

**Senate Community Affairs Committee**

**ANSWERS TO ESTIMATES QUESTIONS ON NOTICE**

**HEALTH PORTFOLIO**

**Budget Estimates 2017 - 2018, 29 & 30 May 2017**

**Ref No:** SQ17-000832

**OUTCOME:** 5 - Regulation, Safety and Protection

**Topic:** Nano-hydroxyapatite in Toothpastes

**Type of Question:** Written Question on Notice

**Senator:** Rice, Janet

**Question:**

A 2013 paper estimates that between 18-19 metric tonnes of nano-hydroxyapatite (n-HA) is used annually in toothpastes in the US alone (Keller et al. 2014).

The European Commission's Scientific Committee on Consumer Safety (SCCS) has concluded that the needle-like form of nano-hydroxyapatite should not be permitted in oral products such as toothpaste and mouthwash because of its potential toxicity. \*

- a) Is nano-hydroxyapatite permitted in oral cosmetics in Australia?
- b) If yes to a), are there any restrictions on its use?
- c) If yes to a), how much hydroxyapatite is used in oral cosmetics in Australia?
- d) If yes to a), was nano-hydroxyapatite subjected to pre-market safety assessment prior to being used in oral cosmetics in Australia?
- e) If yes to d), please table any such safety assessment(s)
- f) If no to d), on what basis is n-HA deemed safe?
- g) Has the TGA done any testing or conducted any surveys to determine whether n-HA is being used in oral cosmetics in Australia?
- h) If yes to g), please describe or table the results

\* Scientific Committee on Consumer Safety (SCCS) (2016). Opinion on Hydroxyapatite (nano). p. 35,

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_191.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_191.pdf); see

also Schoepf, J. et al. (2016). Detection and dissolution of needle-like hydroxyapatite nanomaterials in infant formula. Nanoimpact. <http://dx.doi.org/10.1016/>

**Answer:**

- a) Hydroxyapatite is listed on the Australian Inventory of Chemical Substances (AICS), which does not distinguish between the conventional form of this material and its nano form because both forms are covered by the same Chemical Abstracts Service (CAS) number (CAS No. 1306-06-5). Therefore, any form of hydroxyapatite may be introduced into Australia for any industrial use, including as a cosmetic ingredient, without pre-market assessment under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). However, if a therapeutic claim were made for such a product (such as a claim to remineralise teeth), the product would need to be included in the Australian Register of Therapeutic Goods.

- b) No.
- c) There are no toothpaste or mouthwash products containing hydroxyapatite or the nano form of hydroxyapatite currently included on the Australian Register of Therapeutic Goods. As notification and assessment of this chemical is not required under the *Industrial Chemicals (Notification and Assessment) Act 1989*, NICNAS does not have information on the amount in use in Australia in any cosmetic products (for which therapeutic claims are not made).
- d) Please see answer to part a) and c).
- e) Please see answer to part d).
- f) Please see answer to part a) and c).
- g) In 2007, the Therapeutic Goods Administration conducted a review of the scientific literature in relation to therapeutic products incorporating nanotechnologies to ensure that the assessment criteria and protocols remained appropriate. The review concluded that no unique/novel toxicity had been identified for any nanoscale material in therapeutic goods. The review also concluded that the hazard associated with exposure to a nanoscale material is better predicted by the conventional (parent) compound than by another nanoparticle.
- h) Not applicable.