Our position on nanotechnology and nanoparticles

Nanotechnology (as distinct from nanoparticles) is currently not relevant for cosmetic materials as we are not aware of any current applications.

We do have materials that are classed as microfine, and their particle size is within the definition of nanoparticles. Our main material of use is microfine titanium dioxide, which is used as a sunscreen in line with common industry practice. Other materials such as fine silica (Aerosil™) used in toothpaste, and microfine zinc oxide can also approach the nanoparticle range.

Our policy on any new material, or new grade of material, requires that we review all the properties of the material and its intended use to satisfy ourselves that such use does not put consumers or the environment at potential risk. If we cannot satisfy ourselves of this fact, or we cannot obtain sufficient data to make a decision, then we will take a precautionary approach and not use the material. This applies as much to nanoparticulates as it does to pigments, solubles or polymers - each material is assessed on its own merits. We do not assume, for example, that a nanoparticulate material is inherently unsafe, just as we do not assume that a naturally occurring material is essentially safe.

We will continue to monitor developments on nanotechnology and nanoparticles and contribute to ongoing debate where applicable.

Dick Metcalfe
Head of Quality and CSR

Position support document

On Nanotechnology and Nanoparticles

Background

Nanotechnology has been a subject of science fiction novels for many years. Today's scientists are starting to turn some of the fiction into reality, and nanotechnology as the potential for use in many differing areas, including pharmaceuticals, sunscreens and cosmetics, coatings and surfaces, fuel cells, batteries, lubricants and catalysts.

There have been many definitions of nanotechnology, and these different definitions have led to misunderstanding of the potential benefits and drawbacks of nanotechnology. The following definitions have been generally agreed among scientist within the area.

- ***Nanoscience*** is the study of and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.[i]

- ***Nanotechnologies*** are the design, characterisation, production and application of structures, devices and systems by controlling shape and size at nanometer scale. [i]

- **Nanoparticle** is any insoluble material that is produced with an average particle size typically below 100 nm, using traditional or new techniques. Materials of this type have been around for many years, a typical example being microfine titanium dioxide as used in sunscreens.

The prefix 'nano' is derived from the Greek word for dwarf. One nanometre (nm) is equal to one-billionth of a metre, 10^{-9}m. A human hair is approximately 80,000nm wide, and a red blood cell approximately 7,000nm wide.

The issue

While nanoparticles have been around for a very long time, there has been a considerable growth in the last few years of nanoparticles and materials produced by nanotechnology. There is a belief that nanotechnology will have an impact across a wide range of sectors, but some experts in the field have suggested that there has been too much 'hype' surrounding nanotechnology and the potential harm and benefits that it could bring. Increased concerns, primarily from the NGO community[ii] but also from some nanotechnologists, have been expressed about the current and potential new developments in nanotechnology. Uncertainties around impact of new materials on human health and the environment and the adequacy of the current legislative systems to cope with this fast emerging field have heightened concerns that this new and emerging technology could have a global impact if not correctly managed and controlled.

The considerable confusion in the areas of nanotechnology and nanoparticles is not helped by industries that have simply renamed their products in order to jump on the 'nanotech' bandwagon. Many of the materials that have been thrown under the 'nanotech' spotlight have been around for many years and it is only been this misunderstanding as to what nanotechnolgy actually is that has raised doubts over the safety and impact on the environment.

The cosmetic and toiletry industry has been highlighted as one of the main areas for concern because some traditional materials are of a size that brings them into the definition of nanopartiocles (<100nM). The concern is that these small particles may pass through the skin's protective barriers and enter the blood stream directly. These concerns have mainly surrounded titanium dioxide.

Product development team action
Our process for the introduction of new materials is tightly monitored. Product development teams must continue to ensure that the processes for product approval are followed. If there is a suspicion that a material is derived from nanoparticles or nanotechnology further information must be sought from Boots UK Safety Assessment Team.

Implementation date: July 2006
Completion date: Not applicable

Key questions

- **What products are be affected by this policy?**
  Currently only a small selection of Boots UK raw materials would be classed as nanoparticles. The main area of use is titanium dioxide and zinc oxides in sunscreens and microfine silica which can be used in toothpastes.

- **Should Boots UK be replacing nanoparticles in products?**
  No.

  Our policy on any new material, or new grade of material, requires that we review all the properties of the material and its intended use, and satisfy ourselves that such use does not put consumers at potential risk. If we cannot satisfy ourselves of this fact, or we cannot obtain sufficient data to make a decision, then we will not use the material. This applies as much to nanoparticulates as it does to pigments, solubles or polymers - each material is assessed on its own merits. We do not assume that a nanoparticulate material is inherently unsafe, just as we do not assume that a naturally occurring material is essentially safe.

