

[REDACTED]

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**From:** Crossley, Steve  
**Sent:** Monday, 22 May 2017 1:13 PM  
**To:** Berven, Leise; Fletcher, Nick; Duffy, Gillian; Webb, Trevor  
**Subject:** RE: nanoparticles in infant formula [SEC=UNCLASSIFIED]

Dear Leise

In my view it would be worthwhile getting

From my reading, [REDACTED] email is clearly saying that hydroxyapatite (HA) and tribasic calcium phosphate (TCP) are different and not common names synonyms for the same thing. This is contrary to the conclusion that I understand we came to earlier last week.

Our non-appearance at Senate Estimates may give us a little bit more time. Nevertheless, my view is that I believe that there is merit in seeking other views from the specific SNAG members with relevant expertise on this topic.

Thanking you.

Kind regards

Steve C.

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**From:** Berven, Leise  
**Sent:** Monday, 22 May 2017 11:38 AM  
**To:** Crossley, Steve; Fletcher, Nick; Duffy, Gillian; Webb, Trevor  
**Subject:** FW: nanoparticles in infant formula [SEC=UNCLASSIFIED]

Hi all,

Please consider [REDACTED] response to my questions. Very helpful, especially the reference & interpretation of the XRD spectra.

[REDACTED] is on the SNAG & he is cc'd. Do we want to obtain other expert opinion from SNAG or other experts as discussed last Friday?

Happy to meet again, if needed.

Leise

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**From:** [REDACTED]@measurement.gov.au]  
**Sent:** Monday, 22 May 2017 11:29 AM  
**To:** Berven, Leise  
**Cc:** [REDACTED]  
**Subject:** RE: nanoparticles in infant formula [SEC=UNCLASSIFIED]

Dear Leise,

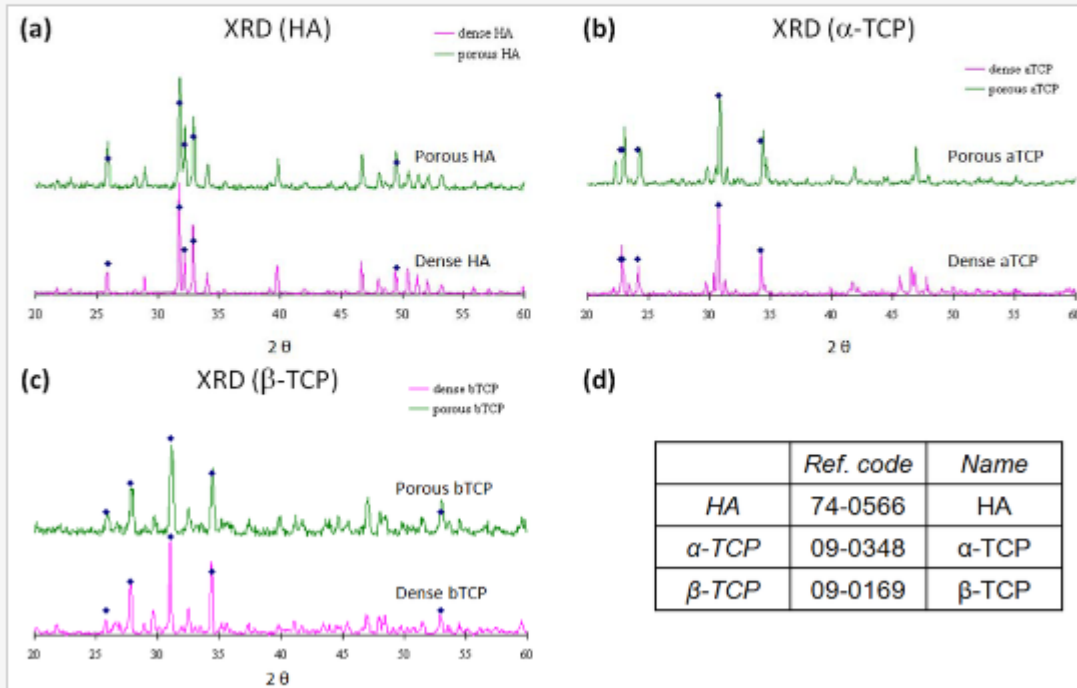
I have looked into your question about the crystallographic data and whether or not the particles are hydroxyapatite (HA) or tribasic calcium phosphate (TCP). From the XRD data and TEM images supplied in the Powerpoint presentation, it appears as if baby formulas (BFs) 1, 2 and 3 have the HA form which seems to result in more strongly shaped particles (needles or rectangular with obvious “corners”) compared to BFs 4, 5, 6 and 7, where the XRD data indicates that they are calcium carbonate and they appear to form more spherical or generally blob-like particles or aggregates thereof.

I would suggest that none of these samples appears to contain TCP.

