PAS 130:2007

PUBLICLY AVAILABLE SPECIFICATION

Guidance on the labelling of manufactured nanoparticles and products containing manufactured nanoparticles

ICS 71.100.99

British Standards

Publishing and copyright information

ISBN 978 0 580 61315 9

Publication history

First published December 2007

Amendments issued since publication

Amd. no.	Date	Text affected

Contents

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, pages 1 to 17 and a back cover.

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Foreword

Publishing information

This Publicly Available Specification (PAS) has been commissioned by the UK Department for Innovation, Universities and Skills (DIUS) and developed through the British Standards Institution. It came into effect on 31 December 2007.

Acknowledgement is given to the following organizations that were involved in the development of this terminology:

- Association of British Healthcare Industries (ABHI);
- BSI Consumer and Public Interest Committee;
- Cosmetic Toiletry and Perfumery Association (CTPA) Ltd;
- Food and Drink Federation (FDF);
- IonBond Ltd;
- Nanotechnology Industries Association;
- Neville Craddock Associates;
- Oxonica;
- Quintiles Consulting Europe;
- Soil Association;
- University of Surrey.

This PAS is not to be regarded as a British Standard. It will be withdrawn upon publication of its content in, or as, a British Standard.

The PAS process enables a specification to be rapidly developed in order to fulfil an immediate need in industry. A PAS may be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or International Standard.

Relationship with other publications

This PAS is issued as part of a suite of nanotechnology PASs:

PAS 131, *Terminology for medical, health and personal care applications of nanotechnologies*;

PAS 132, *Terminology for the bio-nano interface*;

PAS 133, *Terminology for nanoscale measurement and instrumentation*;

PAS 134, *Terminology for carbon nanostructures*;

PAS 135, *Terminology for nanofabrication*;

PAS 136, *Terminology for nanomaterials*.

In selecting a title for this PAS, consideration was given to the need to make the document accessible to a wide range of users, many of whom might be unfamiliar with the latest thinking on terminology for nanotechnologies. Whilst "nanoparticle" has now been defined as "nano-object with all three external dimensions in the nanoscale" (PAS 136, *Terminology for nanomaterials*), colloquial use of the term includes all nanoscale objects, including nanotubes and nanofibres, and that is the sense in which the term "manufactured nanoparticle" is used in this PAS (see **2.3** below).

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a Publicly Available Specification cannot confer immunity from legal obligations.

0 Introduction

0.1 Background

Nanotechnology is an enabling technology founded on harnessing the novel properties of materials with nanoscale dimensions or structures. At the end of 2007, there were over 500 "nanotechnology-based consumer products" in the marketplace worldwide and this number is rapidly increasing. Industrial applications are also developing quickly [*A Nanotechnology Consumer Products Inventory*, 2007 [1]].

The Royal Society and the Royal Academy of Engineering Report (2004) states: "We recommend that the ingredients list of consumer products should identify the fact that manufactured nanoparticulate material has been added. There is an additional case in favour of labelling based on a desire for transparency of information about consumer products." [*Nanoscience and nanotechnologies: opportunities and uncertainties*, 2004 [2]].

This PAS builds on these recommendations by providing guidance for both suppliers and users of manufactured nanoparticles (MNPs) and products containing manufactured nanoparticles (PCMNPs). Currently, there is no generic labelling requirement for either MNPs or PCMNPs, or other regulation specific to the nanoscale properties of nanomaterials.[1)] It is generally agreed that nanotechnology brings opportunities for new industrial and consumer applications as well as concerns about possible adverse effects on health and the environment. This means that the use of nanotechnology presents manufacturers, retailers and consumers with new opportunities, potential risks, and responsibilities, all at the same time. The potential risks associated with the use of MNPs in consumer products are not well understood.

