



May 17, 2016

Robert M. Califf
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We are writing to alert the Food and Drug Administration about the use of potentially dangerous engineered nanomaterials in baby formulas sold throughout the United States. 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 of these products.

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.

Nanoparticles found in popular baby formulas tested by Friends of the Earth

Baby Formula Brand	Nanoparticles Found
Gerber® Good Start® Gentle	Nano-hydroxyapatite (nano HA)
Gerber® Good Start® Soothe	Titanium dioxide and silicon dioxide (limited amount of particles detected)
Enfamil™	Nano-hydroxyapatite (nano HA) in needle-like and non needle-like form
Similac® Advance® OptiGRO™ (liquid)	Titanium dioxide (nano TiO2 laboratory

	results inconclusive)
Similac® Advance® OptiGRO™ (powder)	Nano silicon dioxide (laboratory results inconclusive)
Well Beginnings™ Advantage®	Nano-hydroxyapatite (nano HA)

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 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).

The Food and Drug Administration is charged with ensuring the safety of the U.S. food supply, however, your agency does not screen for or ensure the safety of these novel nanomaterials in baby formulas and other food products. Baby formulas are intended for our most vulnerable population and should be regulated with the utmost of care. A product fed to millions of infants should not be permitted to go to market if we are not certain that the ingredients it contains are safe for human consumption. All infant formulas should be thoroughly tested for safety.

We therefore urge the FDA to:

Assess the safety of and recall baby formulas with nanoparticle ingredients



Friends of the Earth recommends that the FDA conduct a thorough review of the nanoparticle ingredients found in baby formulas. The agency must, in the meantime, use its authority to enforce a manufacturer recall of baby formulas containing engineered nanoparticles as these ingredients may put human health at risk.

Regulate nanomaterials as new substances

All deliberately manufactured nanomaterials must be subject to rigorous nano-specific health and environmental impact assessment and must be demonstrated to be safe prior to approval for commercial use in foods, food packaging, food contact materials, agricultural applications or other consumer products.

Ensure transparency in safety assessment and product labeling

- All relevant data related to safety assessments and the methodologies used to obtain them must be placed in the public domain.
- All manufactured nano-ingredients must be clearly indicated on product labels to allow members of the public to make an informed choice about product use.
- The presence of nanomaterials must be disclosed to workers and other downstream users along the supply chain.
- Public involvement in decision-making is required.

Enact a moratorium on new commercial nanotech products

Government regulators should deny products produced with nanomaterials access to the market until they determine how to properly assess and manage them to protect human health and the environment.

We furthermore request an in-person meeting with your staff. 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**