



Nature's Best

LACTOFERRINE Ultrapure Powder



LACTOFERRINE⁹⁵ ND Pharma



ND Pharma & Biotech

www.ndpharmabiotech.com

Lactoferrine

Lactoferrine, also known as lacto-transferrin, is a multifunctional protein of the transferrin family. The antimicrobial activity of lactoferrine is related to its affinity for Fe^{3+} (Therefore its high ability to compete in the free state with iron-dependent microorganisms), and direct action on the outer membrane of negative Gram bacteria. Many of these studies show that lactoferrine has interesting anti-infective, Immunomodulator and promotional properties of proper bowel ecology. During antibiotic therapy, lactoferrine may on one side increase susceptibility of bacteria to drug therapies and on the other, in synergy with probiotics, promote the growth of beneficial bowel bacterial strains (Lactobacillus or Bifid-bacterium) that depend less on the availability of iron.



About Us

ND Pharma & Biotech Co. is a Biopharmaceutical, Biotechnology, Alimentary and Global Chemical Company specialized in Pharma, Food and Chemical Industries. Within the Food & Nutrition sector we operate in food marketing and international business development. Our people are experts in networking specialized in food ingredients and food technology with a strong focus on New Developments and Added-Value Products for diverse markets.

Thanks to its Quality Products and Excellence in Service our reputation has grown rapidly and we are currently serving European Markets through a network of distributors and agents companies in the United States, Russia, Latin America, Turkey, UAE, India, Bangladesh, South Africa and Canada.



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Lactoferrine

Lactoferrine have:

Antimicrobial proprieties:

Low natural iron saturation - High affinity for iron - Stimulates cell growth - Modulates immune defences.

Ingredient: **LACTOFERRIN 95%**

Product Description: is a freeze-dried protein purified directly from premium quality, fresh bovine milk and/or whey. It has a high affinity for iron and, therefore, is an excellent inhibitor of a wide range microorganisms that require iron for growth. As well as being necessary for normal growth of intestinal cells, lactoferrine functions as an antioxidant in iron mediated oxidation reactions and as an anti-inflammatory agent. It also may play an important role in the transport of iron across the duodenal mucosa. These proprieties make lactoferrine particularly suitable for selected food and pharmaceutical products.

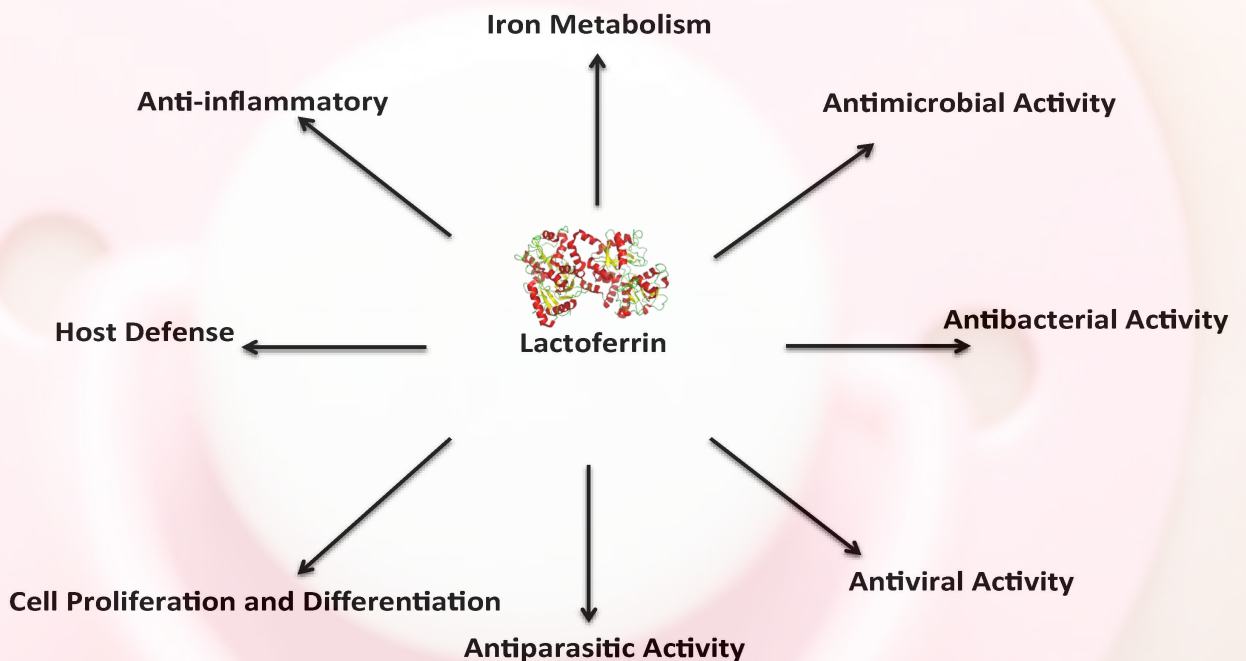
Shelf-Life: 24 months from production date, in original unopened packing under recommended storage conditions.

Storage: Store in cool and dry place free from toxic chemicals and odours. Storage temperature: Ambient

Storage humidity: <85%

Packaging: 5-10 kg PE or Industrial 25 Kg Bag. Packaging materials are declared safe for use in contact with foodstuffs (EU Reg. 1935/2004 on General Requirements for all food contact materials and Regulation 10/2011 on plastic materials and articles intended to come into contact with food).

Lactoferrine 95 is a Product of The EU.