Labelling and specifications are important tools for addressing these new conditions. Product specifications enable businesses to reliably select or avoid ingredients based on their nanoscale properties, to meet general regulatory requirements and other essential conditions of business such as insurance contracts. Appropriate consumer product labelling is necessary to identify ingredients in nanoparticle form and to inform consumers of their presence in final products.

Labelling should take into consideration the level of knowledge and understanding of those who are intended to read the label, in order to avoid any misinterpretation that could lead to confusion and misuse of products.

Openness and transparency should accompany the responsible introduction of new technologies to the marketplace. Labelling, as part of this approach, helps consumers to make informed choices and should facilitate traceability and the monitoring of health and environmental impacts.

A common approach to labelling for this area could also help to avoid confusing or inappropriate use of the term "nano".

1) There are sectoral labelling and safety requirements that may be relevant to nanotechnology.

0.2 Purpose of this guidance

The purpose of this guidance, is

- to promote a standardized approach to labelling;
- to ensure that users of MNPs and PCMNPs can correctly identify the MNP contents for the purposes of making informed decisions in selection, purchase, distribution, handling, use and disposal;
- to inform regulatory authorities and assist healthcare professionals, technicians, health and safety officers and others to make informed decisions in relation to matters of occupational, consumer, public and environmental health and safety;
- to standardize the use of the term "nano" in labels;
- to provide guidance on the use of other specific terms in these labels.

For a list of possible application areas for MNPs, see Annex A.

0.3 Conceptual framework

0.3.1 Context

This guidance is set within the context of general risk governance concepts such as transparency, upstream public engagement, the precautionary principle, life cycle approach and traceability, which are briefly considered in **0.3.2** to **0.3.6**.

0.3.2 Transparency

Transparency enables accountability and the freedom and availability of information, putting an onus on the provider to supply information sufficient to allow users to make informed choices.

0.3.3 Upstream public engagement

The concept of upstream public engagement is the assumption that, in general, it is right and beneficial for the public to be informed about and engaged with new developments at the earliest possible stage. Thus it puts the onus on scientific, engineering, commercial and regulatory developers to initiate such engagement as far as possible.

0.3.4 Precautionary principle

The precautionary principle is the concept that lack of scientific evidence of risk should not prevent appropriate precautionary actions being taken. These should be proportionate, non-discriminatory, and consistent with previous action, considering both costs and benefits and be subject to review.

NOTE See European Commission, Communication on the Precautionary Principle 2 February, 2000 – COM (2000) 1 final [3].

0.3.5 Life-cycle approach

This approach encourages manufacturers, distributors and others to promote the safe and responsible use of nanoparticles across entire sourcing, production, supply and disposal chains [*Proceedings of the Workshop on Nanotechnology and Life Cycle Assessment*, 2007 [4]].

0.3.6 Traceability

Traceability is the system that enables products and their ingredients to be identified retrospectively at any stage in the life-cycle. Labelling is one source of information that facilitates this, e.g. contact information for the producer and precise identification data such as designation, model, production batch, serial number and/or date of manufacture.

NOTE Traceability is essential if circumstances arise after a product has been placed on the market that require the producer to take action to withdraw, recall or issue warning notices to consumers. Producers have a responsibility as well as a financial incentive to take measures in advance to limit such action to just those products affected, by uniquely identifying products and batches.

1 Scope

This Publicly Available Specification (PAS) provides guidance on the format and content of voluntary labels for manufactured nanoparticles and products or substances containing manufactured nanoparticles.

This PAS also provides guidance on the use of the term “nano” in product labelling.

This PAS does not substitute for labelling that is required by law, but provides guidance on additional labelling.

This (voluntary) guidance is designed for use by businesses and other organizations involved in the manufacture, distribution, supply, handling, use and disposal of manufactured nanoparticles (MNPs) or products containing MNPs (PCMNPs) and/or products exhibiting nano-enabled effects.

