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Nanomaterials, sunscreens and cosmetics: SMALL INGREDIENTS, BIG RISKS

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In one of the most dramatic failures of regulation since the introduction of asbestos, corporations around the world are rapidly introducing thousands of tonnes[1] of nanomaterials into the environment and onto the faces and hands of hundreds of millions of people, despite the growing body of evidence indicating that nanomaterials can be toxic to humans and the environment_[2].

Friends of the Earth believes that there are at least several hundred cosmetics. sunscreens and personal care products which contain engineered nanomaterials that are commercially available right now.

Our research demonstrates that nanoparticles have entered just about every type of personal care product on the market, including deodorant, soap, toothpaste, shampoo, hair conditioner, sunscreen, anti-wrinkle cream, moisturiser, foundation, face powder, lipstick, blush, eye shadow, nail polish, perfume and after-shave lotion.

Nanoingredients in products reviewed for this report include nanoparticle metal oxides, nanoemulsions and nanoencapsulated delivery systems. Disturbingly, our report has identified seven face creams that list carbon fullerenes as

ingredients – a substance found to cause brain damage in fish[3] and toxic effects in human liver cells[4].

Nanotechnology involves the manipulation of materials and the creation of structures and systems that exist at the scale of atoms and molecules The properties of nanoscale materials (measuring < 100nm) differ significantly from larger scales[5]. Altered properties can include colour, transparency, solubility and chemical reactivity[6] among others, making nanomaterials attractive to the cosmetics and personal care industries. However nanomaterials also introduce new and often heightened risks of toxicity[7] that remain poorly understood.

Preliminary scientific research has shown that many types of nanoparticles can be toxic to human tissue and cell cultures, resulting in increased oxidative stress, inflammatory cytokine production, DNA mutation and even cell death_[8]. In its 2004 report, the United Kingdom's Royal Society recommended that "ingredients in the form of nanoparticles should undergo a full safety assessment by the relevant scientific advisory body before they are permitted for use in products"[9]. Despite this warning companies are rushing to incorporate nanomaterials into personal

care products and cosmetics despite a regulatory vacuum and an absence of requirements for nanomaterial safetytesting.

Two years after the Royal Society's report, there are still no laws governing the use of nanomaterials in consumer products to ensure that they do not cause harm to the public using them, the workers producing them, or the environmental systems in which waste nanoproducts are released.

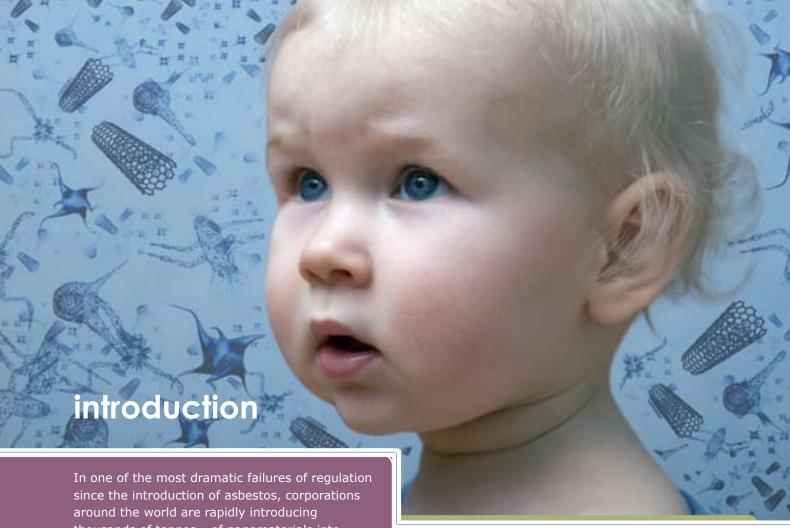
The failure of government regulators to take seriously the early warning signs surrounding nanotoxicity suggests that they have learnt nothing from any of the long list of disasters that resulted from the failure to respond to early warning signs about previously percieved "wonder"

materials (like asbestos, DDT and PCBs)[10] Friends of the Earth believes there should be a moratorium on the further commercial release of personal care products that contain engineered nanomaterials, and the withdrawal of until adequate, publicly available, peercompleted and adequate regulations have been put in place to protect the general public, the workers manufacturing these products and the environmental systems in which waste products will be released.

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thousands of tonnes[11] of nanomaterials into the environment and onto the faces and hands of hundreds of millions of people, despite the growing body of evidence indicating that nanomaterials can be toxic for humans and the environment[12].

In the absence of mandatory labelling of nanoscale ingredients, it is difficult to estimate the number of cosmetics, sunscreens and personal care products containing nanoparticles that are now commercially available. Estimates necessarily rely on information that product manufacturers - or the few government regulators collecting data on the use of nanomaterials - choose to make publicly available and readily accessible.

Friends of the Earth believes that there are at least several hundred cosmetics, sunscreens and personal care products which contain nanomaterials that are on the global market right now. This figure is likely to be a conservative estimate.

