



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Minute

Michael Wiseman
Manager, Listing
Office of Complementary Medicines
TGA

Re: Sodium Fluoride as an active

Please find attached a review on the use of sodium fluoride as an active in pharmaceutical products. On the basis of this review, I recommend that sodium fluoride be allowed for use as an active in Listed medicines on the basis that:

- the preparation includes at least one other therapeutically active Listable ingredient;
- the concentration of the fluoride ion is not more than 1000mg/kg (1000ppm);
- the substance is for use only in pastes, powders or gels for the cleaning of teeth;
- claims in relation to fluoride content are restricted to those relating to improvements in oral hygiene or use of fluoride for the prevention of tooth decay.

Dr Peter Bird
Head, OTC Medicines Section
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