Nanoparticulates in the liquid state, e.g. “nano” emulsions, are not included in the scope of this PAS, unless encapsulated in a solid or gel shell. Despite this exclusion, manufacturers of products containing nanoparticulates in the liquid phase might find the guidance in this PAS helpful.

This guidance does not apply to nanoparticles that are produced by natural processes (e.g. volcanic) and which are not subjected to further processing. Nanoparticles that are incidental (e.g. diesel combustion and similar environmental contaminants) are also outside the scope of this guidance.

Reference is made to the appropriate labelling of products producing nano-enabled effects, whether or not these are produced with the use of MNPs.

2 Terms and definitions

For the purpose of this PAS, the following terms and definitions apply.

2.1 label
written, printed or graphic information provided on the product, its container or packaging

2.2 labelling
information about a product provided by its manufacturer or supplier

NOTE Such information can relate, among other things, to contents, identification, technical application, storage, transport or use.

2.3 manufactured nanoparticle (MNP)
solid entity with size from approximately 1 nm to 100 nm in at least two dimensions that has been produced by a manufacturing process

NOTE 1 This definition includes processed nanoparticles.

NOTE 2 For examples of MNPs and their characteristics, see Annexes B and D.

NOTE 3 The lower limit in this definition (approximately 1 nm) has no physical significance but is introduced to avoid single and small groups of atoms from being designated as nanoparticles, which might otherwise be implied by the absence of a lower limit.

NOTE 4 The upper limit of approximately 100 nm does not imply that particles with larger dimensions might not be of significance from a health or environmental point of view.

2.4 nano-enabled effect
effect which is enabled by the use of a nanomaterial or nanostructure

NOTE 1 Examples of nano-enabled effects are non-wetting surfaces produced using "lotus leaf" type nanostructured surfaces, enhanced solubility of nanoparticles of a material with otherwise low solubility, and "transparent" metal oxide based sunscreens containing non-light-scattering nanoparticles of, for example, titanium dioxide.

NOTE 2 The presence of a nano-enabled effect does not necessarily require the presence of a nanomaterial in the product used to produce it. For example, a polymer which spontaneously self assembles to form a nanostructured, non-wetting film is not necessarily itself a nanomaterial prior to its application to the surface being treated.

2.5 product containing manufactured nanoparticles (PCMNP)
any product in which MNPs are intentionally added, mixed, attached, embedded or suspended

NOTE For examples of application areas for MNPs, see Annex A. For examples of MNPs and their uses, see Annex B.

2.6 processed nanoparticles
naturally occurring nanoparticles that are processed in some way prior to supply to a customer or inclusion in a product

NOTE Such processing could include chemical, e.g. functionalization; physical, e.g. thermal treatment; or mechanical, e.g. high shear rate mixing. Processing that is intended to concentrate the number density of nanoparticles is also included.

2.7 consumer products
products intended to be, or likely to be, used by consumers

2.8 products or substances for professional use
products or substances supplied to a party with recognized competence to select and use them appropriately

2.9 products or substances for business to business use
goods supplied by one commercial entity to another commercial entity for further processing, incorporation into other products or for resale with or without repackaging

3 Use of the term "nano"

It is recommended that the term "nano" should only be used on a product label if the product does in fact contain manufactured nanoscale entities or produces a nano-enabled effect (see **2.4**).

For products producing a nano-enabled effect, it is recommended that a description is included of how the effect is achieved (e.g. "The self-cleaning is achieved by the active liquid ingredient in this material drying to form a nano-structured film that displays the lotus-leaf effect.")

4 What should be labelled?

Labelling is recommended for:

- MNPs.
- PCMNPs, except where the nanoparticle component of the product is intimately bound and could not be released under reasonable and foreseeable conditions of use or disposal.
- PCMNPs which are components of complex systems (e.g. a vehicle, mobile phone or game console), which could be expected to release MNPs under reasonable and foreseeable conditions of use or disposal.
- By-products, where MNPs, generated as by-products, are present in MNPs and PCMNPs and might affect the technical properties of the product or pose a risk to health or the environment.