The Australian Therapeutic Goods Administration has stated that there are close to 400 sunscreen products alone that contain nanoparticle titanium dioxide and/ or nanoparticle zinc oxide that are currently commercially available in Australia [13]. However the TGA has failed to disclose the names of these products, leaving the public to guess which of its sunscreens contain nanomaterials. There is no information available on the use of nanomaterials within the non-therapeutic cosmetics and personal care sectors in Australia.

The United States Food and Drug Administration has not disclosed any relevant figures for the United States.

This report, based on preliminary web searches of publicly available information, contains the details of 116 cosmetics, personal care products and sunscreens that now incorporate nanomaterials.

Personal care products containing nanomaterials have been released commercially without adequate – if any – safety assessment of new nanomaterials, and without any regulations in place to protect workers, the public and the environment from the risks of nanotoxicity.

Nanotechnology is a powerful new technology for taking apart and reconstructing nature at the atomic and molecular level. Nanotechnology and nanoscience encompass the study of phenomena, materials and systems at the atomic, molecular and macromolecular scales, where properties differ significantly from those at the larger

Engineered nanomaterials are deliberately manufactured and can be distinguished from nanoparticles that 'exist in nature' (e.g. as a result of volcanoes or forest fires), or are byproducts of other human activities (e.g. high energy industrial processes such as welding or grinding).

Engineered nanomaterials include particles of all sizes and shapes that exist at a scale of 100nm or less, or that have at least one dimension that affects their functional behaviour at this scale[15].

A nanometre (nm) is one billionth of a metre. By way of comparison, a DNA molecule is roughly 2.5 nm, a red blood cell 7,000 nm, and a human hair cell a whopping 80,000 nm wide.

Nowhere are nanomaterials entering manufacturing and reaching the consumer faster than in personal care products and cosmetics. In 2004, the United Kingdom's (UK) Royal Society noted that of the engineered nanomaterials in commercial production, the majority were being produced for use in the cosmetics industry[16].

The recent rush to incorporate nanomaterials in personal care products and cosmetics is especially concerning given the poorly understood risks of nanotoxicity.

Use of personal care products poses clear risks of exposure to untested nanomaterials: they are used daily, are designed to be used directly on the skin, may be inhaled and are often ingested. Furthermore, many cosmetics and personal care products contain ingredients that act as 'penetration enhancers'[17], raising concerns that they may increase the likelihood of skin uptake of nanomaterials and possible entry into the blood stream.

In 2004 the world's oldest scientific organisation, the Royal Society, warned that the risks of nanotoxicity were significantly serious as to warrant nanomaterials being assessed as new chemicals[18]. It warned that the toxicity of nanoparticles cannot be predicted from the

known properties of larger sized particles of the same substance.

The Royal Society recommended that "ingredients in the form of nanoparticles should undergo a full safety assessment by the relevant scientific advisory body before they are permitted for use in products"[19]. They also recommended that products containing nanoscale ingredients should be clearly labelled, to enable people to make an informed decision about using these products[20].

But despite recognition at the highest scientific levels of the enhanced risks associated with nanomaterials used in cosmetics and personal care products, there are as yet no regulations anywhere in the world that specifically cover their manufacture and marketing.

Meanwhile, there is no requirement anywhere in the world for labelling of nano-scale ingredients to allow the public to make an informed choice about using nanoproducts.

Friends of the Earth is concerned that the nanotechnology industry is rapidly introducing potentially hazardous nanomaterials into our bodies and into our environment without adequate scientific study to ensure that we understand its risks and can prevent harm occurring to people and environment.

Friends of Earth believes there should be a moratorium on the further commercial release of personal care products that contain nanomaterials, and the withdrawal of such products currently on the market, until adequate, publicly available, peer-reviewed safety studies have been completed, and adequate regulations have been put in place to protect the general public, the workers manufacturing these products and the environmental systems in which waste products will be released.

This report is focussed on the use of nanoparticles in the personal care industry, recognising that this sector is one of the primary early adopters of nanomaterials[21]. We recognise that the impacts of nanotechnology reach far further than those associated with the toxicity of personal care products. Nanotechnology's broader impacts on the environment, risks for workers, socio-economic impacts and ethical problems are discussed elsewhere. Please refer to the Friends of the Earth website for more information on these aspects of this emerging technology.



Size matters - nanoparticles present higher risks of toxicity than larger sized particles

The fundamental properties of matter change at the nano-scale. The properties of atoms and molecules are not governed by the same physical laws as larger objects or even larger particles, but by "quantum mechanics".

The physical and chemical properties of nanosized particles can therefore be quite different from those of larger particles of the same substance. Altered properties can include but are not limited to colour, solubility, material strength, electrical conductivity, magnetic behaviour, mobility (within the environment and within the human body), chemical reactivity and biological activity[22].

