

Eka Chemicals position regarding colloidal silica and nanoparticles

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Summary

Colloidal silica is an old technology while modern "nano" colloidal silica products are engineered to have specific properties. In addition to long experience of colloidal silica Eka Chemicals has made several studies with modern colloidal silica products, which have confirmed that these materials are not dangerous to health when inhaled. We have further approached other producers of similar products to come to a shared testing program in line with the REACH legislation, which has now come into effect. The absence of any reported adverse effects of colloidal silica over several decades support our conclusion that colloidal silica can be used safely in applications recommended by Eka Chemicals.

Although we believe that the existing risk assessment methods in principle provides a suitable framework for the assessment of nanomaterials currently produced by Eka Chemicals, we recognize that new approaches and methods may need to be developed to assess and control the potential risks of newly emerging technologies.

Colloidal silica meets the size definition for nanoparticles and is manufactured using technology based on chemical understanding and techniques that date back to the early 1950s. So, this particular nano-technology has been with us for many decades. Engineering improvements now allow us much better control over the manufacturing process and thus much better size and density control. Chemical innovations over time now allow us to devise and manufacture surface-modified colloidal silicas that meet specialized customer requirements. Overall, this is an old technology which has been engineered and improved to produce modern more specified products. – different from old with respect to certain technical aspects, but, not different from before with respect to the existence of smaller particles and thereby increased risk for toxicological hazards.

Modern "nano" colloidal silica products are engineered to have specific properties and represent the continuation of decades of development. Colloidal silica products have been widely used in a variety of industries for decades without evidence of hazard, as described below. The colloidal silica products in the nanoparticle size range have a much longer history of safe widespread use than recently invented nanomaterials such as carbon nanotubes or quantum dots.

Eka Chemicals has made several acute inhalation toxicity studiesⁱ with modern colloidal silicas, which have confirmed that these materials are not dangerous to health when inhaled.

The studies were done according to standard EU / OECD protocol under quality assurance according to GLP. Testing conditions were carefully chosen to ensure that the material would get deeply into the lungs by delivery as a respirable liquid aerosol (mean droplet size less than 3 micrometer). Steps were taken to prevent, that the silica nanoparticles would form larger-than-nanosize aggregates.

Under these conditions, the acute LC50¹ of the four tested colloidal varieties were all higher than 5000 mg/m³ (dry silica weight). This means that these materials are not considered to be dangerous to health by inhalation according to world-wide accepted standards and can be used without restrictions.

¹ LC 50 is the concentration in air at which 50% of test animals die either during the test or during a 14-day recovery data. In fact, the LC50 could not be established since no animals died in three out of four tests (CC30, i.e. surface-modified silica) , and only 2 out of 10 animals in the fourth (conventional colloidal silica)

The acute tests described above represent a worst-case scenario; Eka is confident that under normal conditions of use recommended by Eka, the aerosol droplet size will never reach such small dimensions and that the concentration in air will be orders of magnitude lower than used here. Therefore, it is the opinion of Eka Chemicals that the use of our colloidal silica products in any application we recommend is safe.

Skin exposure to colloidal silica may also occur during downstream use and in household applications. At present, there is no indication that nano-sized particles penetrate the skin. Data from the cosmetics industry show that nanoparticles used in e.g. sun blocking creams do collect in the deeper structures of the skin, but do not penetrate. It seems reasonable to assume that the negatively charged, highly hydrophilic colloidal silica particles will also not penetrate the skin.

In the paper industry, exposure to colloidal silica based nanoparticles is limited to its use on the paper machine. As once dried, colloidal silica will not be present as nano particles in the final article. Therefore exposure to nanoparticle of colloidal silica is limited to site operations which are well controlled through good manufacturing practices and industrial hygiene measures.

Eka Chemicals has approached other producers of similar materials to share experiences and come to a shared testing program in line with the REACH legislation which has now come into effect. We expect to be able to announce a testing program in the next few months which will be based on existing practices such as the Dupont and Environmental Nano Risk Framework or the CEFIC LRI research project on a tiered approach to testing and assessment of nanomaterial safety to human health.

The absence of any reported adverse effects of colloidal silica over several decades and recent tests support our conclusion that colloidal silica, including nanosized particles can be used safely in applications recommended by Eka Chemicals. Eka Chemicals is currently not supplier of other nano-particle compounds than silica.

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ⁱ RCC Study Number B13195
Bindzil CC30 Standard: 4-Hour Acute Inhalation Toxicity Study in Rats

RCC Study Number B13230
Bindzil 30/360: 4-Hour Acute Inhalation Toxicity Study in rats

Study Number B13206
Bindzil CC30 Methanol free: 4-Hour Acute Inhalation Toxicity Study in Rats

RCC Study Number B13217
Bindzil CC30 Ethanol-Based: 4-Hour Acute Inhalation Toxicity Study in Rats

STUDY NUMBER B13230
Bindzil 30/360:4-Hour Acute Inhalation Toxicity Study in Rats,
2nd AMENDMENT TO REPORT: histopathology