NOTE 1 Examples of MNPs and their uses are given in Annexes A and B.

NOTE 2 For examples of possible activities for which labelling might be relevant, see Annex C.

5 Content of labels for PCMNPs for consumer use

5.1 General

This guidance provides recommendations for labelling to be provided for PCMNPs that is additional to that required by any legal obligation or known risks of the product (whether due to use of MNPs or to other features of the product).

Depending on the nature of the product and how it is distributed and used, it might be necessary to present some information, additionally, in media other than labels on the product or packaging.

Products likely to be used by consumers within the European Union are required to conform to the General Product Safety Directive (GPSD). Consumer products should not be sold with known irreducible risks inherent in their use unless consumers are provided with appropriate information (i.e. warnings and/or instructions) enabling them to assess the risks and protect themselves from harm.

5.2 Information required for purchase

All relevant information should be provided to enable consumers to make an informed choice between products before purchase, without opening any retail packaging.

It is recommended that labels on any of the following goods should include a statement (in the form of the most appropriate of the examples listed in **8.1**) so that it is visible and legible prior to sale to consumers expecting to find it:

a) Containers of MNPs;

b) Products (or their packaging) containing or comprising MNPs;

c) Products (or their packaging) using nano-enabled effects;

d) Products that use the prefix “nano” in promotional or descriptive information (however, see Clause **3**).

Typically this should be on the outside of retail packaging, together with (and no less prominent than) such information as a list of ingredients, technical specification, claims of intellectual property or indications of compliance with specific standards.

5.3 Information required for use (instructions for use)

Consumers using PCMNPs for the first time may not be prepared for any greater effectiveness, efficiency, capability or other difference compared to similar non-MNP products. Consumers should therefore be informed or reminded in the instructions for use of different effects, if it is necessary to have a different expectation (for example in the case of a powder that is substantially more readily dispersible, a racquet with greater elasticity, a skateboard or ski with less friction or an abrasive that should be used more sparingly). It may also be helpful to repeat this kind of advice on a label that has to be removed from the product in order to use it.

If any different handling, maintenance, cleaning, storage or disposal of the product is advised as a consequence of nanoparticle content (i.e. that differs from normal practice or advice for similar non-MNP products), this should be advised in instructions and, wherever possible, on labels permanently attached to the product itself, or where that is impractical, on packaging in which the product is intended to be kept by the consumer. In the event that this is not possible, such information should be combined with accompanying instructions for use, which should be prominently headed: "**IMPORTANT. KEEP FOR FUTURE REFERENCE**".

Labelling should similarly be provided, if, as a consequence of nanoparticle content, any difference is advised in normal first aid or other medical treatment when compared with existing non-MNP products. This would be relevant in the event of accidental contamination or injury or in respect of action to be taken in the event of any other unintended emergency (e.g. exposure to extreme heat or fire).

The above instructions should be integrated with other information required for use on labels and/or other media and be prepared and presented in accordance with BS EN 62079:2001, or comparable published guidance to best current practice on preparing instructions for use of consumer products.

5.4 Information required after purchase

Information should be provided to maximize and simplify the traceability of PCMNPs that are likely to be used by consumers. As a minimum, wherever possible, the following information should be given in such a way that it is visible and easily readable by consumers expecting to find it, on labels permanently attached to the product itself or (where that is impractical) on packaging in which the product is intended to be kept by the consumer:

a) name, address and contact details of the producer; and

b) identification data that can be used to trace the product back as precisely as is reasonably practicable or necessary to its date of manufacture, raw material supplier, and/or quality inspection checks; e.g. data such as commercial designation, model/version and (as appropriate) a production batch, serial number or date of manufacture.

It is recommended that where customer service departments exist in more than one country, the telephone numbers for all countries in which the product is likely to be sold and/or used are listed in accompanying documents or instructions for use, which should be prominently headed: "**IMPORTANT. KEEP FOR FUTURE REFERENCE**".