Nanotoxicology is an emerging field, with a small number of peer-reviewed studies published to date. It is often suggested by nano proponents that we do not yet know enough about the behaviour of nanoparticles to determine whether they pose enhanced risks to human health. However, the existing body of toxicological literature[23A] suggests clearly that nanoparticles have a greater risk of toxicity than larger particles. This body of evidence has been sufficient for the world's oldest scientific organisation to warn that we should not continue to release products containing nanomaterials until we have vastly improved requirements for safety testing[23B].

There is a general relationship between particle size and toxicity; the smaller a particle, the greater its surface area to volume ratio, and the more likely it is to prove toxic[24]. Toxicity is partly a result of the increased chemical reactivity that accompanies a greater surface area to volume ratio₁₂₅₁.

The small size, greater surface area and greater chemical reactivity of nanoparticles results in increased production of reactive oxygen species (ROS), including free radicals[26]. ROS production has been found in a diverse range of nanomaterials including carbon fullerenes, carbon nanotubes and nanoparticle metal oxides[27]. ROS and free radical production is one of the primary mechanisms of nanoparticle toxicity; it may result in oxidative stress, inflammation, and consequent damage to proteins, membranes and DNA[28].

Size is therefore a key factor in determining the potential toxicity of a particle. Other factors influencing toxicity include shape, chemical composition, surface structure, surface charge, aggregation and solubility[29].

Because of their size, nanoparticles are more readily taken up by the human body than larger sized particles and are able to cross biological membranes and access cells, tissues and organs that larger sized particles normally cannot[30]. Nanomaterials can gain access to the blood stream following inhalation or ingestion, and possibly also via skin absorption, especially if the skin is damaged[31].

Once in the blood stream, nanomaterials can be transported around the body and are taken up by organs and tissues including the brain, heart, liver, kidneys, spleen, bone marrow and nervous system[32].

Once in the blood stream, the major distribution sites for nanoparticles appear to be the liver, followed by the spleen[33]. The length of time that nanoparticles may remain in vital organs and what dose may cause a harmful effect remains unknown[34].

Diseases of the liver suggest that the accumulation of even harmless foreign matter may impair its function and result in harm[35]. Carbon nanotubes (nano-scale cylinders made of carbon atoms) have been shown to cause the death of kidney cells and to inhibit further cell arowth₁₃₆₁.

Many types of nanoparticles have proven to be toxic to human tissue and cell cultures, resulting in increased oxidative stress, inflammatory cytokine production, DNA mutation and even cell death_[37].

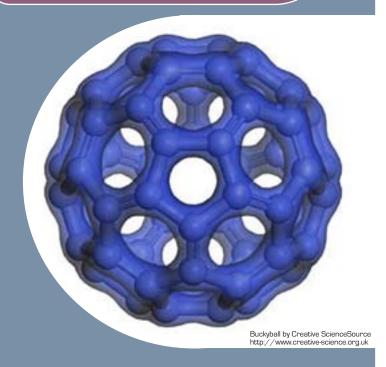
Unlike larger particles, nanoparticles may be transported within cells and be taken up by cell mitochondria[38] and the cell nucleus[39], where they can induce major structural damage to mitochondria[40], cause DNA mutation[41] and even result in cell death[42].

Nanoparticles of titanium dioxide and zinc oxide used in large numbers of cosmetics, sunscreens and personal care products are photoactive, producing free radicals and causing DNA damage to human skin cells when exposed to UV light_[43].

Nanoparticle titanium dioxide has been shown to cause far greater damage to DNA than does titanium dioxide of larger particle size. Whereas 500nm titanium dioxide particles have only a small ability to cause DNA strand breakage, 20nm particles of titanium dioxide are capable of causing complete destruction of supercoiled DNA, even at low doses and in the absence of exposure to UV[44].

The potential for sunscreens containing nanoparticles to result in harm is made greater as ROS and free radical production increases with exposure to light and UV[45].

The alarming case of carbon fullerenes (buckyballs)



Carbon fullerenes (buckyballs), currently being used in some face creams and moisturisers (see product lists following), have been found to cause brain damage in fish[46], kill water fleas and have bactericidal properties[47]. Even low levels of exposure to fullerenes have been shown to be toxic to human liver cells[48].

Researchers are investigating the ability of surface coatings and modifications to make nanomaterials such as fullerenes safe. However studies have shown that both surface coatings and modifications can be weathered over a 1-4 hour period by exposure to the oxygen in air, or by ultraviolet irradiation[49], suggesting that the protective qualities of surface coatings can be short-lived. There is also a concern that ingested coatings could be metabolised to expose the core harmful nanomaterial_[50].

In the absence of independent safety testing, it defies belief that regulators would permit fullerenes – nanoparticles linked to brain damage



in moisturisers and face creams. Yet in an act of disturbing regulatory negligence, that is exactly what has happened.

