

19/09/19

Mark Rakers

Director

Button Batteries Taskforce
Consumer Product Safety Branch
Australian Competition & Consumer Commission
GPO Box 3131
Canberra, ACT 2601

Dear Mark,

Thank you for the opportunity for Sivantos Pty Ltd to respond to the **Button Battery Safety Issues Paper**. Please find below Sivantos' responses to the questions raised (outlined on page (vii)) in the Issues Paper.

Feel free to contact me if you have any questions.



Paul Guthrie

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Sivantos – A Global leader in Hearing Aid Development

Sivantos designs, develops and manufactures hearing aids and is the world's largest manufacturer supplying one in four hearing aids globally. Sivantos has a long history full of innovative spirit, life-changing technologies and many world's firsts in the hearing aid industry. Formerly Siemens Audiology, Sivantos' origins date back to the year 1878. Currently, Sivantos supplies hearing aids in over 120 countries worldwide.

Sivantos Australia

In Australia, Sivantos is a long-standing market leader supplying in excess of 150 000 hearing aids annually. Sivantos is contracted to provide hearing aids through the Australian Government Hearing Services Program.

Since 2003, Sivantos has been chosen to be the main hearing aid supplier to Australian Hearing; the largest provider of government-funded hearing aids in Australia. In fact, the majority of hearing aids fitted by Australian Hearing are supplied by Sivantos. This supply arrangement is the result of several rigorous competitive tenders that followed the comprehensive Commonwealth procurement guidelines.

The selection criteria for the tender included amongst other items:

- Technical quality of the hearing aids
- Demonstrated research or commitment to and access to research and development including new technologies

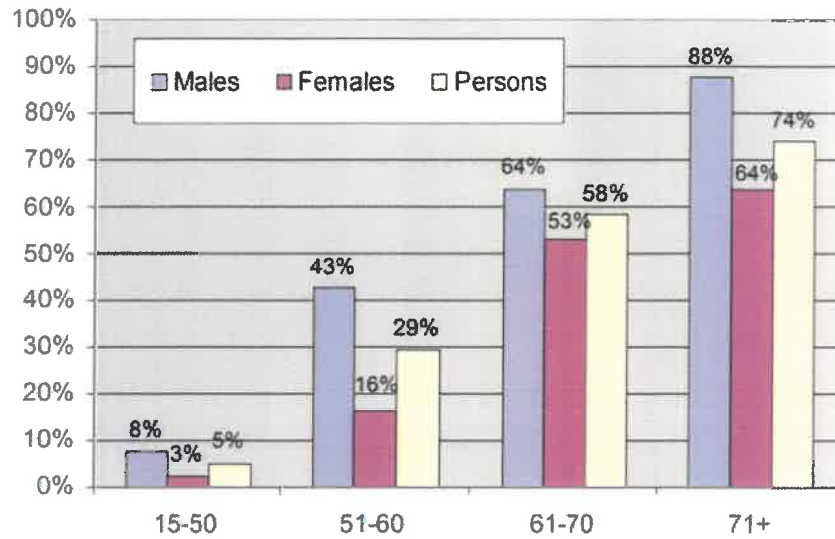
Australian Hearing supports clients of all ages and is the main service provider for the Paediatrics. The tender process involved a thorough evaluation process assessing the hearing aids suitability for each of the client groups Australian Hearing services.

The Hearing Aid Market

Hearing loss can reduce an individual's capacity to communicate and participate in social situations as well as impact their education and employment opportunities. Unfortunately, it is estimated that only 1 in 6 hearing impaired individuals use hearing aids.

Whilst hearing loss can affect anyone, the prevalence rates are primarily related to the ageing population. Most hearing aid wearers are elderly. In fact, it is estimated that in Australia, the average age of a hearing aid wearer is ~78 years (for estimated hearing loss prevalence rates, see graph below).

HEARING LOSS PREVALENCE RATES WITH AGE in YEARS (WORSE EAR)



Access Economics, Listen Hear! The economic impact and cost of hearing loss in Australia, (February 2006)

In view of this, hearing aids need to be designed to ensure they can be independently managed by elderly wearers which often experience reduced dexterity. Sivantos is focused on improving the quality, design, safety, functionality and of course audiological performance of our hearing aids with the goal of increasing hearing aid performance and usage.

Questions for response

What data or information can you provide on the size and value of the Australian market, or for a segment of the market, for button batteries or for products that contain button batteries?

We estimate that in Australia there are approximately 1.5 million hearing aids in active use. The annual size of the zinc-air button battery market used in these hearing aids is approximately 20 million units (retail value \$15 million).

What information can you provide on the range of products that you supply that contain button batteries?

Sivantos is a hearing aid manufacturer and wholesaler of hearing aids. All of our current non-rechargeable hearing aids use disposable **zinc-air button** batteries. All our current rechargeable hearing aids use lithium-ion batteries that are fully enclosed within the device housing and only accessible with special tools. None of our hearing aids use lithium button batteries.

Do you think the recommended safety actions in the Code should be made mandatory? What impact would mandating these requirements have on Australian suppliers?

We believe that hearing aids should be exempt from the code.