6 Content of labels for PCMNPs or MNPs for professional use

6.1 General

The labelling of products that are likely to be used only by professional users should meet the same user needs and follow the same information structure as required for consumer products, (particularly in respect of their ability to be identified and traced), but with allowance for the greater level of common knowledge of hazards, competence in skilled procedures, familiarity with generic terminology and ready access to appropriate handling equipment that may be presumed to be available to those professionals.

NOTE 1 Unlike consumers, professional users can be expected to possess and use the knowledge and skills appropriate to their profession when selecting and using specialist products, without direct supervision, but they may not have control over which products are purchased for use in their workplace. They may also be handling small quantities of a large range of types of products or substances for a variety of successive tasks.

Products that are intended for professional use, but which it is foreseen may also be used by consumers, should be labelled according to **5.2** and **5.3** and (if it is foreseen that they might be directly purchased by some consumers) also according to **5.4**.

NOTE 2 Although there is no umbrella legislation giving common information requirements for products that are not used by consumers, for every product sector there are likely to be some specific legal requirements, transportation rules or health and safety at work guidance to specify minimum information that is to appear on labels on each product, unit or container. Moreover, the General Product Safety Directive 2001/95 [2] (GPSD) [5] and Product Liability Directive 1985/374 [3] [6] specify that, producers owe a duty of care to foreseeable users of their products, whether they are consumers, professionals or employees without relevant expertise.

6.2 Information required for purchase

Product-specific information that a professional user might need should be available at the time a purchase decision is made. Depending on normal practice in the commercial sector, this may need to be provided on the product itself or its packaging, and/or full technical specifications of the product might be available through catalogues, web sites or other reference sources (e.g. formularies or standards) that are likely to be accessible to a professional user.

Specifications and/or promotional material should indicate whether product-specific training is recommended by the producer, and the availability of providers.

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2) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:011:0004:0017:en:pdf

3) http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1985/L/01985L0374-19990604-en.pdf

It is recommended that all PCMNPs sold for professional use should indicate the presence of MNPs in any technical specification available to potential purchasers and on any label listing ingredients, either in the form of the most appropriate of the examples listed in **8.1**, or in some more precise description likely to be understood by the intended professional user.

6.3 Information required for use (instructions for use)

It should be expected that individual units of products or substances for professional use might be handled and/or disposed of by non-specialists, and that any additional information the latter need when handling the unit or its packaging should be given in the labelling of the smallest unit in which the product or substance is provided to a professional user.

Products sold for professional use should be labelled so as to be precisely identifiable visually (without reference to any source other than the user's professional knowledge) in any form, units or packaging in which a professional user is likely to receive them (excluding outer packaging intended purely for shipping of goods to an identified recipient). For example, whilst a branded product name and model number on a component or a generic chemical name on the container of a substance might be sufficient for some professions, more detailed information might be needed for other professions. A bar-code alone would not enable the product to be identified correctly without access to code-reading equipment.

Products intended for professional use should be clearly labelled with unit-specific information. For substances this should include unit quantity, concentration and expiry dates. For products this should include a serial or batch number or production date.

Necessary additional instructions for use will vary with the profession, product or practice. It may be appropriate to assume a minimum professional competence when providing information on labels or instructions for use. In some cases it might be that product-specific training is required. In such cases, a warning of the need for specific training should appear on the labelling of the smallest unit in which the product or substance is provided to a professional user.

NOTE All instructions accompanying professional products should be tested with potential users to ensure they are easily understood.

6.4 Information required for use after purchase

The traceability information described in **5.4** a) and b) should be presented on a label permanently attached to the product itself or, where that is impractical, on packaging or accompanying documentation of the smallest unit in which the product is likely to be stored by a professional user. If space is limited on the label permanently attached to the product, priority should be given to retaining the batch number or date of manufacture.