The risks associated with this rash incorporation of fullerenes into cosmetics is underscored by the recent comment by Professor Robert F. Curl Jr., who shared the 1996 Nobel Prize in Chemistry for his co-discovery of fullerenes, that he would avoid using cosmetics containing fullerenes until their risks were better understood: "I would take the conservative path of avoiding using such cosmetics while withholding judgment on the actual merits or demerits of their use"[51].

In fact, when a scientist at an international nanotoxicology meeting recently asked her two hundred colleagues present who would feel comfortable using face cream that contained fullerenes, less than ten indicated that they

The sobering reality is that whereas these two hundred scientists are in a position to understand the significance of the health risks posed by fullerenes, and are able to make a decision to avoid such products, most consumers lack this vital information, and rely on government regulators to protect their safety by preventing such dangerous products from being released onto the market.

Skin penetration by nanoparticles - insufficient evidence means the jury's still out, but the uptake of nanoparticles through broken skin should be taken seriously

Some cosmetics manufacturers[53], and even the Australian Therapeutic Goods Administration[54], claim that the potential for nano-ingredients in sunscreens and personal care products to be toxic to living cells and tissues is not a serious concern because nanoparticles remain in the outer layers of dead skin. The problem is that no one knows if this assertion is accurate.

We do know that broken skin is an ineffective barrier and enables particles up to 7,000nm in size to reach living tissue[55]. This suggests that the presence of acne, eczema or shaving wounds is likely to enable the uptake of nanoparticles.

The Royal Society has called for additional research into the influence of skin condition, including sun burn, on the uptake of nanomaterials, especially in the assessment of nanomaterials found in sunscreens and cosmetics[56]. However the fact that many cosmetics and personal care products are used on blemished skin or following shaving has been largely ignored in the discussion about skin uptake of nanomaterials found in personal care products to date.

If nanoparticles are able to penetrate the outer layer of dead skin cells and gain access to the living cells within, they can join the blood stream and circulate around the body with uptake by cells, tissues and organs[57].

Other substances, for example organic liquids, pharmaceuticals_[58] and phthalate monoesters in personal care products[59], are known to access the blood stream via skin uptake. However there has been very little published research into skin uptake of nanomaterials in cosmetics and personal care products that are already commercially available.

Penetration of intact skin is in part dependent on particle size, meaning that skin uptake of





nanoparticles is comparably more likely than uptake of larger particles[60]. The ability of 1000nm particles to access the dermis when intact skin is flexed has been demonstrated[61]. This suggests that uptake of 100nm particles is possible in at least some circumstances.

Preliminary study of the ability of zinc oxide and titanium oxide nanoparticles to cross the skin has produced conflicting results. Most studies found that these nanoparticles did not reach the living cells[62], while at least two pilot studies suggest that they did[63]. However, the few studies that have examined the ability of nanoparticles to cross the skin have generally been narrow in scope and have not adequately investigated the role of key variables that may influence skin uptake.

It is especially important to investigate the role of base carriers that enhance skin uptake of nanoparticles by altering skin structure or increasing the solubility of the nanoparticle in the skin_[64]. Skin Deep, a recent report by US-based Environmental Working Group on the health risks of commercially available cosmetics and personal care products, found that more than half of all cosmetics contained ingredients that

act as "penetration enhancers"[65]. This suggests that testing of skin uptake of nanoparticle ingredients should be undertaken in the context of whole products, recognising that other product ingredients may play a penetration enhancing role.

Exposure to nanomaterials in "real life" conditions should also be investigated given that flexing [66] and massage_[67] have been demonstrated to increase skin uptake of larger particles, drugs and dyes.

Physical and chemical properties of nanoparticles that may influence skin uptake and that require investigation are: particle size and shape, surface characteristics including the presence of coatings, electronic charge and dose.

Publicly funded research into the interactions between nanomaterials and the skin is being undertaken currently by both the EU and the USA. However little of this information has yet been published in peer-reviewed, publicly accessible literature, and most studies are likely to continue for several years before publishing their results.



the broader risks of nano-cosmetics - for workers and the environment

It is important to recognise that the increasing use of nanomaterials in the manufacture of cosmetics poses new risks both for the workers who manufacture them, and the environmental systems in which they are released. Yet the new risks posed by nanomaterials are not managed through existing regulatory systems.

Risks associated with occupational exposure

Because workers handling nanomaterials are likely to be exposed at much higher levels than the general public, and on a more consistent basis, workplace exposure to nanomaterials is particularly concerning.

It is not just researchers developing nanomaterials who face workplace exposure. Workers may be exposed to nanoparticles during the manufacture, packaging, handling, transport and use of products containing nanomaterials. Exposure may also occur in cleaning and maintaining research, production and handling facilities[68].

Rates and levels of existing workplace exposure to nanomaterials within all these sections of the production chain are unknown. The US National Science Foundation estimates that by 2015 2 million workers world-wide will be directly employed in nanotechnology industries[69]. By this point, the number of workers exposed routinely to engineered nanoparticles in the workplace throughout the production supply chain of products using nanomaterials will clearly be much larger.

