

From: info@tga.gov.au

Date: 18/01/2013 9:45:28 AM

To: John Teagle

Subject: Re: Fw: Re: Fw: Sodium Fluoride (S7 poison) [SEC=UNCLASSIFIED]

Dear Mr Teagle

Thank you for your emails to the Therapeutic Goods Administration (TGA) and our apologies for the delay in responding.

Scheduling is a national classification system that controls how medicines and poisons are made available to the public. **Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison, required to protect public health and safety. The Schedules are set out in the current Poisons Standard, a legislative instrument made under the Commonwealth *Therapeutic Goods Act 1989*. The requirements mandated by these Schedules are generally given legal effect through State and Territory legislation.**

The Poisons Standard is also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) which can be accessed through www.comlaw.gov.au. Where a substance is included in a Schedule in the SUSMP this has the effect (the Scheduling Requirements) of restricting the labeling packaging, availability and supply of any product containing that substance. The Scheduling Requirements for each Schedule are set out in the SUSMP.

In responding to your query, we note from your emails that your primary concern appears to be about a substance called "sodium fluoride". This substance is what is known as a "salt", that is it readily dissolves into in water releasing the fluoride ion. Sodium fluoride is included in the SUSMP entries for "fluorides". You should also note that atomic fluorine "F" may be strongly bound into many other substances including some medicines and household products such as Teflon. These substances are not salts and do not release fluoride ion when added to water and are therefore not considered to be fluorides or a source of fluoride. **While some of these other fluorine containing substances may have individual entries in the SUSMP, they are not included in either the entry for the parent acid or the entries for "fluorides". They are also not permitted additives to water.**

As noted in the SUSMP, substances are not scheduled simply on the basis of a universal scale of toxicity. Although this is one of the factors considered, the decision to include a substance in a particular Schedule also takes into account many other criteria such as the purpose of use, potential for abuse, safety in use and the need for the substance. These criteria are set out in the *NCCTG Scheduling Policy Framework 1 July 2010*, available from the TGA website (www.tga.gov.au).

"Fluorides" for human use, that is for dental products, medicines and the like, are listed in Schedules 2, 3 and 4 of the current SUSMP. The entries for "fluorides" in Schedules 5 and 6 are for uses other than human use. Please note however, that although fluorides for human uses are listed in Schedules 2, 3 and 4 and conditions/requirements are specified for their supply to the public, there is a specified concentration of fluorides (15mg/kg and less), below which they are excluded from the all the scheduling requirements in the SUSMP. Fluorides are not listed in Schedule 7 of the current SUSMP.

Fluoride scheduling was first considered in 1956 and since then fluoride has been considered on numerous occasions. In 2007, the then National Drugs and Poisons Committee (NDPSC) decided to establish a Fluorides Working Party (FWP) to address the issues of concern in relation to contemporary human exposure to fluoride (acute toxicity in children and adults and fluorosis in children and adolescents). The acute oral toxicity of fluoride is generally recognised as 5mg/kg and the acceptable daily intake for fluoride in children 1 to 3 years of age, in relation to the incidence of dental fluorosis, is 0.7mg.

In 2011, the National Health and Medical Research Council (NHMRC) published the latest version of the *Australian Drinking Water Guidelines*, which are available on the NHMRC website at <http://www.nhmrc.gov.au/guidelines/publications/eh52>. The guidelines contain a specific chapter on drinking water treatment chemicals, including fluoride. The guidelines advise that the use of fluoride is controlled by State and Territory legislation and regulations, and local regulations. Table 8.1 provides the names of the relevant legislation and regulations, by State and Territory, under which fluoride is controlled. It

is worth noting that NHMRC's website advises that the guidelines undergo rolling revision to ensure it represents the latest scientific evidence on good quality drinking water. You may wish to contact the NHMRC about having your views considered in the next update of their guidelines.

I hope that this information is of assistance.

Yours sincerely

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