7 Content of labels for PCMNPs or MNPs for business-to-business use

7.1 General

Labelling of MNPs and PCMNPs supplied by one business to another business under contract should be sufficient to ensure unambiguous identification by the intended recipient. The purchaser should be equipped and staffed to take responsibility for subsequent labelling for identification and safety purposes, and maintenance of production control systems from the point of receipt onwards.

7.2 Information required for purchase

It is recommended that for business-to-business supply of MNPs and PCMNPs, a technical specification or list of ingredients (made available to the purchaser before purchase) should be given, either in the form of the most appropriate of the examples listed in **8.1**, or in some more precise description likely to be understood by the intended professional user. Any contract or conditions of purchase (or a catalogue or promotional material where this is relied on as a specification of the goods) should either refer to this technical specification, or list of ingredients, or itself include a similar statement.

If the supplier considers that specific training of the purchaser's staff in handling and use of its products will be required in order for the purchaser to be able to take full responsibility for subsequent labelling of the MNPs or PCMNPs it handles or produces, this should be stated in the pre-sale documentation.

The contract, technical specification or other documentation should state how the containers, units or packaging of products are to be labelled so as to provide unambiguous identification by the intended recipient. Where agreed, this may be no more than a bar code (plus any labelling required for other legislative or health and safety purposes), provided the systems employed by both parties ensure batch control.

7.3 Information required for use (instructions for use)

Depending on normal practice in a sector or specific terms in a particular contract, products might or might not need to be labelled with information or instructions for use by staff in the recipient business.

7.4 Information required after sale

Both supplier and recipient should take responsibility for co-ordinating (and if appropriate, auditing) their systems for identification, labelling and record keeping so as to ensure maintenance of traceability from batches of the products output by the recipient back to batches of materials or components produced by the supplier.

8 Label statements

8.1 Examples of label statements

- Having regard to whether the label is addressing consumers or professional users, examples of general label statements relevant to MNPs and PCMNPs might include the following:
- Contains manufactured nanoparticles;
- This product contains manufactured nanoparticles;
- Contains manufactured nanoparticles of X [chemical substance];
- This product contains manufactured nanoparticles of X;
- Contains 0.1g nanoparticles of X;
- Contains a dispersion of manufactured nanoparticles of X in Y.
- Titanium dioxide, size range X nm – Y nm, specific surface area Z $m^2\ g^{-1}$.

8.2 Other specific information

Consideration should be given, where relevant, to the inclusion of other specific information about the MNPs such as:

- Whether free or not, i.e. whether bound in a solid matrix;
- Whether a mixture of MNPs (e.g. Contains nanoparticles of both TiO_2 and ZnO);
- Any special disposal requirements (e.g. “Return to…”, “Do not burn…”, “Do not flush into public waste water system”);
- The specific source of the MNPs (e.g. derived from clay);
- Description of the function(s) of MNPs (e.g. use of the material in nanoparticle form ensures more complete dissolution and hence faster assimilation);
- Packaging information (e.g. for safe opening);
- Date information regarding the MNPs (e.g. normal practice);
- If unstable under specific conditions (e.g. UV, friction);

9 Characterization and hazards

This guidance is not intended to assist in the characterization of specific MNPs (See PD 6699-1, *Nanotechnologies – Part 1: Good practice guide for specifying manufactured nanomaterials*). However, when labelling an item, it is relevant to consider hazards that might be associated with its particular characteristics and use. It is recommended that state-of-the-art life-cycle and risk-assessment methods, protocols and data should be applied to evaluate potential nanoscale-related hazards posed by the product in question.

Such life-cycle and risk-assessment should take into account the relevant peer-reviewed (eco)toxicological and relevant hazard related results, e.g. explosivity and inflammability.

For examples of MNP characteristics, see Annex D.

