Sikkerhed:

Universitetet i Ghent, Belgien. Hospitalsstudie – hele sikkerhedsafsnittet:

PIP products are demonstrated to be completely safe to use. Several reasons are:

- The probiotic bacteria used in the PIP products are members of the genus *Bacillus* and belong to biosafety class 1, as listed by the American Type Culture Collection (ATCC). The following table presents all four bio-safety classes:

Class	Description	Risk
Class 1	Class 1: Non-pathogenic organisms	NONE
Class 2	Micro-organisms and parasites that may cause disease, but with an unlikely spread and for which efficient prophylaxis or treatment exists.	Low
Class 3	Micro-organisms and parasites that are able to spread and cause disease, but subjective to efficient prophylaxis or treatment	Average
Class 4	Micro-organisms and parasites with large scale spreading and serious illness, for which no prophylaxis or treatment exists.	High

A NUMBER OF PROBIOTIC *BACILLUS* SPECIES HAVE BEEN GRANTED THE GRAS (GENERALLY RECOGNIZED AS SAFE) LABEL BY THE FOOD AND DRUG ADMINISTRATION (FDA) AND CAN AS SUCH BE USED FOR HUMAN PURPOSES WITHOUT ANY HAZARD.

THE PIP BACTERIA BELONG TO THE GROUP OF SPORULATING PROBIOTICS, OF WHICH OVER HUNDRED COMMERCIAL PHARMACEUTICAL AND NUTRITIONAL PRODUCTS ARE AVAILABLE FOR HUMAN ORAL CONSUMPTION. A regular dose of these preparations is 10 billion bacteria per day, which is about 10.000 x more concentrated than the PIP products.

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- Additional to the safety classification by ATCC, the producer of Chrisal's PIP bacterial strains performed a large number of toxicity tests to guarantee the safety of PIP bacteria. No single toxic effect from any of PIP's *Bacillus* strains was ever detected.

- In addition to all the testing done in this study, Chrisal itself, in collaboration with external and accredited laboratories, performed an ongoing series of multiple safety tests, all of which data has been available to the study group and others. In all these tests, all the PIP products were certified as safe to use.

- In view of antibiotic resistance, *Bacillus* strains are Gram-positive organisms, which have much less tendency to develop, acquire or transfer antibiotic resistance. Although certain *Bacillus* strains are intrinsically resistant to certain cephalosporin, macrolide and quinolone antibiotics, from scientific literature, it can be concluded that in all the history of research and studies through to this moment, no *Bacillus* strains are known to transfer this antibiotic resistance to other organisms, neither *in vitro* nor *in vivo*.

- Members of the genus *Bacillus* are used intensively in different kinds of industries because of their high enzyme production capacity. Examples are in food preservation, as well as in washing powders, waste water treatment, and other such usese…

<u>IN CONCLUSION</u>

The probiotic PIP bacteria are perfectly safe to use. These organisms have been officially classified as "save organisms" and have been used for decades without any negative effect. During the course of this specific study patients were not washed directly with these products and so did not come into contact with the cleaning products themselves. However, a direct contact with the PIP bacteria was possible through the

treated surfaces in the patent areas. Given the fact that the PIP beneficial bacteria replace pathogenic bacteria, the only result of a patient's contact with any of these surfaces treated with PIP is a lower chance of contact with pathogens.

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Vandini et. al, 2014. Studie ved tre Europæiske hospitaler, uddrag:

"The most important question concerns the safety of applying microbial cleaning as biocontrol system in healthcare facilities.

Obviously the identification and safety assessment of the bacterial strains used in the products is of utmost importance, as well as the production processes involved throughout the whole production chain. The strains used in this study (Bacillus subtilis, Bacillus pumilus and Bacillus megaterium), were food grade organisms, for which substantial safety and toxicity data existed by the manufacturer, and are also known to be not harmful to humans [48–51]. In addition, all production and quality control processes were ISO9001:2008 certified. Furthermore, the use of probiotics for several biotechnological and biopharmaceutical applications, as indicated by the very recent employment of B. subtilis as a biocontrol agent in aquaculture [52], agriculture [53–55], as adjuvant [56,57] or, in the spore form, as delivery system for development of new vaccines [58–63] has been subject to study and control."