There are currently no known safe levels of exposure to nanomaterials and no reliable systems and equipment to protect workers from nano exposure[70]. It is clearly in the long term interests of the nano industry to develop a set of best practice guidelines and sophisticated safety control systems that will protect workers from nanomaterial exposure as soon as possible. However, even should such safety control systems be developed, they are likely to be expensive. It is important to question whether or not they will be employed at each link in the manufacturing, handling, transporting and cleaning chain, and what sort of workplace environment this will constitute for the millions of workers involved.

Environmental risks

As the nanotech industry expands, nanopollution will also expand as a result of both manufacturing waste streams being discharged, and accidental releases during handling or transport. Domestic nano waste discharge will also expand as ever greater quantities of cosmetics, sunscreens and personal care products containing nanomaterials are washed off in the shower and join water waste streams, or are washed off swimmers and sunbathers directly into oceans and lakes.

Remarkably little information exists on the potential of nanomaterials to cause environmental harm. There is no body of



literature equivalent to that which exists for the potential of nanomaterials to cause harm to humans that examine the impacts of nanotoxicity on non-human animals, micro-organisms and plants[71]. Preliminary study in this area has begun, however it has received even less funding than the relatively small amount available for the examination of nanotoxicity's implications for human health_[72].

The little research completed cautions against broad extrapolation of results. However the preliminary findings indicate the potential for serious environmental impacts and point to the urgent need for further study.

One example of dangerous environmental impacts already discovered by the scant research concerns carbon fullerenes. Fullerenes have been found to cause brain damage in largemouth bass_[73], a species accepted by regulatory agencies as a model for defining ecotoxicological effects. Fullerenes have also been found to kill water fleas and have bactericidal properties[74].

Nanoparticles also have a demonstrated ability to bind to sediments and soil particles. Rice University's Center for Biological and Environmental Nanotechnology has pointed out the tendency for nanoparticles to bind to contaminating substances already pervasive in the environment like cadmium and petrochemicals. This tendency would make nanoparticles a potential mechanism for long range and wide-spread transport of pollutants in groundwater[75].

Early studies also suggest that microorganisms and plants may be able to produce, modify and concentrate nanoparticles that can then bioaccumulate (or even biomagnify) along the food chain[76].

The antimicrobial properties of nanoparticles have led to concerns that they may shift into microbial populations and disrupt signalling between nitrogen-fixing bacteria and their plant hosts[77]. Any significant disruption of nitrogen fixing could have serious negative impacts for the functioning of entire ecosystems. High levels of exposure to nanoscale aluminium (currently used in face powders and sunscreen) have been found to stunt root growth in five plant species[78].



eminent scientific bodies warn that the health risks of nanocosmetics require further investigation prior to product commercialisation



While we know very little about the toxicological effects of nanomaterials such as titanium dioxide and zinc oxide on the human body, we know even less about a host of other nanomaterials currently being used in cosmetics, including carbon fullerenes (buckyballs), and iron, aluminium, zirconium, silcon and manganese nano oxides.

One of the key problems is that we don't know how much safety research the sunscreen and cosmetics manufacturers are actually conducting. Some manufacturers claim that their products are "photostable"[79] (i.e. do not produce reactive oxygen species or free radicals when exposed to light or UV), or that their technology "helps to keep free radicals at bay"[80]. However in the absence of peer-reviewed, publicly accessible information from cosmetics companies, it is impossible to know how adequate safety assessment has been.

As Sue Windebank, senior spokesperson for the UK Royal Society said last year[81]:

"It seems that there is really very little publicly funded research looking into the effects of nanoparticles being taken into the body through the skin... The cosmetics companies may of course be doing their own research, but much of the information about what kind of safety assessments are being undertaken is not publicly listed."

"Our concern is that manufacturers ensure that the toxicological tests that they use recognize that nanoparticles of a given chemical will often have different properties to the same chemical in its larger form and may have greater toxicity....It is certainly not a cloak and dagger situation with the cosmetics companies, but it would help if they were more transparent about the results of their safety tests."

This sense of frustration has been echoed by Dr Bethany Halford, scientist and science journalist, writing in Chemical & Engineering News about the lack of safety data available for the face creams that contain fullerenes, for which she was assured by the manufacturer that (unpublished) safety testing had been carried out:

"Why don't manufacturers make [safety] data readily available to their customers...? It doesn't seem that much to ask when you're paying about \$250 for a jar of face cream."

The UK Royal Society has made clear its view that greater safety testing of products that contain nanomaterials, and greater transparency in the conduct of safety testing, is required. In its 2004 joint report with the UK Royal Academy of Engineering, the Royal Society called for companies wishing to commercialise cosmetics containing nanomaterials to publish peerreviewed, publicly accessible, safety studies, and then label their products to allow consumers to make an informed choice:

"We recommend that ingredients in the form of nanoparticles undergo a full safety assessment by the relevant scientific advisory body before they are permitted for use in products...