  The titanium dioxide that we (and other companies) use in sunscreens was reviewed by the Scientific Committee for Non-Food Products (SCCNFP) for inclusion in annex VII of the Cosmetics Directive (76/768/EEC), the list of permitted sunscreen agents. In their review, SCCNFP[iii] concluded that microfine titanium dioxide does not penetrate the skin and does not represent a safety risk to consumers under foreseeable conditions of use. This finding matched our own conclusions and experience from using similar materials over a number of years. This conclusion has recently been supported by a literature review carried out by the Australian Therapeutic Goods Administration[iv] into the use of nanosized zinc and titanium oxides in sunscreens. In addition, Oxonica's Optisol grade is designed to minimise any residual risk from the known ability of titanium dioxide to generate free radicals in sunlight under certain circumstances. The other benefits to the consumer involve greater performance for the same level of titanium dioxide making the products more cost effective, and a reduction in the whitening effect associated with titanium dioxide, giving better cosmetic acceptability for the same level of performance

Microfine zinc oxide has also been reviewed by SCCNFP who asked for clarification of some points, particularly skin penetration. From our own work we believe that skin penetration is low. Moreover, zinc oxide is known to be very slightly soluble in water. It is predictable that the main effect of reducing the particle size of zinc oxide will be to increase the rate of solubility (which will none the less still be very low). The toxicity of microfine zinc oxide can therefore be related to the toxicity of soluble zinc: since zinc is an essential micronutrient the body is well able to tolerate the low levels resulting from use in sunscreens. In addition, zinc oxide (both pigmentary and microfine grades) has a long history of safe use in a wide range of cosmetic products.

- **Are there alternatives to nanoparticles in sunscreens?**
  Boots UK has a wide range of sun products both with and without titanium dioxide. Sunscreen products that do not contain microfine titanium dioxide will not include 'Titanium dioxide' in the ingredient list. Since it is a legal requirement to have full disclosure of ingredients on cosmetic products, this should be true for any sunscreen product, though of course we can only guarantee its accuracy for Boots brand products.

- **How are Boots UK contributing to the development of this new and emerging science?**
  Boots UK does not consider its current use of materials that approach the nanosize range as being of health concern to our customers.

  As part of our commitment's to lead on the management of chemicals and chemical issues, Boots UK takes part in DEFRA Stakeholder Forum on nanotachnology, [v]which ensures the 'wider concerns and perspectives get built into early policy deliberations, including the formulation of policy and control research objectives and more immediate actions to manage risks.'

  We will continue to input into these meetings to ensure that concerns of our customers are represented.

Key technical information

Nanoparticles: any insoluble material that is produced with an average particle size typically below 100 nm, using traditional or new techniques. Materials of this type have been around for many years, a typical example being microfine titanium dioxide as used in sunscreens.

Monosize nanoparticles: highly uniform particles in the nanoparticle size region. These materials have very interesting optical properties (mainly colour), and need careful handling in order not to destroy those properties. Our current understanding is that such have not been commercialised yet, at least for cosmetic use.

Novel nanomaterials: novel substances manufactured using novel techniques. A typical example is carbon nanotubes, which can be grown to carefully regulated sizes with properties depending on their chemistry as well as their size. Since these are novel substances they cannot legally be commercialised without full safety evaluation - which would be true whatever their particle size. Our current understanding is that there is no existing or planned usage of such materials in cosmetics.

Nanomachines: constructed devices with functional mechanical properties and a physical size measured in nanometres. While such devices are causing excitement especially in the medical world, they are a long way from being commercially available. It is difficult at present to see such machines having a role in cosmetic science.

Nanomanipulation: using novel techniques to manipulate atoms and molecules directly, usually for the purpose of producing highly structured arrays. Nanomanipulation is one of the techniques used to produce nanomachines, but it is also a technique being investigated for producing computer chips and other electronic devices. The results of nanomanipulation may be highly structured at the nanometre scale, but they are often not nanoparticles.

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[i] The Royal Society & The Royal Academy of Engineering - Nanoscience and Nanotechnologies July 2004
[ii] http://www.foe.org/camps/comm/nanotech/
[iii] SCCNFP/0005/98
[iv] Australian Therapeutic Goods Administration
[v] http://www.defra.gov.uk/Environment/nanotech/index.htm