

The BriteSmile Whitening Gel Abstract for Study III: Mutagenicity

Objective : To determine the potential for BriteSmile Whitening Procedure Gel (BriteSmile Gel) to induce mutations in tester strains of *Salmonella typhimurium* . BriteSmile Gel contains 15% hydrogen peroxide (HP), and it is used in conjunction with a visible wavelength light source to whiten teeth. BriteSmile Gel is formulated with a light-activated component to reduce the contact time needed for tooth bleaching. Inclusion of a light activated component enables a lower HP concentration to be used to provide tooth whitening. **Methods:** To assess the mutagenic potential of BriteSmile Gel, five tester strains of *Salmonella typhimurium* (TA97a, TA98, TA100, TA102, and TA1535) were exposed to BriteSmile Gel at levels up to 5 mg/plate in the presence and absence of an external metabolic activation source (S9, an Aroclor-induced rat liver homogenate). **Results:** No mutagenic activity was seen in any of the five tester strains in the presence of S9, and no mutagenic activity was seen in TA97a, TA98, TA100, and TA1535 in the absence of S9. A weak mutagenic response was seen in TA102, a tester strain that is sensitive to oxidative mutagens. For comparison, aqueous hydrogen peroxide was also included in TA102 without S9. HP was mutagenic (exceeded twice background) at 0.15 and 0.2 mg/plate. BriteSmile Gel was also weakly mutagenic at similar levels of HP without S9. These results are similar to other published results that show a weak mutagenic response for HP in tester strain TA102 in the absence of S9. **Conclusion:** The biological relevance of this positive response is questionable as intracellular and extracellular defense mechanisms are present in the oral cavity that decompose HP. The response of BriteSmile Gel is more appropriately compared to tests performed in the presence of S9 in which no mutagenic activity was detected. Supported by BriteSmile, Inc., Walnut Creek, CA.