10 Form of labels

10.1 Label text

In addition to fulfilling mandatory requirements, labels provide a wide range of information, according to the product sector, including brand name, other brand related material, proprietary and instructional information.

Label statements about MNPs and PCMNPs should be easy to understand, clearly legible, conspicuous and indelible.

Where an ingredients list is included, it is recommended that those in MNP form are identified.

10.2 Negative labels

Where the use of negative labelling is considered (e.g. “this product does not contain manufactured nanoparticles”), care should be taken that it is accurate and verifiable and has regard to the Unfair Commercial Practices Directive [7]. Where a product produces a nano-enabled effect which does not result from the use of nanoparticles the label might state this.

11 Uncertainty and change

In view of the rapid developments in nanoscale technologies regarding the characterization and effects of MNPs, labels should not imply knowledge or properties for which there is limited or no scientific data available.

Users of this guidance will, as far as possible, need to keep abreast of the research in the areas of public and occupational health, safety and environment in respect of MNPs and PCMNPs when considering what is relevant for the purposes of labelling.

12 Links

Links to other bodies of possible relevance to the context of this guidance are given in Annex E.

Annex A (informative) Possible application areas for MNPs

MNPs are involved in an increasing number and range of applications, and may roughly be divided into the following categories:

- Agricultural;
- Construction;
- Business to business materials;
- Bearings and lubricants;
- Catalysts;
- Cleaning products;
- Coatings and surfaces;
- Cosmetics;
- Electronic components;
- Energy generation and storage;
- Environmental remediation and filtration;
- Fibre optics and lasers;
- Flame retardants;
- Food and drink ingredients;
- Food contact materials;
- Food supplements;
- Fragrances;
- Garden-care products (including insecticides, herbicides and fertilizers);
- General packaging materials;
- Home-care products (including cleaning, polishing and air fresheners);
- Imaging;
- Insulation materials;
- Lightweight materials and components;
- Magnetic fluids;
- Medical and healthcare;
- Printing;
- Personal care (including sunscreen, moisturizers, toothpaste, soaps)
- Recreational and sports;
- Security and defence;
- Sensors;
- Textiles and clothing;
- Tyres;
- Vehicle-care products;
- Veterinary products;
- Water purification and desalination.

NOTE Also see http://www.nanotechproject.org/44

Annex B (informative) Examples of MNPs, chemical substances and uses

This list of MNP chemical substances and uses is illustrative only and, as such is far from exhaustive, and new manufactured nanoparticle types can be introduced at any time.

- Metals, such as gold, titanium, iron, copper, aluminium, and silver, which can be used, for example, in catalysts, medical devices, and explosives;
- Metal oxides, such as titanium oxide, iron oxide, zinc oxide, aluminium oxide, etc., which can be used, for example, in polishing agents, coatings and cosmetics;
- Ceramics (nanocrystals, clays) such as talc, mica, vermiculite, which can be used in plastic drinks bottles, juice cartons and tennis balls;
- Forms of carbon such as fullerenes, nanotubes, and nano-fibres, some used in anti-static coatings, field emitters, electronic devices and tyres;
- Elemental or compound nanoparticles, for example silicon, and cadmium selenide, used in sols, colloids, nanowires, and quantum dots.

Annex C (informative) Possible activities for which labelling might be relevant

- Business-to-business transactions;
- Clean-up (spills);
- Collection for recycling;
- Consumer use;
- Disposal processing;
- Distribution and storage;
- Inspection and monitoring;
- Manufacturing waste (particulates);
- Nanoparticle application manufacture;
- Nanoparticle manufacture – intermediate (for specific applications);
- Nanoparticle manufacture – primary;
- Professional use;
- Raw material processing;
- Recycling;
- Research and development;
- Retail;
- Processing from re-use;
- Sample identification (e.g. laboratory).