We recommend that manufacturers publish details of the methodologies they have used in assessing the safety of their products containing nanoparticles that demonstrate how they have taken account that properties of nanoparticles may be different from larger forms...

We recommend that the ingredients lists of consumer products should identify the fact that manufactured nanoparticulate material has been added".[82]

The call for new safety assessment of nanoingredients in cosmetics has even been echoed by some industry commentators, including Simon Pitman, editor of CosmeticsDesign.com and CosmeticsDesign-Europe.com, who warned last

"Nanotechnology creates substances with new chemical properties that we do not yet understand. A science with such huge potential deserves closer attention to the possible

risks, before it falls the wrong side of belated discoveries of toxicity."[83]

Mathew Nordan, vice president of research for nanotechnology research firm Lux Research Inc., has also argued for (government funded) toxicological testing of each nanomaterial to assess its threats to human and environmental health, stating: "It only takes one bad apple to spoil the bunch."[84]

nanoparticles and the cosmetics industry



A very small sample of some of the products on the market that are thought to contain nanomaterials is included in the appendix of this report. This information is sourced from publicly available websites, and relies on the accuracy of information provided by the manufacturer or product distributor. We also acknowledge the work conducted by the Woodrow Wilson Center for International Scholars in its inventory of consumer products_[85] which was consulted in the compilation of this database.

The database includes 116 products: 71 cosmetics, 23 sunscreens and 22 personal care products that are now thought to incorporate nanomaterials. We recognise that this data represents a small fraction of personal care products containing nanomaterials that are currently on the market, and may not reflect the overall pattern of nanoparticle use across these sectors.

Products listed in this database include deodorants, soap, toothpastes, shampoos, hair conditioners, sunscreens, anti-wrinkle creams, moisturisers, foundations, face powders, lipstick, blush, eye shadow, nail polish, perfumes and after-shave lotions. Manufacturers include L'Oréal, Estée Lauder, Proctor and Gamble, Shiseido, Chanel, Beyond Skin Science LLC, Revlon, Dr Brandt, SkinCeuticals, Dermazone Solutions and many more.

The database shows that a wide range of nanomaterials is already being incorporated into personal care products. Nanoscale ingredients

listed in the database include nanoparticles of titanium dioxide, zinc oxide, alumina, silver, silicon dioxide, calcium fluoride and copper, as well as nanosomes, nanoemulsions and nanoencapsulated delivery systems. Disturbingly, seven face creams list fullerenes as ingredients - a substance found to cause brain damage in fish_[86] and toxic effects in human liver cells_[87].

On its website[88], the United States Food and Drug Administration notes that: "FDA is aware that a few cosmetic products claim to contain nanoparticles to increase the stability or modify release of ingredients".

Our findings suggest that this estimate is seriously outdated; regulators in both Australia and the United States need to take seriously the rapid market expansion of personal care products and cosmetics containing nanomaterials.

where are the regulators?



Increasing numbers of cosmetics and personal care products contain nanomaterials and increasing numbers of scientific papers are demonstrating the general risks associated with nanotoxicity. Yet there has been little effort on the part of the regulators to slow the expansion of the nanocosmetics sector until we can carry out safety testing that ensures that personal care products containing nanomaterials are safe for the workers who manufacture them, the public who use them and the environment in which waste nanoproducts are inevitably released.

In Australia, the National Industry Chemicals Notification and Assessment Scheme (NICNAS) regulates the safety of ingredients in cosmetics and personal care products and the Therapeutic Goods Administration (TGA) regulates sunscreens. However these regulators fail to distinguish between nanoparticles and larger sized particles.

Manufacturers of cosmetics and personal care products are not required to seek approval from



NICNAS for the use of nanoparticle ingredients where the use of larger sized particles of the same substance has already been approved. Manufacturers of all sunscreens must apply to the TGA for marketing approval, but current regulations do not require manufacturers to distinguish between larger sized particles and nanoparticles.

Australian regulation of nanomaterials in personal care products therefore remains based on the flawed assumption that the toxicity of nanoparticles can be predicted from the known properties of larger-sized particles of the same substance. This flies in the face of recommendations from the UK Royal Society for nanoparticles to be assessed as new chemicals[89].

In the US, manufacturers of sunscreens are required to seek pre-market approval from the Food and Drug Administration (USFDA) if their products are "new drug" products. However in 1999, the USFDA made a decision to allow nanoparticle ingredients to be used in sunscreens without new safety assessments, based on previous safety assessment of larger sized particles[90].

The USFDA has virtually no authority over cosmetics and personal care products and cannot require manufacturers to conduct safety studies. Only 11 percent of the 10,500 ingredients used in cosmetics products have been assessed for safety by the industry-funded Cosmetics Industry Review Panel[91]. A recent report by the Woodrow Wilson Center's Project on Emerging Nanotechnologies[92] criticised strongly the current approach to regulating cosmetics as wholly inadequate to dealing with the risks posed by nanotechnologies:

"Although the FDCA [Food, Drug and Cosmetic Act] has a lot of language devoted to cosmetics, it is not too much of an exaggeration to say that cosmetics in the USA are essentially unregulated."

