Peroxides have been used for tooth bleaching/whitening for more than 30 years. The safety and efficacy of hydrogen peroxide and carbamide peroxide bleaching/whitening agents is well documented and there are many different products (10 - 30% carbamide peroxide releasing 3.6 - 10% hydrogen peroxide) currently available via dental offices. Tooth whitening products with varying levels of hydrogen peroxide or hydrogen peroxide releasers (typically up to 10% hydrogen peroxide) are sold directly to consumers.

Based upon the published data, the International Agency for Research on Cancer (IARC) has concluded that there is limited evidence in experimental animals for the carcinogenicity of hydrogen peroxide. IARC stated that there was ‘inadequate evidence in humans for the carcinogenicity of hydrogen peroxide’, despite the significant industrial exposure to this chemical and its widespread use.

A critical analysis of the non-clinical data, including in vitro and in vivo genotoxicity, carcinogenicity and tumour initiation-promotion studies, leads to the conclusion that exposure to hydrogen peroxide from the use of tooth whitening product under recommended or exaggerated use conditions is not a significant risk for the development of oral cancer.

A chemical that has a tumour-promoting action requires long-term, sustained high-dose exposure for neoplastic lesions to develop. Without such exposure, lesions either fail to develop or regress. In addition, such exposures generally produce clear evidence of tissue damage at the affected site (e.g., fore-stomach and skin). A pre-clinical study conducted to assess the toxicity of hydrogen peroxide when administered orally in drinking water to mice with low catalase levels, demonstrated that stomach and/or duodenum lesions regressed upon cessation of hydrogen peroxide treatment.

Exposure to 30% hydrogen peroxide in a hamster buccal pouch assay failed to induce tumours despite evidence of chronic inflammation. No visible pathological changes that could plausibly be related to future preneoplastic or neoplastic lesion development were seen in any subjects in more than 100 clinical trials with tooth whitening products. Any effects of hydrogen peroxide from tooth whitening products use, even over 6-months of continuous exposure, are mild, transient, and involve only gingival irritation and tooth sensitivity, both of which resolve within a few days after use of the product is stopped. These studies, many of which have included smokers, provided no evidence to indicate that the rate or severity of the adverse effects of tooth whitening products were significantly different from non-smokers. In addition, concentrations of hydrogen peroxide achieved in the saliva in contact with the floor of the mouth, one of the more common sites for oral cancers in the general population, are very low within 15 (0.0001%) to 60 (<0.00007%) minutes of the application of tooth whitening products. The gingiva, in contrast to the floor of the mouth, is a very rare site for the development of oral cancer.

A 7.5-year follow-up study on a small group of tooth whitening products users does exist in the scientific literature. During the exposure portion of this study subjects received 6-months of continuous hydrogen peroxide treatment for tetracycline stains. No evidence of adverse effects in the oral cavity were noted in 9 of the 15 who agreed to a clinical examination, and none of the 15 participants in the study reported any side effects that they believed to have been treatment-related.

Whilst hydrogen peroxide at high concentrations is weakly carcinogenic to the duodenum of mice that are catalase deficient, peroxidase/catalase activity of saliva in humans would protect against the effects of hydrogen peroxide in the oral cavity.

Increased cancer risk from combined exposures can arise when one exposure and other concomitant exposures each convey a cancer risk. For example, combined smoking and asbestos exposures, which individually present cancer risks, present greatly increased risks for lung cancer when exposure is combined. Since there is no established human cancer risk from tooth whitening products or hydrogen peroxide, there is no basis to postulate that tooth whitening products would increase cancer risk in smokers and/or heavy drinkers.

Therefore, the results of initiation-promotion or combined exposure studies, cannot be extrapolated to suggest a potential risk of hydrogen peroxide to the oral mucosa of heavy smokers and/or drinkers from tooth whitening product under recommended, exaggerated or extended, conditions of use. This conclusion is also supported by the fact that there are many common tumour promoters, including food ingredients such as sodium chloride, butylated hydroxyanisole, glycerin, and sucrose, but no known
tumour promoter for the oral cavity. 

Reference list:
This paper represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.