Here is an XRD plot from an open access paper on bone biomaterials ([Lee et al., 2011, J. Funct. Biomater. 2011, 2, 308-337; doi:10.3390/jfb2040308](#)) comparing HA to TCP:

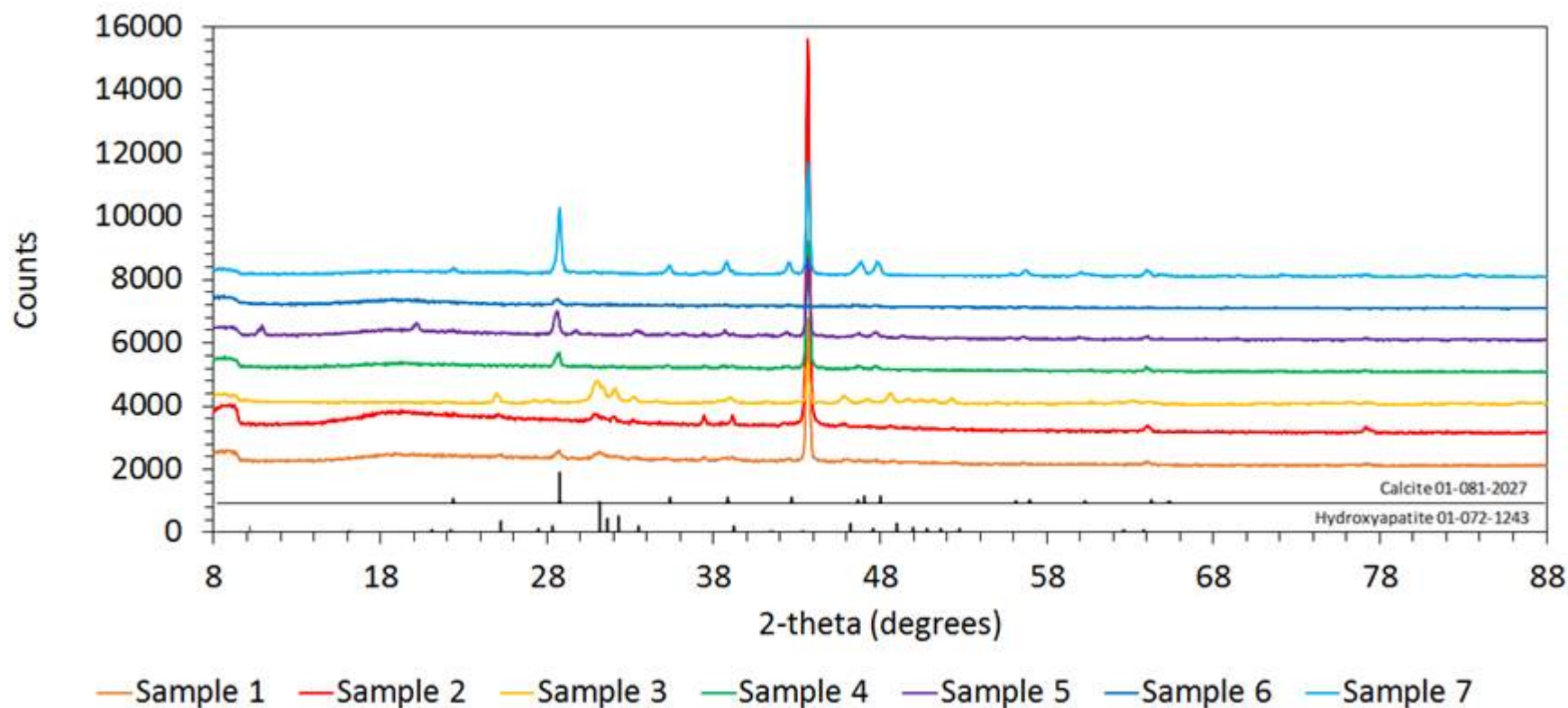


**Figure 1.** XRD spectra of porous and dense: (a) hydroxyapatite, HA; (b)  $\alpha$ -TCP and (c)  $\beta$ -TCP discs; and (d) the corresponding matches from the database (the spots on the spectrum indicate the positions of the five most intense peaks from the powder X-ray data of the database).



If we compare this to the data from the Powerpoint presentation:

## XRD Results of Infant Formula



Comparing these two sets of data seems to indicate that the peaks for the BF correspond well to the calcite and HA data at the bottom of the combined data plot, and that peaks which would belong to TCP (particularly the peak below 2-theta= 24 ° for  $\alpha$ -TCP and the peak at 2-theta  $\sim$ 35° for the  $\beta$ -TCP) are not found.

I found that the supplementary information for the January 2017 publication also contained more information, particularly about the potential dissolution, which might be useful to you. I have a copy, if you need it!

I'm happy to discuss further if you need more information!

Best regards,

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**From:** Berven, Leise [REDACTED]  
**Sent:** Thursday, 18 May 2017 4:15 PM  
**To:** [REDACTED] <[\[REDACTED\]@measurement.gov.au](mailto:[REDACTED]@measurement.gov.au)>  
**Subject:** nanoparticles in infant formula [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thanks so much for talking to me. I have attached the relevant papers.

I'd be very grateful for your view about the characterisation of the nanoparticles detected in the infant formula samples. Specifically about whether the needle-particles are indeed hydroxyapatite -  $\text{Ca}_5(\text{PO}_4)_3\text{OH}$  – or could be some other form of calcium phosphate, e.g. calcium phosphate tribasic

Note that the [EC SCCS opinion](#) indicates hydroxyapatite and calcium phosphate tribasic are chemical names for the same thing – despite them having different chemical formulas. Perhaps this because using common and IUPAC chemical names.

Happy to chat further.  
Leise

**Leise Berven, PhD**  
Senior Scientist  
Scientific Strategy, International and Surveillance



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