made on this task through the ***Proposal for Regulatory Reform of Industrial Nanomaterials***, released on 9 November 2009 by NICNAS. This proposal has been developed by NICNAS regulatory scientists with input from an expert advisory group comprising academics, community representatives and industry representatives. Importantly, the details in this proposal represent the agreed consensus position of all advisory group members.

Wider consultation on the NICNAS proposal is now being undertaken. Industry believes this consultation stage is important for ensuring that the agency receives comments and input from the public, businesses and environmental groups.

The key elements of NICNAS's proposals include:

- excluding 'novel' materials in the nano-size range from low-volume exemptions that exist under NICNAS's regulatory rules; and,
- proposals for consideration of the many existing chemical ingredients that could be available either now or in the future in nano-form; for example, silver as nano-silver or gold as nano-gold.

Industry understands that NICNAS aims to complete the consultation on its proposal with a goal of implementing the priority measures it has recommended early in 2010.

Our industry remains committed to working collaboratively with the Government and the nation's safety regulators to ensure Australia's regulatory system achieves the right balance for public health protection and encouraging nanotechnology innovation.

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Media contact - Craig Brock 02 9281 2322 or 0422 363 646

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³ European Commission, Health & Consumer Protection Directorate-General, Scientific Committee on Consumer Products, "Opinion on the Safety of Nanomaterials in Cosmetic Products", 18 December 2007