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TITANIUM DIOXIDE MANUFACTURERS ASSOCIATION
for a brighter future

Titanium Dioxide Manufacturers Association: Q&A on Titanium Dioxyde (TiO_2)

What is Titanium Dioxide (TiO_2)?

Titanium dioxide is a naturally occurring mineral which is used widely for the unique way it interacts with light. Because it is bright and naturally opaque it is used as a pigment to colour things white. It also is used to brighten other colours, and to reflect UV rays.

Are there different types of TiO_2?

Titanium dioxide occurs naturally in the pure phase as the minerals rutile and anatase although it is most commonly found combined with iron in the black mineral ilmenite, which is processed industrially into the form of a bright white powder – TiO_2. Despite having different names, like titanium white and E171, most titanium dioxide has the same properties.

Most TiO_2 comes in the form of larger particles used in pigments. In some applications titanium dioxide is made into a very fine powder, which no longer gives products a white colour. One example of this is the use of titanium dioxide in sunscreens, where it is used for its unique ability to reflect UV-rays.

Where is TiO_2 produced in Europe?

Titanium dioxide is produced in facilities around Europe, including in Belgium, Czech Republic, Finland, Germany, Italy, Norway, Poland, Slovenia, Spain and the UK.

In which kinds of products do you find TiO_2?

Titanium dioxide is used most commonly as a pigment. It is used in paint, plastics and paper as well as in inks fabrics and textiles. It is also used in sunscreens and as a food colouring material. Many of the things around you are given their white colour and opacity by titanium dioxide.

Why is TiO_2 used in these products?

Titanium dioxide is used because of the properties which give it its bright white colour. This colour, and the way it improves the opacity of products, give it a wide variety of applications in industrial and consumer goods. Because it is safe, it can be used as a food colourant, and because it absorbs UV light it is used in sunscreens to protect your skin from the sun. For most of these applications, it cannot easily be substituted, and often the alternatives offer both poorer quality and health and environment performance.

Is TiO_2 safe?

Titanium Dioxide is safe in all of the applications in which it is used. Titanium dioxide normally is found in particles which are big enough to scatter light, and so be used as pigments. These particles are too large to be absorbed into the body.

Does TiO_2 cause cancer?

Titanium dioxide has been commercially available since 1916, and since then there has been no evidence of it causing cancer in humans. Recent studies of workers in the TiO_2 manufacturing industry, and therefore those most likely to be exposed to the substance, have found no evidence of an increased risk of lung problems. The International Agency for

Research on Cancer (IARC) has suggested titanium dioxide is “possibly carcinogenic to humans” (Group 2B), but the key animal study suggesting a risk to human health was conducted in a single species, the rat, with tumours observed only at an exposure level many times higher than ever encountered by workers or consumers on a daily basis. However, it is generally recognised that this is due to rats suffering from something called “lung overload” which is not observed in other species such as hamsters, mice or indeed humans.

How is TiO_2 regulated in Europe?

In Europe a number of bodies ensure that the substances available to the public are safe in the applications in which they are used. Aside from national bodies, the European Union’s REACH legislation sets up a framework to monitor the chemicals we use to ensure their safety. Industry has registered the substance under this legislation and has a duty to ensure any risks from the substance are managed. The European Food Safety Authority (EFSA) examines the substances in our foods, including titanium dioxide, and gives each additive an ‘E-number’. For TiO_2 that number is E171.

Should workers be worried about their exposure to TiO_2?

The current evidence indicates that workers should not be concerned. Four large epidemiology studies in North America and Europe, involving more than 24,000 workers in the titanium dioxide manufacturing industry, indicated no association with increased risk of cancer or with any other adverse effects from exposure to TiO_2.

What is the EU’s classification and labelling process?

The EU classification and labelling process is an ongoing regulatory regime that seeks to harmonise the classification of substances on the basis of their hazard properties and provide labels that allow the safe handling and use of the substances. This process only looks at the inherent properties of the substance, based on available scientific data, to establish hazard classifications. It is not intended to assess whether a substance poses an actual risk to humans in its current applications and uses. Over 200 substances have already undergone this process.

Why is the EU seeking to classify TiO_2 as cancer causing?

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has proposed to classify TiO_2 as a Carcinogen, based on studies in which rats have been made to inhale exceptionally high concentrations of poorly soluble dusts, not just TiO_2. Because rats react in a unique way to dust inhalation, the effects of such studies have been scientifically demonstrated not to be relevant to humans. This proposal is being evaluated by the scientific bodies of the European Union. Based on this evaluation, the European Commission will assess whether it is relevant to take any additional measure to address the safety of the substance.

What effect would a classification have on the marketing and use of TiO_2?

A classification of TiO_2 would require all manufacturers to label TiO_2 in the same way. It would also mean additional controls on the exposure of the substance to workers, and potential further assessment regarding its use in specific applications.