Annex D (informative) Examples of MNP characteristics

- Agglomerate;
- Aggregate;
- Aspect ratio;
- Bio-reactive;
- Chemically bonded nanoparticles;
- Electrically charged;
- Explosive and inflammable;
- Free nanoparticles;
- Inorganic – metallic;
- Inorganic – non-metallic;
- Long-term persistent;
- Materials generating nanoparticles;
- Mobility in biological tissue;
- Mobility in environment;
- Mobility in fluids and gases;
- Multi-waandlled;
- Nanocrystals and quantum dots;
- Nanofibres;
- Nanofilms – by agglomeration;
- Nanofilms – not by agglomeration;
- Nanotube;
- Non-transient or stable;
- Optical properties;
- Organic;
- Organic-inorganic mix;
- Oxidative;
- Physically bonded nanoparticles;
- Polymeric;
- Self-assembling;
- Shape-specific properties;
- Single-walled;
- Size-specific properties;
- Specific quantum effects;
- Surface area: volume ratio;
- Toxic or non-toxic;
- Transient or unstable;
- Variable shape;
- Variable size.

Annex E (informative) Other bodies relevant to labelling

Community Health & Consumer Protection Directorate (EC)

http://ec.europa.eu/dgs/health_consumer/index_en.htm

Environmental Protection Agency

http://www.epa.gov/

Food and Drug Administration (FDA)

http://www.nanotechia.co.uk/news/global/fda-nanotechnology-task-force-sees-no-need-for-gen

For the original report see:

http://www.fda.gov/nanotechnology/taskforce/report2007.pdf

Health & Safety Executive

www.hse.gov.uk

International Council on Nanotechnology (ICON)

http://icon.rice.edu/

Institute of Occupational Medicine (UK)

http://www.iom-world.org

International Risk Governance Council

www.irgc.org

International Organization for Standardization

http://www.iso.org/iso/home.htm

Nanotechnology Industries Association

http://www.nanotechia.co.uk/

National Institute for Occupational Safety & Health (USA)

http://www.cdc.gov/niosh/topics/nanotech/strat_planINTRO.html

Trading Standards (UK)

http://www.tradingstandards.gov.uk/index.cfm

Bibliography

Standards publications

PAS 136, *Terminology for nanomaterials*

PD 6699-1, *Nanotechnologies – Part 1: Good practice guide for specifying manufactured nanomaterials*

PD 6699-2, *Nanotechnologies – Part 2: Guide to safe handling and disposal of manufactured nanomaterials*

BS EN 62079:2001, *Preparation of instructions – Structuring, content and presentation*

Other publications

[1] Woodrow Wilson International Center for Scholars, Washington, DC. *A Nanotechnology Consumer Products Inventory*, 2007.
See
http://www.nanotechproject.org/44]

[2] The Royal Society and the Royal Academy of Engineering (2004). *Nanoscience and nanotechnologies: opportunities and uncertainties*, p. 73.
See
http://www.nanotec.org.uk/finalReport.htm.

[3] European Commission, Communication on the Precautionary Principle 2 February 2000 – COM (2000) 1 final.

[4] European Commission, DG Research and the Woodrow Wilson International Center for Scholars (2007). *Proceedings of the Workshop on Nanotechnology and Life Cycle Assessment*.
See
ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/lca_nanotechnology_workshopoct2006_proceedings_en.pdf

[5] General Product Safety Directive (GPSD). Directive 2001/95/EC of the European Parliament and of the Council of 3rd December 2001 on General Product Safety: OJ L 11, 15.1.2002, p.4-17.
See
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:011:0004:0017:en:pdf

[6] Product Liability Directive. Council Directive of 25th July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products: OJ L 210, 7.8.1985, p.29.
See
http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1985/L/01985L0374-19990604-en.pdf

[7] Unfair Commercial Practices Directive. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC, and Regulation 2006/2004 of the European Parliament and of the Council.
See
http://eur-lex.europa.eu/LexUriServ.do?uri=OJ:L:2005:149:0022:0039:EN:PDF

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