Risky nanoparticles found in baby formula:

Backgrounder

17 March 2016

Summary of findings and concerns

- Independent testing[1] commissioned by Friends of the Earth US on six samples of baby formula available online in Australia has found intentionally produced nanoparticles.
- Four of the samples contained nano hydroxyapatite, including three in asbestos-like needle form.[2] The European Union Scientific Committee on Consumer Safety (SCCS) has argued that this form of nano hydroxyapatite - found in the Gerber®, Well Beginnings™, and Enfamil® formulas - is potentially toxic and should not be used in toothpaste.[3]
- The testing also suggested that two samples were likely to contain nano titanium dioxide and one was likely to contain nano silica.
- None of these nano-scale ingredients have been tested to ensure they are safe for use in baby foods or are labelled, either in the US or Australia.
- All of these nanoparticles raise health concerns.
- The failure of our food regulator Food Standards Australia New Zealand (FSANZ) to ensure pre-market safety testing breaches policy guidelines set by Food Regulation Ministerial Council and unnecessarily puts babies at risk.
- Friends of the Earth is calling for an urgent recall of any baby formula containing nanoparticles until safety testing is undertaken.

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

Baby Formula Brand	Nanoparticles Found
Gerber® Good Start® Gentle	Nano hydroxyapatite (nano HA) – needle-like form found in dry formula not liquid
Gerber® Good Start® Soothe	Nano titanium dioxide and silica (likely) Nano hydroxyapatite needle-like form found in dry formula not liquid
Enfamil™	Nano hydroxyapatite (nano HA) in needle-like and non needle-like form
Similac® Advance® OptiGRO™ (liquid)	Nano titanium dioxide (likely)
Similac® Advance® OptiGRO™ (powder)	Nano silica (likely)
Well Beginnings ™ Advantage®	Nano-hydroxyapatite (nano HA)- needle-like form

Health Concerns

Nano hydroxyapatite

The most concerning of the nanoparticles found in the tested infant formulas is nano hydroxyapatite in needle-like form. The European Commission's Scientific Committee on Consumer Safety (SCCS) found that the needle-like form of nano hydroxyapatite is potentially toxic, could be absorbed by

cells, and should not be used in toothpaste, teeth whiteners and mouth washes.[4] A material that should not be used in cosmetics should certainly not be used in baby formula.
A recent safety assessment of nano hydroxyapatite suggests that there is a moderate risk of systemic toxicity associated with it, including genetic and immune system damage. Many risks could not be assessed due to insufficient data - including risks of endocrine disruption, developmental toxicity, reproductive toxicity and carcinogenicity. Therefore no finding of safety could be made.[5]

A precautionary approach to baby foods, which prevents the use of poorly tested and poorly understood ingredients in such foods, seems obvious. However, such a precautionary approach is not being taken either in the US or in Australia.

We believe that nano hydroxyapatite is being used in baby formula as a source of calcium.

Nano titanium dioxide

The European Chemical Agency (ECHA) is currently reviewing the use of nano titanium dioxide because of concerns it may be harmful to the environment and human health.[6] Nano titanium dioxide is highly mobile in the body and has been detected in both humans and animals in the blood, liver and spleen. Studies show that nano titanium dioxide can damage DNA, disrupt the function of cells, interfere with the defence activities of immune cells and - by adsorbing fragments of bacteria and 'smuggling' them across the gastro-intestinal tract - can provoke inflammation.[7]

Nano titanium dioxide is added to baby formula as a whitener or brightener. It has no nutritional value.

Nano silica

Several studies have shown that nano-silica can cause liver toxicity. Recently, the European Commission's Scientific Committee on Consumer Safety (SCCS) reviewed data relating to the use of nano silica in cosmetics and found there was insufficient data to deem nano silica safe.[8] Nano silica is also currently being reviewed by the EU to determine if there are health concerns associated with its use in food.

Nano silica is generally added to foods as an anti-caking agent. It has no nutritional value.