What are the next steps in the classification process?

Today, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) has reached an opinion according to which titanium dioxide should be classified as a

carcinogen 2. The European Commission will now evaluate the opinion and decide what, if any, regulatory measures will be taken. If a proposal for classification is adopted, the classification will mean a number of changes in the way users of titanium dioxide handle and use the substance, and the labelling information for titanium dioxide will change as such and in mixtures containing above 1% / 0.1%. For certain end uses, it may also lead to a regulatory re-evaluation of the use of the substance in these products.

Is TiO_2 safe for the environment?

TiO_2 is a natural inorganic compound, insoluble in water, which has been evaluated as being not persistent nor bioaccumulative or toxic pollutant in the environment or the food chain.

Is TiO_2 safe for workers?

TiO_2, its formulations and articles are used by millions of workers; by way of example, 1 million workers apply paints and coatings and 4.5 million workers are involved in the use of plastics. When it comes to long-term exposure, extensive epidemiological studies on more than 24,000 titanium dioxide workers exposed over several decades have shown no indication of any forms of cancer arising from exposure to titanium dioxide.

What are nanomaterials?

According to the European Commission nanomaterials are usually considered to be materials with at least one external dimension that measures 100 nanometers or less or with internal structures measuring 100 nm or less. They may be in the form of particles, tubes, rods or fibres.

How are nanomaterials regulated?

Nanomaterials are regulated at a European level, as all other forms of chemicals, under the REACH Regulation and the Classification and Labelling Regulation, which sets up a framework to ensure the safe management of chemicals placed on the European market. This includes the submission of safety data by industry and where necessary regulatory measures to reduce any risks arising from the production and use of substances.

Which applications of TiO_2 contain nanomaterials?

The most commonly used form of TiO_2 is pigmentary, used in the vast majority of consumer applications, which is not a nanomaterial as otherwise it would not scatter visible light effectively and make things white. Nano-scale TiO_2, due to its transparency and UV absorbing properties, is used in certain applications such as sunscreens where it provides additional protection against the sun's rays. It is also used in certain combustion processes (boilers, power plants and diesel engine) as a catalyst, where it helps convert harmful emissions of nitrogen oxide into harmless water and nitrogen.

How does the industry ensure the safety of nano-scale TiO_2?

Industry is committed to managing any risks from its products as part of its commitment to product stewardship and in compliance with regulatory processes such as REACH, the European chemicals legislation. This is true for both pigmentary and nano-TiO_2. In addition, it has initiated and sponsored research into the safety of nanomaterials and nano-enabled products. Significant progress has been made in test methods, data collection and assessments to evaluate any potential risks of nanomaterials in common applications.

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What is the industry's position on the regulation of nano-scale TiO_2?

We believe that nanomaterials are similar to other chemicals/substances in that each substance should be assessed on its own merits. Evaluation should be on a case-by-case basis using existing regulation, such as REACH and the Classification and Labelling Regulation, and is sufficient to ensure the safety of workers, consumers and the environment. Our assessment, as outlined in the REACH dossier, leads to a "no classification" for the substance, both in its pigmentary and nano-forms.

Is nano-TiO_2 used in food?

TiO_2's unique properties ensure food products are consistent in their colour, opacity and texture. It is a premium solution to satisfy food manufacturers and consumers' demands for quality and affordable food products. Particles of TiO_2 manufactured for food use are strictly controlled when it comes to the distribution of particle size: this is essential to ensure that the pigments will be consistent in their colour, opacity and texture. Nano-sized particles cannot be used to achieve this objective, as they are transparent.

Is TiO_2 safe for use in food?

TiO_2 has been safely used in food for more than half a century. EU authorities apply stringent conditions of purity to ensure that it does not interact with other components in your food and is safe to be ingested. Pigmentary TiO_2 that meets the requisite EU purity standards is permitted for use in foods as colourant and is referred to as E171. TiO_2 nanomaterials are not used as a food colourant because they are transparent.

The European Food Safety Agency (EFSA) completed in 2016 its re-evaluation of all colours permitted for use in food in the European Union. For titanium dioxide, EFSA concluded there is no indication of health concerns for consumers.

Is nano-TiO_2 safe for use in cosmetics?

TiO_2 in cosmetics can be used in nano and in non-nano forms. In non-nanoforms, it is used to achieve whiteness, colour, opacity or brilliance to the product. In nano-form, it is an important active ingredient for sunscreen products. Nano-sized titanium dioxide, which is different and much smaller than pigmentary products of TiO_2 in order to be transparent not white on the skin, not only manages to reflect incoming UV rays in a much more efficient manner, but it is also more stable than organic chemical UV filters, so you don't have to reapply the sun cream as often. There is no evidence to suggest that nano-titanium dioxide would be harmful to the skin.