Hearing aids are medical devices and are not consumer electronic devices. Sivantos supplies hearing aids for distribution by independent, credentialed, licensed hearing health care professionals who provide service and support for hearing impaired consumers in compliance with all applicable regulations and law.

As a requirement for distribution, Sivantos requires that all hearing aids be fitted 'face-to-face' to ensure that wearers are trained to safely manage their hearing aids. In addition, all Sivantos hearing aids are provided with a comprehensive userguide and safety manual.

<https://www.signia-pro.com.au/purchasing-distribution-guidelines/>

Non-rechargeable hearing aids use **zinc-air button batteries**. As highlighted in this current "Button Battery Safety Issues" paper (page 9) *"they are not implicated in significant injuries"*.

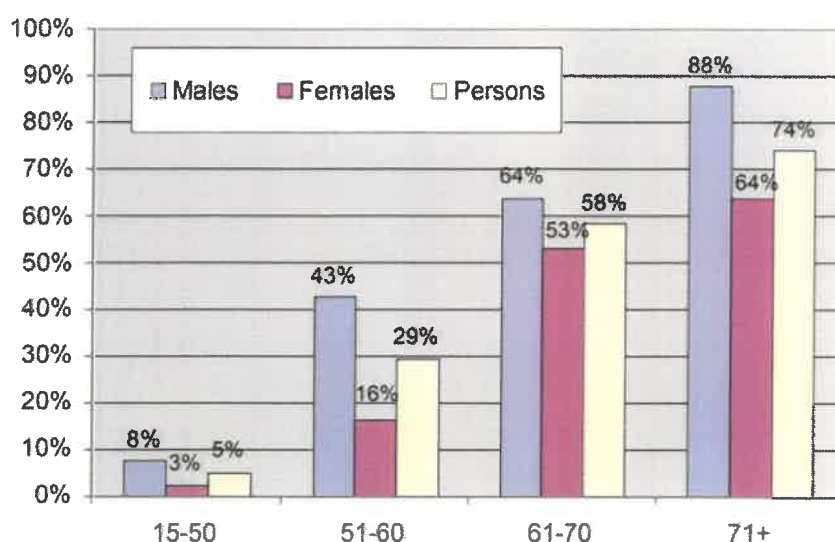
Our internal assessment is that zinc-air batteries poses low health risk for the following reasons:

- o Small size (<1cm diameter), low probability to be get stuck in the gastrointestinal tract
- o No sharp edges
- o Low voltage (<1.6V), output voltage drops to 0 if swallowed due to lack of oxygen (Zinc Air requires oxygen)
- o Toxicity risk is low as stomach acid neutralises caustic potash

For the paediatric population (children under 3 years) we offer special hearing aid models with a battery door lock. This door can be locked and unlocked using a special tool. These hearing aids are designed to be managed by a third party (caregiver). This solution is not suitable for geriatric wearers due to complexity with respect to management.

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In view of this, hearing aids need to be designed to ensure they can be independently managed by elderly wearers which often experience reduced dexterity. The current hearing aid battery compartment designed fulfils these manageability requirements.

Mandatory application of the battery code would make independent management of hearing aid battery changes virtually impossible for many wearers.

If you are a supplier, do you supply products that comply with the Code? If no, please explain why. If yes, what actions do you have in place to reflect the Code?

Currently our hearing aids meet the current code as its requirements *"do not apply to professionally prescribed and fitted medical devices such as hearing aids"*.

As outlined in question 4, the application of the code to non-paediatric hearing aids would make independent management of hearing aid battery changes virtually impossible for many wearers due to the reduced dexterity often experienced by the elderly.

Sivantos has been supporting battery safety with hearing aids with the following initiatives:

Design

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Labelling

All Sivantos hearing aids are currently supplied with both a userguide and a safety manual which contains battery safety warnings.

"the instruments are not intended for children under the age of 3 years or person with a developmental age of under 3 years"

"Choking hazard! Your hearing instruments contain small parts which can be swallowed."

- *Keep hearing instruments, batteries and accessories out of the reach of children and mentally disabled persons.*
- *If parts have been swallowed consult a physician or hospital immediately*

Sivantos recently added the local Poisons Hotline number and hearing aid storage recommendations/warnings to the safety guide

"If battery is swallowed contact the Poisons Information Hotline on 13 11 26 for Australia and 0800 764 766 for New Zealand."

"When not in use, please store your hearing instruments in the supplied jewel case or charging case (if applicable) and keep out of the reach of children."

The hearing aid storage recommendation/warning was also added to a sticker attached to the hearing aid storage case (supplied as standard with each hearing aid delivered).

Education

Sivantos only supplies hearing aids for distribution by independent, credentialed, licensed hearing health care professionals who provide face-to-face service and support for hearing impaired consumers in compliance with all applicable regulations and law.

During 2019, Sivantos ran a battery safety education campaign which included:

- Regular company communications to Hearing Care Professionals on the battery safety topic
- The inclusion of safety information and training into our regular Hearing Care Professional product and clinical training sessions (both face-to-face training and webinars)

Are there any button battery products that you think should be exempted from any mandatory safety or information standards? Please provide reasons why.

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