



May 17, 2016

David Michaels
Assistant Secretary of Labor for Occupational Safety and Health
U.S. Occupational Safety & Health Administration
200 Constitution Avenue, NW
Washington, D.C. 20210

Dear Assistant Secretary Michaels:

We are writing to alert the U.S. Occupational Safety and Health Administration about the use of potentially dangerous engineered nanomaterials in baby formulas sold throughout the United States and the potential impact for workers exposed to these materials. Friends of the Earth commissioned an independent laboratory analysis with a world-class nanotechnology research facility at the Arizona State University (ASU) to test for the presence of engineered nanomaterials in popular baby formulas. Researchers tested a selection of six baby formula samples gathered from retailers in the San Francisco Bay Area: Gerber® Good Start® Gentle, Gerber® Good Start® Soothe, Enfamil™, Similac® Advance® OptiGRO™ (liquid), Similac® Advance® OptiGRO™ (powder), Well Beginnings™ Advantage®. Please see the attached Friends of the Earth report and laboratory analysis summary document for additional details.

We found nano-sized structures and particles of potential concern in all six of the baby formulas tested. These include: nano-hydroxyapatite (nano HA) in needle-like and non needle-like form, nano titanium dioxide (TiO₂), and nano silicon dioxide (SiO₂) (the nano TiO₂ and SiO₂ results were inconclusive).

Recent studies have found that these nanomaterials may pose risks to human health if ingested or inhaled. Especially concerning: the nanomaterials found in the three powdered formulas we tested provide a probable inhalation hazard for babies, parents and other care givers, as well as workers involved in the manufacturing or disposal of these products.

In the food sector, workers may come into contact with nanomaterials during production, packaging, transport and waste disposal of food, food packaging and agrochemicals (European Food Safety Authority (EFSA), 2009). In the absence of a mandatory worker notification, product labeling, or registration for nanomaterial use, many workers may be unaware that they are handling nanomaterials or that they may need to use protective equipment. Additionally, it is not currently clear in the literature if existing Personal Protective Equipment (PPE) can protect individuals from nanoscale particles.

To date, there is very little data relating to the exposure of workers to nanomaterials. A number of nanomaterials used in the food industry, such as nano zinc oxide and nano titanium dioxide, have been shown to be harmful when inhaled, raising occupational health and safety concerns for workers handling these materials. Your agency has cautioned, "...certain inhaled nanoparticles may be deposited in the respiratory tract and may cause inflammation and damage to lung cells and tissues" (OSHA, 2013). OSHA has furthermore stated that nanoscale titanium dioxide (TiO₂) particles have higher mass-based potency than larger particles and that occupational

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exposure (by inhalation) to nanoscale TiO₂ particles is considered a potential occupational carcinogen (OSHA, 2013). Studies have also shown that nanomaterials can enter the bloodstream via the lungs, raising major occupational health and safety concerns (Oberdörster et al., 2005).

The European Union Scientific Committee on Consumer Safety (SCCS) finds that nano-hydroxyapatite in needle form — one of the nanomaterials we found in Gerber®, Well Beginnings™, and Enfamil™ formulas — is potentially toxic, could be absorbed by and enter cells, and should not be used in cosmetics such as toothpaste, teeth whiteners and mouth washes. A material that should not be used in cosmetics raises greater concern when used in food especially for workers handling these materials in raw form.

Nano-hydroxyapatite: Potential uses in baby formula

Nano-hydroxyapatite is most likely a calcium source for these baby formulas or is potentially used as an abrasive or stabilizer. Conventional hydroxyapatite is used as a calcium source for supplements and is derived from the bones of cows. Hydroxyapatite forms 70 percent of our bones (International Osteoporosis Foundation, 2015). Through nanotechnology, hydroxyapatite can now be manufactured into needle-like nanoparticles to take advantage of properties at the nanoscale. Nano HA is described in scientific literature as a novel ingredient used experimentally for rebuilding bones in surgery and to repair tooth enamel (Huber et al., 2006; McArthur et al., 2013; Tschoppe et al., 2011). Toothpaste containing nano HA can be purchased in the United States, many brands and dozens of products are available for purchase online (Amazon, 2015). Friends of the Earth did not find any description of nano HA use in baby formula, however, some manufacturers list a food use for this ingredient among other advertised applications (Del Nanbio Technology GMBH, 2015).

Nano hydroxyapatite: Health concerns

In October of 2015, the European Union Scientific Committee on Consumer Safety (SCCS) provided evidence that needle-like nano-hydroxyapatite is potentially toxic could be absorbed and enter cells and should not be used in cosmetics such as toothpaste, teeth whiteners and mouth washes (EU SCCS, 2014; EU SCCS, 2015). The SCCS opinion states: “The available information indicates that nano-hydroxyapatite in needle form is of concern in relation to potential toxicity. Therefore, needle-shaped nano-hydroxyapatite should not be used in cosmetic products.”

Some chemical company material safety data sheets (MSDS) list hydroxyapatite as an inhalation hazard and cite the lack of data available to provide a complete safety profile (Sigma-Aldrich, 2008; Merz NA, Inc., 2015). Other similarly shaped needle-like nanoparticles have been shown to have the potential to cause diseases in the lungs similar to those caused by inhalation exposure to asbestos, including mesothelioma and lung cancer (Poland et al., 2008; Jacobs, 2014; HHS et al., 2013). Additionally, a 2014 study found that both nano HA and nano titanium dioxide (TiO₂) increased reactive oxygen species (ROS) and inflammation in cells (Tay et al., 2014).

We therefore urge OSHA to:

- Adopt nano-specific regulations to protect workers from and inform them of potential exposure
- Prioritize research on occupational exposure and personal protective devices in the workplace



We look forward to working with you on addressing this issue. Thank you for your attention to this matter and for considering our request.

Respectfully submitted,

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Attachments:

- **Summary of test results**
- **Friends of the Earth report: “Nanoparticles in Baby Formula: Tiny new ingredients are a big concern”**
- **Laboratory analysis**