In one of the few concrete responses from governments to the Royal Society's recommendations, last year the European Union requested its Scientific Committee on Consumer Products to review previous decisions to allow nanoparticle titanium dioxide and zinc oxide to be permitted for use in sunscreens without new safety assessments[93]. However there are as yet no specific regulations applying to the use or manufacture of nanoparticle ingredients in cosmetics and personal care products.

research and review underway



The emerging findings of the apparent dangers of nanoparticles have rung alarm bells for eminent scientific bodies including the Royal Society and the Science Council of Japan, both of whom have called for greater public funding of the health risks posed by nanoparticles as a matter of urgency[94].

But whereas governments world-wide have invested billions of dollars of public money in nano research[95], they have been more interested in supporting research into profitable commercial applications of nanotechnology, or military research, than health and safety testing.

For example, in the US\$1.3 billion budget for the US National Nanotechnology Initiative[96], only \$38.5 million (less than 4%) was earmarked for the study of the health, safety and environmental impacts of nanotechnology. Conversely, the US Department of Defense received \$436 million (33.5% of the nanotechnology budget).

However, growing evidence of the toxicological risks posed by nanomaterials has prompted increased (albeit inadequate) public funding of studies investigating nano's threats to health, safety and the environment:

• In the USA, government agencies including the Food and Drug Administration and the National Institute of Environmental Health Sciences are cooperating through the National Toxicology

Program to study the skin absorption and phototoxicity of nanoparticles of titanium dioxide and zinc oxide preparations used in sunscreens and cosmetics. The NTP is also looking at the uptake and toxicity of fullerenes.

- The Australian government has not yet recognised formally the need to fund nanotechnology research into health and environmental risks of nanomaterials. The Therapeutic Goods Administration recently published a literature review of existing studies into the potential for nanomaterials in sunscreens to be absorbed through the skin[97]. However that review failed to clearly recognise the inadequacies of studies conducted to date or the need for more thorough research
- The European Union has launched a research project called "Nanoderm" to investigate the quality of the skin as a barrier to formulations containing nanoparticles[98]
- Japan has launched a collaborative research initiative that includes an evaluation of nanomaterials' implications for: risk assessment; health issues; environmental issues; ethical and social issues; and public acceptance[99]
- The UK Government has not earmarked any specific money for study of the health impacts of nano-cosmetics and other consumer products (earning them a sharp rebuke from the Royal Society[100]), but has invited research bids for areas it has identified as priorities for nanotechnology research, including the impacts of nanomaterials for human health and the environment

Most of these studies will take several years before publishing results, and much further work will then be required before reliable conclusions can be drawn.

Civil society groups such as Friends of the Earth and others have argued that the sensible response to a situation where the risks of nanotoxicity have been clearly identified, but remain poorly understood, is to place a moratorium on the commercialisation of nanoproducts until the necessary safety research has been conducted.





The early warning signs surrounding nanotoxicity are serious and warrant a precautionary approach to the commercialisation of all products containing nanomaterials.

Based on this report, Friends of Earth believes there should be a moratorium on the further commercial release of sunscreens, cosmetics and personal care products that contain engineered nanomaterials, and the withdrawal of such products currently on the market, until adequate public, peer-reviewed safety studies have been completed, and adequate regulations have been put in place to protect the general public, the workers manufacturing these products and the environmental systems in which waste products will be released.

This report is focussed on the use of nanoparticles in the personal care industry, recognising that this sector is one of the primary early adopters of nanomaterials and that the risks associated with nanotoxicity are both immediate and significant.

Friends of the Earth recognises that nanotechnology has a huge transformative potential and may have a significant disruptive impact on our world, beyond the immediate issues of nanotoxicity. We believe that ethical concerns, and the likely far-reaching socioeconomic impacts of nanotechnology, must be addressed alongside concerns over nanotoxicity before the commercialisation of nanotechnology proceeds. For further discussion of these issues, please refer to the Friends of the Earth website.

Specifically, Friends of the Earth is calling for an immediate moratorium on the commercial release of all nanotechnological materials and products until such time as:

- all nanomaterials and products are subjected to rigorous health and environmental impact assessment, including evidence based testing, prior to commercial production and/ or environmental release
- nanomaterials are assessed as new substances, even where the properties of larger scale counterparts are well-known, because of the radically altered characteristics of nanomaterials compared to larger sized particles
- a regulatory framework is established that protects the health of workers and the general public from the risks associated with exposure to nanomaterials, and the environmental systems in which waste nanoproducts will be released
- safety assessments are based on the precautionary principle and the onus is on proponents to prove safety, rather than relying on an assumption of safety
- risk assessment includes the entire life cycle of the products in question, from 'cradle to grave'
- all relevant data related to safety assessments, and the methodologies used to obtain them, are placed in the public domain
- skin uptake of nanomaterials is assessed based on whole product assays, and 'real life' conditions given that flexing, massage and penetration enhancing ingredients have been demonstrated to increase skin uptake of larger particles, drugs and dyes
- nanoparticle ingredients are clearly indicated on product labels to allow consumers to make an informed choice about product use.

