

Illegal and potentially toxic nanoparticles found in popular Australian infant formula products



FSANZ must immediately recall affected products

Independent testing¹ commissioned by Friends of the Earth has found nanoparticles in popular Australian infant formula products that are both illegal in Australia and potentially dangerous.

Three of the seven samples tested contained nano-hydroxyapatite particles. These are prohibited from use in infant formula in Australia in any form.² Nano-hydroxyapatite has been found to cause cell death in the liver and kidneys of rats.³

Two of these samples, Nestlé NAN H.A. Gold 1 and Nature's Way Kids Smart 1, were found to contain a needle like form of hydroxyapatite. The European Commission's Scientific Committee on Consumer Safety (SCCS) has concluded that this form of nano-hydroxyapatite should not be permitted in oral products such as toothpaste and mouthwash because of its potential toxicity.⁴

Altogether 5 of the 7 samples were found to contain nanoparticles that are not approved for use in infant formula, and breach the Food Regulation Ministerial Council's policy for ensuring the safety of infant formula.⁵

Friends of the Earth are calling for an immediate recall of affected products.

The test results

Seven samples were sent to Arizona State University, one of the world's leading laboratories for the testing of nanomaterials.

Infant Formula Brand	Nanoparticles found by Arizona State University	Allowed in infant formula in Australia?
Nature's Way Kids Smart 1	Nano Hydroxyapatite Needle-like form	NO SCCS has concluded this is potentially toxic
	Nanoparticles containing silicon and oxygen - most likely nano-silica (100% of particles were nano)	NO SCCS has concluded there is insufficient data to establish safety. ⁶
Nestlé NAN H.A. Gold 1	Nano Hydroxyapatite Needle-like form	NO SCCS has concluded that this is potentially toxic. ⁷
Heinz Nurture Original 1	Nano Hydroxyapatite rectangular form	NO SCCS has concluded there is insufficient data to establish safety. ⁸
Aptamil Profutura 1	Calcite nanoparticles (approx. 20% of particles were nanoscale)	NO Larger particles of calcite are approved for use in infant formula but nano-calcite is untested and unregulated.
Blackmores Newborn Formula	Calcite nanoparticles (approx. 38% of particles were nanoscale)	NO Larger particles of calcite are approved for use in infant formula but nano-calcite is untested and unregulated.
Karicare Plus 1	No nanoparticles found	N/A
A2 Platinum 1	No nanoparticles found	N/A

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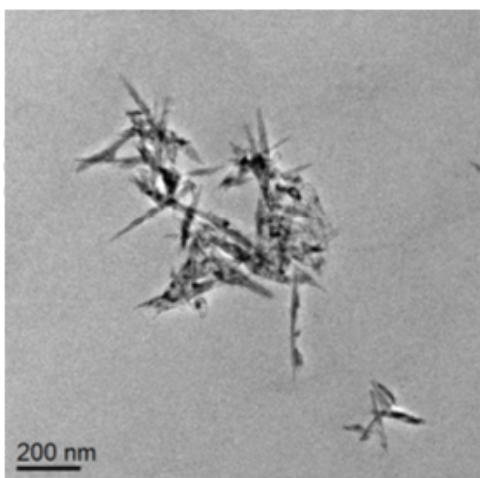


Fig. 1: Nano hydroxyapatite found in Nestlé NAN H.A. Gold 1 infant formula

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.

Nano-hydroxyapatite - Serious health concerns

No form of hydroxyapatite is permitted in infant formula in Australia. Virtually all food grade nano-hydroxyapatite is synthetically produced. Although nano-hydroxyapatite is present in bones, it does not occur naturally in milk. These test results confirm that the needle-like form of nano-hydroxyapatite was intentionally added to the infant formula. The European Commission's Scientific Committee on Consumer Safety (SCCS) has concluded that the needle-like form of nano-hydroxyapatite is potentially toxic and should not be permitted in oral products such as toothpaste and mouthwash.⁹ At the time the SCCS made that recommendation it wasn't aware that nano-hydroxyapatite was being used in infant formula.

