

May 17, 2016

Miles D. White Chairman and Chief Executive Officer, Abbott Abbott Laboratories, U.S. Corporate Headquarters 100 Abbott Park Road Abbott Park, Illinois 60064-3500

Dear Mr. White,

We are writing to alert your company about the potentially hazardous engineered nanomaterials (engineered particles which are less than 500 nanometers in size) contained in your baby formula products sold in 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. ASU 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<sup>TM</sup>, Similac® Advance® OptiGRO<sup>TM</sup> (liquid), Similac® Advance® OptiGRO<sup>TM</sup> (powder), Well Beginnings TM Advantage®. Please see the attached Friends of the Earth report and laboratory analysis summary document for additional details. We hope to work with your company to address this situation as quickly as possible.

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 though likely).

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.

A growing body of science indicates that engineered nanomaterials pose risks to the health of consumers and the environment. These ingredients are already making their way into the food supply in absence of mandatory safety assessment, oversight or labeling. Consumers are increasingly concerned and are beginning to ask if they can purchase food and products they can trust to be free of engineered nanomaterials.

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 <sup>TM</sup>	Nano-hydroxyapatite (nano HA) in needle-
	like and non needle-like form



Similac® Advance® OptiGROTM (liquid)	Titanium dioxide (nano TiO2 laboratory
	results inconclusive)
Similac® Advance® OptiGRO <sup>TM</sup> (powder)	Nano silicon dioxide (laboratory results
	inconclusive)
Well Beginnings TM Advantage®	Nano-hydroxyapatite (nano HA)

# Nano hydroxyapatite

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." A material that should not be used in cosmetics raises greater concern when used in food.

Some chemical company material safety data sheets (MSDS) list hydroxyapatite as an inhalation hazard and note that there is currently insufficient data 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).

Friends of the Earth and our ally organizations are urging all companies using nanomaterials in their baby formulas to:

## Recall all formula containing nanomaterials

Manufacturers should remove all baby formulas containing nanoparticles from store shelves until the safety of these ingredients can be substantiated and appropriately regulated by the FDA.

## Remove all nanomaterials from product formulas

All baby formula and food manufacturers should review the ingredients contained in their products to ensure that they are free from manufactured nanomaterials; this may involve inquiries with third party ingredient suppliers.

## Create nanomaterial policies

- Companies should create clear policies to avoid the use of engineered nanomaterials in their products until nanotechnology-specific regulation is put in place to protect the public, workers and the environment from potential new hazards associated with nano-toxicity.
- Manufacturers should refer to the *Nanomaterials Policy Recommendations* published by a coalition of domestic and international advocacy groups, including Friends of the Earth, to help inform companies and consumers about the potential risks of nanomaterials (As You Sow et al., 2015). Please also refer to our guidance document published in 2007 called *Principles for the*



<u>Oversight of Nanotechnologies and Nanomaterials</u> (more than 70 groups from six continents have endorsed these principles).

Ensure transparency in the supply chain

- If companies continue to use nano-ingredients, they must be clearly indicated on product labels, allowing members of the public to make informed choices about product use.
- Companies producing baby formulas containing nanomaterials must create a registry of potential side effects as reported by consumers (parents of babies consuming these products). This should be modeled after the registries that pharmaceutical companies are required to create which both receive reports of side effects of new products and incorporate this information into required consumer education inserts at point of sale.

Our previous correspondence requesting your company's policy on the use of engineered nanomaterials in infant formula is attached for your reference.

Please do not hesitate to contact us at 510-900-3145 or <u>larcher@foe.org</u> to discuss this important issue or to arrange a meeting. We look forward to hearing from you soon on this issue of vital importance to your customers and the general public.

Respectfully submitted,

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Please send responses to: Ian Illuminato, Friends of the Earth, 2150 Allston Way Suite 360 Berkeley, California 94704, iilluminato@foe.org, +1 510-900-3145.

### **References:**

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## **Attachments:**

- Letter requesting company policy on nanomaterials dated April 12, 2016
- Summary of test results
- Friends of the Earth report: "Nanoparticles in Baby Formula: Tiny new ingredients are a big concern"
- Laboratory analysis