

TABLE 14.—PLAQUE/GINGIVITIS SCORES FROM THE TRUELOVE STUDY (REF. 349)

Agent	Prebrush score	Postbrush score
Test product (0.25% SLS)	2.56	1.11
Other product (0.3% SLS)	2.94	1.23
Placebo	2.50	1.16

The results of the Emling study (Ref. 361) suggested a somewhat greater plaque score reduction with the test product containing 0.25 percent sodium

lauryl sulfate than the placebo (see Table 15 of this document). However, gingivitis scores were not measured in this study or in several other

unpublished studies with the same experimental protocol that produced similar results (Refs. 362 and 363).

TABLE 15.—PLAQUE SCORES FROM THE EMLING STUDY (REF. 361)

Agent	Prebrush score	Postbrush score
Test product (0.25% SLS)	3.12	2.05
Placebo	3.09	2.82

In addition, Beiswanger et al. (Ref. 364) were unable to detect a statistically significant difference in the degree of plaque reduction between active and placebo rinses.

Van Dyke *et al.* (Ref. 365) also monitored gingival changes under conditions of prebrushing rinsing. They reported statistically significant reductions of plaque scores for both the placebo and the test rinse as compared to baseline scores. Although there was a statistically significant advantage of the test rinse over the placebo (1.61 versus 1.84 mean score) at interproximal surfaces for plaque scores, these differences were not clinically significant. Further, there were no differences in gingivitis scores before and after treatment, or between test and placebo scores.

Kohut and Mankodi (Ref. 366) found no difference between test and placebo prebrushing rinses, either in the degree of plaque or gingivitis reduction. Similar results were reported by Singh (Ref. 367) and by Pontier et al. (Ref. 368) in children undergoing orthodontic treatment. In a 6-month clinical study, Lobene *et al.* (Ref. 369) failed to show that a test product containing 0.25 percent sodium lauryl sulfate was superior to a placebo in reducing plaque, gingivitis, or calculus.

The Subcommittee concludes that sodium lauryl sulfate is effective to facilitate the removal of food and other particulate material and provide a clean tooth feeling, primarily through its surfactant properties and its affinity for binding to tooth surfaces. Sodium lauryl sulfate appears to have a minor inhibitory effect on plaque formation, following an initial dental prophylaxis.

Although sodium lauryl sulfate has antibacterial properties in vitro, it is not clear to what extent this antibacterial effect is exerted in vivo. The antiplaque effect of sodium lauryl sulfate is at best moderate. Sodium lauryl sulfate does not have a significant effect on gingivitis. The role of sodium lauryl sulfate as a facilitator of plaque removal when used in a prebrushing rinse is marginal and does not result in any beneficial clinical improvement, such as gingivitis reduction or inhibition of calculus formation. Sodium lauryl sulfate is a safe and effective foaming ingredient when used in toothpaste.

The Subcommittee concludes that sodium lauryl sulfate at 0.1 to 5 percent concentration in an oral rinse or dentifrice dosage is safe, but that there are insufficient data available to permit final classification of its effectiveness as an antiplaque and antigingivitis agent.

g. *Zinc citrate.* The Subcommittee concludes that zinc citrate is safe, but there is insufficient evidence to support its effectiveness as an OTC antigingivitis/antiplaque agent.

Zinc citrate has a chemical formula of  $Zn_3(C_6H_5O_7)_2$  and is prepared from zinc carbonate and citric acid. It is described as a dihydrate, odorless powder, that is slightly soluble in water (Ref. 370). Based on the known abilities of zinc to inhibit crystal formation and of citrate to inhibit crystal aggregation, zinc citrate replaced zinc chloride (highly effective but with a disagreeable taste) as a toothpaste ingredient to inhibit dental calculus formation (Ref. 371). Zinc citrate trihydrate ( $Zn_3(C_6H_5O_7)_2 \cdot 3H_2O$ ) has been used to inhibit supragingival calculus formation.

i. *Safety.* Zinc is ubiquitous in our environment and is an essential trace element in humans. Its role in humans continues to be the subject of investigation. The overall safety of zinc citrate has been well and extensively documented (Ref. 372). Acute toxicity studies in animals have shown zinc citrate to be only slightly toxic. Zinc citrate fed to rats for up to 13 weeks produced toxic effects only at high levels. No toxic effects were observed when toothpaste containing up to 10 percent zinc citrate was fed to rats and dogs for up to 18 months. In humans, zinc salts are considered relatively nontoxic (Ref. 372).

Zinc citrate had no adverse effects on fertility, the fetus, or neonate in rats and rabbits (Ref. 372). This finding correlates with published findings on other zinc salts. No mutagenic effects have been reported from in vivo studies. Zinc does not have genotoxic effects or pose a carcinogenic hazard at levels normally found in the body (Ref. 372). The oral irritation potential of toothpastes containing zinc citrate is no greater than that of other marketed toothpastes.

ii. *Effectiveness.* The Subcommittee reviewed five short-term clinical studies, two 6-month studies, and a 3-year trial assessing the effect of zinc citrate on gingivitis (Ref. 373). The five studies had in common a 21-day experimental period in which subjects, following a 4-week period of tooth cleaning and oral hygiene instruction, refrained from brushing one lower quadrant of teeth. An impression of each lower tooth arch was made and a plaster mold prepared. A plastic "tooth shield" was heated and vacuum fitted to