The SCCS stated that “based on the available information, systemic effects or systemic uptake of orally administered nano-hydroxyapatite cannot be excluded.”¹⁰ The committee concluded that “if systemically available nano-hydroxyapatite will be distributed to the liver, kidneys and lungs.”¹¹ This is disturbing, given that nano-hydroxyapatite has been found to cause cell death in the liver and kidneys of rats.¹²

The SCCS raised concerns at how little data was available on nano-hydroxyapatite. Many potential risks could not be assessed due to insufficient data - including the risks of endocrine disruption, developmental toxicity, reproductive toxicity and carcinogenicity.¹³ In light of this the SCCS concluded that no conclusion of safety could be made.¹⁴ We emphasise this because FSANZ has a history of asserting the safety of nanomaterials based on an absence of evidence of harm - rather than evidence of safety.¹⁵

A 2014 study estimated that the amount of nano-hydroxyapatite entering the environment in 2013 from its use in toothpaste alone to be between 18 and 19 metric tonnes.¹⁶ This suggests the widespread use of nano-hydroxyapatite in consumer products - despite the lack of evidence of safety.

The SCCS did not directly consider the impacts on infants and children of consuming nano-hydroxyapatite in infant formula. However, given that they have recommended against their use in toothpaste because of the ingestion risk, they should clearly not be in use in infant formula.

Babies are at greater risk of suffering health effects from exposure to toxic nanoparticles because of their more vulnerable physiology. Babies' immune, central nervous, reproductive and digestive systems are still developing and exposure to toxicants can lead to irreversible damage. Nanoparticles are known to be more reactive, more likely to move through cells and tissue and to have greater bioavailability.

In light of these serious health concerns, and the fact that infant formula may be the only food an infant receives, Friends of the Earth is calling for FSANZ to immediately recall these brands.

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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.¹⁷ Nano-silica is also currently being reviewed by the EU to determine if there are health concerns associated with its use in food.

Nano-calcite

Calcite at a nanoscale has never been subject to a safety assessment or regulatory approval. It is infants and children consuming these untested materials. FSANZ needs to do significantly more to ensure companies using these nanoparticles can establish the safety of these particles, otherwise they should not be sold.

Regulatory failure

When testing commissioned by Friends of the Earth US last year revealed the presence of nano-hydroxyapatite, nano titanium and nano silica in infant formula, FoE Australia raised concerns that these products could be imported into Australia.¹⁸ In response, our food regulator Food Standards Australia New Zealand (FSANZ) stated that these substances are not permitted additives in infant formula and accused FoE of "causing unnecessary concern amongst caregivers."¹⁹ Friends of the Earth are not aware of the agency taking any action to ensure these ingredients are not being used in infant formula in Australia.

FSANZ often claims that nanomaterials occur naturally and incidentally in food, suggesting there is little or no intentional use of nanomaterials in food. However, both these test results and food testing results from 2015²⁰ clearly show that these are not naturally occurring particles and that FSANZ is deliberately misleading the public.

FSANZ also claims that there is no evidence that the use of nanomaterials in food is widespread.²¹ This claim is nonsense. In 2015 Friends of the Earth tested 14 processed food samples. Every one contained high levels of added - not naturally occurring - nanoparticles.²² Tests in France produced similar results²³ - all six products tested contained engineered nanoparticles. This testing of infant formula as well as similar testing in the United States in 2016 all directly contradict FSANZ's claim.

While nanomaterials are assessed for safety and labelled in Europe, FSANZ has ignored the presence of nanomaterials in food, and requires neither safety testing nor labelling. Many of those foods, particularly lollies, are widely consumed by children.

Ignoring Ministerial guidance

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."*²⁴

As a result of this higher level of exposure and 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,

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*but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.*²⁵

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.²⁶

FSANZ must have regard to this policy in setting its standards for infant formula. It 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”.²⁷

Nor can the agency fall back on the myth that the safety of particles at a conventional scale means that the particles are also safe at a nanoscale. The scientific consensus is just the opposite: As the Australian Pesticide and Veterinary Medicines Authority has noted, there is a:

*“general consensus that as a result of an increased surface area, altered surface chemistry, and increased potential for dissolution, there is a potential for nanoparticles to exhibit a toxicity profile that deviates from that of conventional materials of the same composition.”*²⁸

Friends of the Earth are concerned about not just the presence of nano hydroxyapatite in infant formula but about the behaviour of our food regulator FSANZ. The agency is increasingly compromised by its close relations with big food multinationals and increasingly unwilling to put safety first and act in the public interest.

