

Considerations about the inclusion of fluoride gels, fluoride oral rinses, and fluoride varnishes in the Essential Medicines List.

Submitted by Clifton Carey, PhD Professor Craniofacial Biology and Orthodontics at the University of Colorado, School of Dental Medicine Aurora, Colorado USA. Convenor for ISO TC106/SC7/WG4 Toothpastes, and U.S. Expert for ISO TC106/SC7/WG3 Oral Rinses and ISO TC106/SC7/WG8 Fluoride Varnish on behalf of the experts in the U.S. Subcommittee 7 (SC7) of the American Dental Association/American National Standards Institute. I serve as vice chair of ADA/ANSI SC7 - Oral Care Products.

The SC7 Oral Care Products encourage the inclusion of fluoride containing oral care products (gels, rinses, varnishes) in the EML because they have been proven to be effective in the prevention of dental caries.

The U.S. Subcommittee 7 (SC7) of the ADA/ANSI calls to your attention that the ADA/ANSI and the ISO TC106 – Dentistry have been developing standards for oral care products for decades. These standards are designed to provide requirements that establish safety limits for fluoride content, erosive capacity, abrasivity and pH. Additional requirements are associated with efficacy including fluoride bioavailability and adjunct ingredients which may enhance and anticaries efficacy. The requirements are based on current published scientific insights.

Fluoride Gels:

ISO 11609 Dentistry — “Dentifrices — Requirements, test methods and marking” provides the requirements for fluoride content and labeling of dentifrice products. These requirements were established based on the existing literature about the safety and efficacy of dentifrices. The standard has been in use for at least 15 years and has been updated regularly to improve safety and efficacy of dentifrices to prevent dental caries.

Mouth rinses:

ISO 16408 “Dentistry – Oral Rinses” provides requirements for fluoridated oral rinses to include safety and efficacy for the prevention of oral disease including dental caries. The requirements of this standard are based on the best research available on the topic. This standard is updated on a regular basis. A few specific comments are listed below addressing items in the application to include oral rinses in the Essential Medicines List.

Page 3, Section 5.3

- For Strength, 0.02% NaF rinse is also common as OTC in US.
- Is there a reason stannous fluoride rinses are not included? They are available OTC in the US and are in the FDA Final Monograph (21 CFR part 355): Anticaries Drug Products for Over-the-Counter Human Use.
- For Dosage, 0.02% NaF, typically used twice daily, is also common as OTC in US.

Page 5, Section 8.2

- For Requirements to ensure appropriate use of the medicine, there may need to be language regarding following the manufacturer's instructions for the specific product being used. Some fluoride rinses are sold to the end consumer in a concentrated form that must be diluted with water prior to use.

Fluoride Varnishes:

ISO 17730 "Dentistry - Fluoride Varnishes" provides requirements for fluoride varnishes including fluoride content and labeling. The requirements are based on safety and efficacy. The standard is based on the current literature on fluoride varnishes and their use.

The U.S. experts (SC7 Oral Care Products) associated with these standards are ready and willing to provide insights to the committee as they consider the applications about fluoride containing oral care products.

Sincerely,

Clifton Carey

Vice Chair SC7 – Oral Care Products.