

Evaluation

To our recent knowledge and as a result of a hazard analysis performed for the use of STOKOSEPT® gel it can be confirmed that STOKOSEPT® gel contains no ingredients which are hazardous for the health of consumers after oral uptake (in amounts as considered above). Even under the worst case-conditions as described above, the calculated possible exposure of consumers to food containing contaminants derived from the use of the product STOKOSEPT® gel does not exceed levels that were regarded as safe for human beings during a lifetime exposure. Furthermore, there are no indications that synergistic toxic effects of the ingredients can occur after ingestion. One exception is the ingredient aminomethyl propanol. For this compound no clear NOEL has been derived from animal studies. However, the calculated worst case exposure results in an amount of aminomethyl propanol that was determined to be without any adverse effects in a 1-year animal feeding study. Assuming realistic exposure conditions the actual uptake of aminomethyl propanol is calculated to be even one fold lower when directly compared to the study mentioned previously. Furthermore aminomethyl propanol is approved by the US Food and Drug Administration for use as indirect food additive.

Therefore, a risk for the health of consumers due to application of STOKOSEPT® gel in processing of foodstuffs can be excluded under foreseeable and appropriate conditions of use.

Regards
Deb-STOKO Europe GmbH

i.A.



Dr. Wolfgang Röcher
(Group Scientific Communications Manager)