FSANZ consistently asserts the safety of nanomaterials that have not been subject to safety assessment. Even when a report they commissioned concluded that the safety of nanomaterials in food could not be determined based on the available evidence, FSANZ’s summary of the report claimed that “none of the nanotechnologies are of health concern.” This is not what the Report concluded.²⁹

We are concerned that FSANZ will make the same assertion in response to the presence of nano-hydroxyapatite in infant formula.

There is no scientific basis for claiming that nano-hydroxyapatite in infant formula is safe. In fact, the most comprehensive review of its safety ever undertaken reaches the opposite conclusion.³⁰

Actions needed

1. FSANZ to initiate an immediate recall of all Nature’s Way Kids Smart, Nestlé NAN H.A. Gold and Heinz Nurture Original infant formula;
2. FSANZ to recall Blackmore’s and Aptamil’s infant formula unless and until those companies can provide evidence that nano-calcite is safe for infants and children;
3. FSANZ to immediately commission testing of all infant formula not tested by Friends of the Earth in order to ascertain what other brands contain hydroxyapatite or other unapproved and potentially harmful nanoparticles;
4. The Therapeutic Goods Association to immediately move to prohibit the use of hydroxyapatite in toothpaste, mouthwash and other oral cosmetics.

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

² Food Code, Schedule 29, Special Purpose Foods, S29-7: *Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes.*

<http://www.foodstandards.gov.au/code/Documents/Sched%2029%20Special%20purpose%20foods%20v157.pdf>

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- ³ Scientific Committee on Consumer Safety (SCCS) (2016). Opinion on Hydroxyapatite (nano). p. 18, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_191.pdf
- ⁴ *Ibid.*, p. 35.
- ⁵ 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>
- ⁶ 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.
- ⁷ Scientific Committee on Consumer Safety (SCCS) (2016).
- ⁸ *Ibid*
- ⁹ *Ibid* p. 35.
- ¹⁰ *Ibid.* p.23.
- ¹¹ *Ibid.* p.23
- ¹² *Ibid.* p.18.
- ¹³ *Ibid* at p. 35
- ¹⁴ *Ibid* p. 34-35
- ¹⁵ See e.g., FSANZ (2016). SQ16-000561 - Response to Senate Estimates Questions on Notice.
- ¹⁶ Cited in Schoepf, J. *et al.* (2017). Detection and dissolution of needle-like hydroxyapatite nanomaterials in infant formula. *Nanoimpact* 5:22-28, p. 27.
- ¹⁷ 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.
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- ¹⁹ FSANZ (2016). Nanoparticles and Infant Formula. <http://www.foodstandards.gov.au/consumer/foodtech/Pages/Nanoparticles-and-infant-formula.aspx>
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- ²¹ FSANZ (2016). Nanotechnology: What is it? <http://www.foodstandards.gov.au/consumer/foodtech/nanotech/Pages/default.aspx>
- ²² Friends of the Earth (2015). Way too little: Our government's failure to regulate nanomaterials in food and agriculture. http://emergingtech.foe.org.au/wp-content/uploads/2014/05/FOE_nanotech_food_report_low_res1.pdf
- ²³ Agir pour l'Environnement (2016). Halloween/Enquete - Plus de 100 sucreries contiendraient des nanoparticules. <http://www.agirpolenvironnement.org/communiqués-presse/halloween-enquete-%E2%80%93-plus-de-100-sucreries-contiendraient-des-nanoparticule-31005>
- ²⁴ 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>
- ²⁵ 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>
- ²⁷ 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>
- ²⁸ APVMA (2015). Nanotechnologies for pesticides and veterinary medicines: Regulatory considerations. http://apvma.gov.au/sites/default/files/publication/15626-nanotechnologies-pesticides-veterinary-medicines_regulatory-considerations_july2015.pdf, p. 93
- ²⁹ Friends of the Earth (2016). This time FSANZ has gone too far. <http://emergingtech.foe.org.au/this-time-fsanz-has-gone-too-far/>
- ³⁰ Scientific Committee on Consumer Safety (SCCS) (2016).