COSMETICS

appendix:

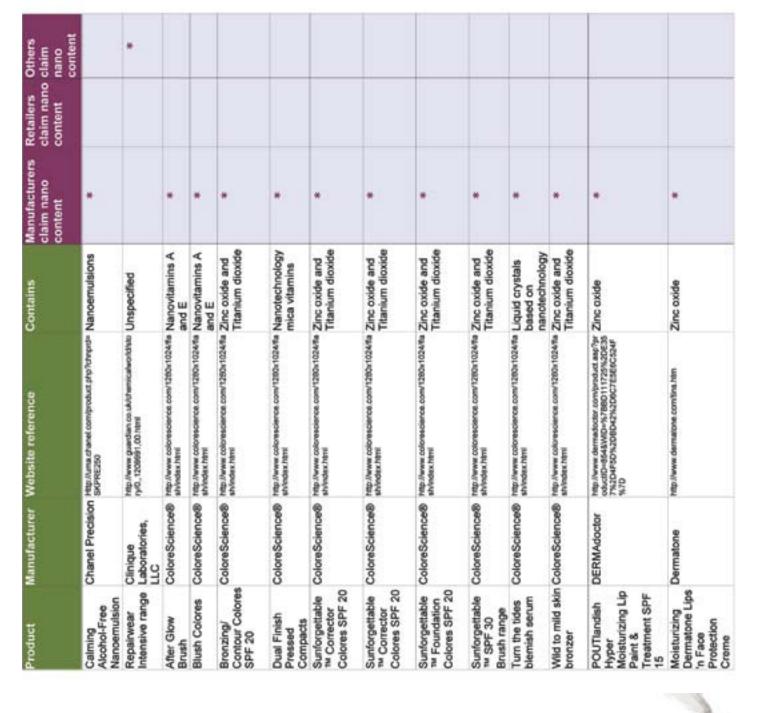
Friends of the Earth database and sunscreen products now of cosmetics, personal care containing nanomaterials

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	Bellapelle ¹¹⁴ Skin Studio	Bellapelle 14 Skin http://www.bellapele.com/products/products "Fullersomes" 14 Studio	"Fullersomes"	*		
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Eternalis** Hydrating Face	Beyond Skin Science, LLC**	http://www.beyondskinscience.com/ProductO_"NanoChem" escription/tabled/72/Default.aspx formulation	"NanoChem" formulation	*		
Etemalis™ Purifying Cleanser	Beyond Skin Science, LLC TM	http://www.beyondskinscience.com/ProductD "NanoChem" escriptionhabid/72/Defaut.aspx formulation	"NanoChem" formulation	*		
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COSMETICS









roduct	Manufacturer	Manufacturer Website reference	Contains	Manufacturers claim nano content	Retailers claim nano content	Others claim nano content	
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aser Relief	Dr.Brandt	http://www.drbrandtskincare.com	Nanocapsules	*			
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Product	Manufacturer	Manufacturer Website reference	Contains	Manufacturers claim nano content	Retailers claim nano content	Others claim nano content
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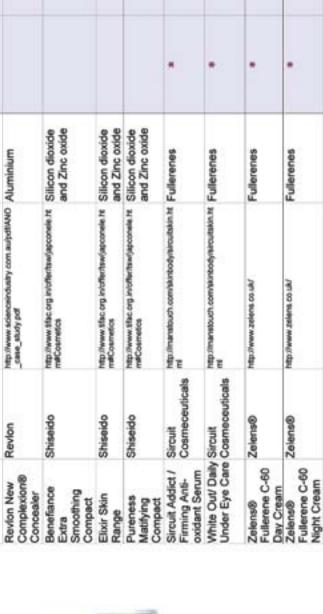
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PERSONAL CARE PRODUCTS

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16. http://www.osmatics.com 17. http://813312.royalbadycare.com 18. http://813312.royalbadycare.com 19. http://813312.royalbadycare.com

15. http://www.ionicmagnesium.com/copper.html IMAGE SOURCE:

Friends of the Earth

SUNSCREENS

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SUNSCREENS

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None Internal





IMAGE SOURCE:

21. http://www.dermatone.com 22. http://www.rsfacebody.com 23. http://www.boats.com 24. http://www.superiorskincare.com.au

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"In one of the most dramatic failures of regulation since the introduction of asbestos, corporations around the world are rapidly introducing thousands of tonnes of nanomaterials into the environment and onto the faces and hands of hundreds of millions of people, despite the growing body of evidence indicating that nanomaterials can be toxic to humans and the environment."