Nanoparticles generally pose new risks because:

- They can be more chemically reactive and more bioactive than larger particles of the same chemicals. Due to their very small size, nanoparticles have been demonstrated to be more likely than larger particles to enter cells, tissues and organs.
- Greater bioavailability and greater bioactivity may introduce new toxicity risks.
- The safety of nanoparticles cannot be inferred from the safety of larger particles of the same chemical.

Regulatory Failure

FSANZ has failed to adhere to the Food Regulation Ministerial Council's policy for ensuring the safety of infant formula

The policy recognises that children are particularly vulnerable:

> *"because they have immature immune systems and organs…For some infants, infant formula products may be the sole or principal source of nutrition. For these reasons, there is a greater level of risk to be managed compared to other populations."*[9]

As a result of this higher level of risk, the policy sets out pre-market safety assessment requirements that clearly capture the use of nanoparticles in baby formula:

> *Pre-market assessment…should be required for any substance proposed to be used in infant formula and follow-on formula that: i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or ii. has a history of safe use in these products in Australia and New Zealand,* ***but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology****.*[10]

Further, the Food Code prohibits the use of nutritive and novel substances in food unless they are expressly permitted. No nano forms of calcium, titanium dioxide or silica have been authorised for use in Australia.[11]

FSANZ cannot simply declare these foods safe. The agency has no scientific basis for doing so. Although the United States Food and Drug Administration has failed to date to regulate the use of nanoparticles in food, they have acknowledged that they "are not aware of any food ingredient...on the nanometer scale for which there are generally available data sufficient to determine that the ingredient is Generally Recognized As Safe".[12]

FSANZ is failing to monitor, test or regulate nanoparticles in food

In 2015 Friends of the Earth commissioned independent testing of a range of processed foods. All 14 samples were found to contain significant quantities of nanoparticles of titanium dioxide and silica.[13]These more recent test results reinforce our concern that our food is being flooded with risky nanoparticles. In response, the agency charged with ensuring the safety of our food - FSANZ - has simply asserted the safety of nanoparticles with no scientific basis and refused to act.

What is Friends of the Earth calling for?

Friends of the Earth is calling for an urgent recall of any baby formula containing nanoparticles until safety testing is undertaken.

Find out more

For more information contact: Jeremy Tager 0400 376 974; Jeremy.tager@foe.org.au

[1] The testing was conducted by the University of Arizona which is internationally known for its work in detection and measurement of nanoparticles

[2] Hydroxyapatite at conventional scale is a naturally occurring mineral in bone and it appears that hydroxyapatite is added to the infant formula to provide calcium.

[3] Scientific Committee on Consumer Safety (SCCS) (2016). *Opinion on Hydroxyapatite (nano)*. http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_191.pdf

[4] European Commission's Scientific Committee on Consumer Safety (SCCS) (2015, October 16).Opinion on Hydroxyapatite (nano). http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_191.pdf

[5] GreenScreen (2016) Assessment of hydroxyapatite (1306-6-5).

[6] ECHA (2013) Justification document for the selection of a CoRAP substance – Titanium Dioxide, http://echa.europa.eu/documents/10162/37e258fd-f57a-4957-b978-4f18fe593938

[7] Friends of the Earth (2015). Study raises more questions about the use of nanoparticles in food. http://emergingtech.foe.org.au/new-study-raises-further-questions-about-the-safety-of-nanoparticles-in-food/

[8] Scientific Committee on Consumer Safety (SCCS) (2015) Opinion on Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form). SCCS/1545/15.March 2015, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_175.pdf p. 46.

[9] Australia and New Zealand Food Regulation Ministerial Council, Food Regulation Standing Committee, Policy Guideline, Regulation of Infant Formula. http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Documents/Infant%20Formula%20May%202011.pdf

[11] Food Standards Australia New Zealand, Australia New Zealand Food Code, Standards 1.1.1 and 1.5.1. http://www.foodstandards.gov.au/code/Pages/default.aspx

[12] U.S. Food and Drug Administration (2014). Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives. Retrieved August 8, 2015 from U.S. Department of Health and Human Services: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm300661.htm

[13] Friends of the Earth (2016). Independent testing finds potentially harmful nanoparticles in common food products. http://emergingtech.foe.org.au/independent-testing-finds-potentially-harmful-nanoparticles-in-common-food-products/