The BriteSmile Whitening Gel
Abstract for Study IV: Genotoxicity

Objective: To determine the potential for BriteSmile Whitening Procedure Gel (BriteSmile Gel) to induce chromosome damage in mice following oral administration. 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 clastogenic potential of BriteSmile Gel, male and female CD-1 mice (5/group) were administered BriteSmile Gel by gavage at levels up to 2,000 mg/kg body weight. Bone marrow was obtained 24, 48, and 72 h after administration, and immature polychromatic e rythrocytes (PCEs) were evaluated for the presence of micronuclei as an indicator of chromosome damage.
Results: There was no evidence of chromosome damage in PCEs from mice administered BriteSmile Gel at levels of 500, 1,000, or 2,000 mg/kg body weight, compared to the vehicle control, water. Cyclophosphamide was included as a positive control, and the number of micronuclei induced in PCEs with cyclophosphamide was significantly greater than that of the control.
Conclusion : These results indicate BriteSmile Gel does not have the potential to cause chromosome
damage in animals following ingestion. Supported by BriteSmile, Inc., Walnut Creek, CA.