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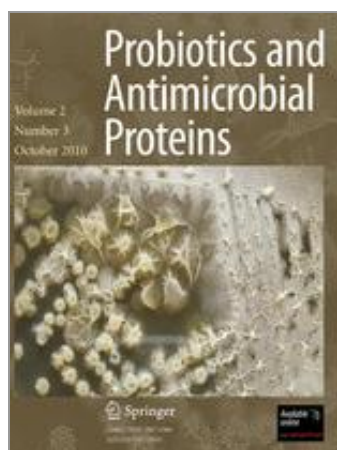
October 2010, Volume 2, Issue 3, pp 135-144

Date: 19 May 2010

Extended Safety Data for the Oral Cavity Probiotic *Streptococcus salivarius* K12

Abstract

Previous studies of the bacteriocin-producing *Streptococcus salivarius* K12 monitored a variety of intrinsic strain characteristics of potential relevance to its application as an oral probiotic in humans. These included the content of antibiotic resistance and virulence determinants, the production of deleterious metabolic by-products and its genetic stability. In the present study, we examined additional safety factors including the responses of rats to either short- or long-term oral dosing with strain K12 preparations. In addition, the potential genotoxicity of strain K12 was tested using a bacterial reverse mutation assay. To determine the occurrence and concentrations in human saliva of *S. salivarius* having the same bacteriocin phenotype as strain K12, saliva samples from 780 children were evaluated. The level of dosing with strain K12 required to achieve oral cavity colonization levels similar to those occurring naturally for this type of bacteriocin-producing *S. salivarius* was established using 100 human subjects. Following the oral instillation of lyophilized *S. salivarius* K12 cells in these subjects, its persistence was not at levels higher than those found naturally for this type of bacterium. The various sets of data obtained in this study showed no evidence of genotoxicity and no acute or subacute toxicity effects associated with strain K12. Based on the previously published data, the long history of use by humans and the information presented here, it is concluded that *S. salivarius* K12 is safe for human consumption.



4 Citations

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1. Introduction