



## Safety Aspects of the Chrisal Probiotic Bacteria

Chrisal pays the utmost attention to the safety of all of its products, both on the chemical and biological level.

For chemical ingredients, a lot of general safety documentation is available and knowledge among customers and the public is large. For the probiotics used in the Chrisal products, however, less knowledge and safety documentation is known among our (potential) customers. As such, we often get questions regarding the safety of our probiotic strains and bacteria in general.

For that purpose, we have drafted this document, to demonstrate the absolute safety of our probiotics. Safety documentation consists of common scientific knowledge about probiotic bacteria, and tests performed specifically on Chrisal products and probiotics.

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### 1. Origin of the Chrisal probiotics

All bacteria used by Chrisal in its products are natural probiotics, also used in food industry as dietary supplements. As such, all Chrisal probiotics are food grade (meaning allowed for human consumption).

#### Definition of a Probiotic:

Live microorganisms that, when administered in adequate amounts, confer a health benefit on the host.

This definition states that probiotics are bacteria that improve your health, which of course, automatically implies **they are absolutely safe**. Also, it states that high enough numbers of probiotic bacteria are needed in order to reach the health benefits.

Chrisal has selected a wide range of probiotic bacteria, Bacillus species, that are classified and recognized as probiotic food supplements. This classification is officially done by two institutions:

## a) ATCC (American Type Culture Collection)

All bacteria that were ever discovered are listed in the official international collection of bacteria. This collection is called the American Type Culture Collection (ATCC) and maintains samples of all bacteria, together with all of the scientific data available about them.



[www.atcc.org](http://www.atcc.org) for all information.

ATCC classifies every existing micro-organism in a biosafety level, level 1 being safe micro-organisms and level 4 being very contagious pathogens.

This biosafety classification is based on U.S. Public Health Service Guidelines <http://www.cdc.gov/biosafety/publications/bmb15/index.htm>

**All Chrisal probiotics classify under Biosafety level 1 and as such, are safe!**

## b) EFSA (European Food Safety Authority)

The second part of the safety classification is done by the European Food Safety Authority (EFSA) who publish a list of micro-organisms that are allowed for human consumption. This list is called the QPS list (Qualified Presumption of Safety) and can be found at this link:



<https://www.efsa.europa.eu/en/topics/topic/qps>

**All probiotic bacteria used in any of the Chrisal products are on the QPS list and as such, are safe for human consumption!**

All Chrisal probiotics are of natural origin and not GMO (Genetically Modified Organisms). They are classified in Biosafety Level 1 (ATCC) and are on the QPS list (EFSA). These official classifications guarantee that Chrisal uses only 100% safe probiotics.

## 2. Specific Safety Experiments on Chrisal Probiotics

Despite the existing official scientific information and classification of our probiotics as being safe; Chrisal has invested significantly in additional safety tests on our probiotics and the products they are used in. We hereby provide an overview:

### a) OECD Tests

An external accredited lab in France was appointed to perform a range of safety trials according to OECD (Organisation for Economic Cooperation and Development) standard normations, including:

OECD423 - acute orale toxiciteit: A test to screen the probiotics for possible toxic effects.

OECD404 - skin irritation: A test to screen whether the probiotics irritate skin.

OECD405 - eye irritation: A test to screen whether the probiotics irritate the eye.

OECD406 – skin sensitisation: A test to screen whether the probiotics affect skin structure

All Chrisal probiotics passed the above tests and did not demonstrate any negative effect.

### b) Cosmetic Registration Tests

Chrisal has a number of probiotic cosmetic products and in Europe such products can not enter the market if they are not registered at the Cosmetic Product Notification Portal, CPNP. In order to register, a wide range of safety documentation has to be provided for which independent safety trials are mandatory.

The following tests were performed by a specialised cosmetics unit of the University of Ferrara (Italy) on the probiotic cosmetic products of Chrisal:

- **Cytotoxicity UNI EN ISO 10993-5** to assess "in vitro" cytotoxic effects (interleukins IL-6 IL-8) and possible irritative nature of the product.
- **In Use Test:** in vivo test with 20 volunteers that use the test product for a month, subjected to microbiological analysis at time intervals to check the microbiological stability during use.
- **PATCH Test:** in vivo dermatological test with 40 volunteers to screen for phenomena of acute irritation.
- **Safety Test:** in vivo dermatological test during 6 months with 40 volunteers dermatological test for phenomena of long term irritation and evaluate the safety of the formulation.

All Chrisal probiotics passed the above tests and did not demonstrate any negative effect.

### 3. Quality Certifications

For a broad range of certifications, safety of the product and its production processes are very important. Chrisal has several international certifications on several of its probiotic products, of which we present the most relevant:

#### a) ISO9001:2008

Besides the actual formulation, the safety of a product is largely depending on the quality of the production process and quality control protocols. Since 1999 Chrisal has the ISO9001:2008 certificate, given after annual external audit.



The Chrisal ISO quality management system involves protocols to manage and improve the quality of all operations within the company, including production, R&D, quality control, sales, administration, general management...

#### b) NSF (National Sanitation Foundation — USA)

Several probiotic products from Chrisal have received the NSF certification in the USA. The NSF certification mark on a product means that the product complies with all standard requirements. NSF conducts periodic unannounced inspections and product testing to verify that the product continues to comply with the standard.



#### c) Green Seal (USA)

Green Seal provides science-based environmental certification standards that are credible, transparent and essential to helping manufacturers, purchasers and consumers make responsible choices that positively impact business behavior and improve quality of life.



A number of probiotic products by Chrisal have been granted the Green Seal mark after thorough inspections of the product, its performance and the production process, including all safety aspects.

## 4. User Experience

Perhaps the most important safety guarantee is the long history of safe use of our probiotic products in many markets. Certainly the most demanding market in terms of safety is healthcare. Already for 10 years, Chrisal has a large number of hospitals that use probiotic products for optimal infection control. These hospitals conducted very long and thorough tests in order to verify the efficacy and safety of the products. Some of the test results were officially published in scientific papers.

The image shows two side-by-side screenshots of PLOS ONE research articles. Both articles are open access and peer-reviewed. The left article, titled "Impact of a Probiotic-Based Cleaning Intervention on the Microbiota Ecosystem of the Hospital Surfaces: Focus on the Resistome Remodulation", is published in February 2016. The right article, titled "Hard Surface Biocontrol in Hospitals Using Microbial-Based Cleaning Products", is published in September 2014. Both articles feature a navigation menu with categories like Abstract, Introduction, Materials and Methods, Results, Discussion, Conclusions, Supporting Information, Acknowledgments, Author Contributions, and References. The right article also includes sections for Reader Comments, Media Coverage, and Figures.

<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0108598>  
<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0148857>

## 5. Conclusion

Based on general scientific information and specific safety research by Chrisal, the above information should demonstrate that the probiotic products from Chrisal are absolutely safe to use. Furthermore, the various quality certifications guarantee a high quality production process.

For all additional questions, please go to [www.chrisal.com](http://www.chrisal.com) for contact details in your region. We will be happy to provide you with profound answers.



## **Probiotic Partners**

Chrisal provides the probiotic technology that powers SmartScrub Restoration. With an extensive background studying the science of beneficial microorganisms, they have led the development of an array of sustainable, bio-based products, specifically designed for SmartScrub Restoration commercial applications.