Lactoferrine

BSE/TSE statement

Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)
ND Pharma & Biotech Certifies that the product in object is from animal origin. Even if the item is derived from animal origin, this product can be considered TSE free (Transmissible Spongiform Encephalopathy) and BSE (Bovine Spongiform Encephalopathy) free.

FOOD GRADE STATEMENT

ND Pharma & Biotech certifies that LACTOFERRINE 95 it's in compliance with Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Regulation (EC) No. 853/2004 laying down specific hygiene rules on the hygiene of foodstuffs and Regulation CE 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

LACTOFERRINE 95 is manufactured in strict accordance with COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

MELAMINE STATEMENT

ND Pharma & Biotech certifies that MELAMINE is NOT used during the manufacturing of LACTOFERRINE 95 and so this molecule is absent in this product according to Reg. EU 594/2012.

LATEX STATEMENT

ND Pharma & Biotech hereby confirms to the best of our knowledge and belief that the natural product LACTOFERRINE 95 is not expected to contain latex due to its origin. Furthermore, no latex is used or added during the production process.

GMO STATEMENT

ND Pharma & Biotech certifies that LACTOFERRINE 95 does NOT contain and NOT derive from GMO (Genetically modified organism) in accordance with the following regulation:

- Regulation EC/1829/03 of the European Parliament and the Council of 22 September 2003.
- Regulation EC/1830/03 of the European Parliament and the Council of 22 September 2003 concerning traceability and labeling of genetically modified organisms (GMO).



Lactoferrine

IONIZING RADIATION STATEMENT

ND Pharma & Biotech certifies that LACTOFERRINE 95 is NOT treated with ionizing radiation according to the following Directives:

- Directive 1999/2/EC of the European Parliament on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionizing radiation
- Directive 1999/3/EC of the European Parliament on the establishment of a Community list of foods and food ingredients treated with ionizing radiation. To reduce the microbiological contamination, steam sterilization is used exclusively.

MATERIAL SAFETY DATA SHEET STATEMENT

According to Annex II of the REACH Regulation 1907/2006/EC and following amendment 453/2010/EC Material Safety Data Sheet must be released only in case of dangerous goods. LACTOFERRINE 95 is a harmless natural product and not a dangerous substance. Therefore, there isn't neither the legal obligation nor the necessity to issue a Safety Data Sheet.

NANOMATERIAL STATEMENT

LACTOFERRINE 95 doesn't contain and can't be considered as engineered nanomaterial. This raw material hasn't been produced using nanotechnology.

EU Regulations 1223/2009 and 1169/2011 describe engineered nanomaterial as any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nano-scale.

Properties that are characteristic of the nano-scale include:

- (i) those related to the large specific surface area of the materials considered; and/or
- (ii) specific physic-chemical properties that are different from those of the non-nanoform of the same material;
- (u) 'means of distance communication' means any means which, without the simultaneous physical presence of the supplier and the consumer, may be used for the conclusion of a contract between those parties.



Lactoferrine

PESTICIDES STATEMENT

The product is NOT treated with PESTICIDES.

The product is TREATED with PESTICIDES.

In any case, the product in object is in compliance with the following Regulations:

- Regulation 396/2005/EC and amendments 2006/125/EC, and amendments 149/2008/EC - 839/2008 on maximum residue levels of pesticides in food and feed of plant and animal origin.

RESIDUAL SOLVENTS STATEMENT

Due to the fact extraction is not the production process to produce LACTOFERRINE 95, we declare that no solvent is used.

VEGETARIAN AND VEGAN STATEMENT

LACTOFERRINE 95 CONTAINS animal derivatives. For this reason, is NOT suitable for VEGAN diets.

LEGISLATION STATEMENT

LACTOFERRINE 95 will be manufactured and packaged in accordance with all current relevant EU legislation. The information stated is based upon the product formulation and the data provided by manufacturer at the date of issue of this booklet. It is the responsibility of ND Pharma & Biotech to ensure this information are appropriate and complete.

- ND Pharma & Biotech informs the customer of any change that could modify any of the above-mentioned declarations.

NOTA LEGAL IMPORTANTE - LEA DETENIDAMENTE

Algunas aplicaciones de este producto pueden estar reguladas o restringidas por los estándares nacionales o internacionales (como por ejemplo en su uso para aditivos alimentarios, preparados a base de aditivos u otros ingredientes, en la industria farmacéutica, etc.). El comprador y el eventual usuario, bajo su exclusiva y entera responsabilidad, deben respetar esos estándares, órdenes de cualquier autoridad competente y todas las patentes y derechos de propiedad intelectual que pudieran existir; y deben cumplir con las leyes y normativa aplicables al producto y/o a su actividad. El comprador y el eventual usuario deben determinar, de manera independiente, la idoneidad de este producto para cualquier propósito particular, uso así como su modo de empleo. Hasta donde alcanza nuestro conocimiento, la información aquí recogida es exacta a la fecha de este documento. Ello no obstante, no realizamos ninguna garantía, expresa o implícita, ni aceptamos responsabilidad alguna en relación con esta información o su uso. Esta información debe ser usada por personas técnicamente especializadas a su solo riesgo y discreción y no se refiere al uso de este producto en combinación con cualquier otra sustancia o cualquier otro proceso. Esto no es una licencia bajo ninguna patente o cualquier otro derecho de propiedad intelectual o industrial. El usuario debe, por si solo, en todo caso, determinar la idoneidad de cualquier información o material para cualquier uso contemplado, el modo de empleo de conformidad con la legislación aplicable y si cualquier patente está siendo o ha sido infringida. Nos reservamos el derecho a añadir, suprimir o modificar la información aquí contenida en cualquier momento sin previo aviso.

IMPORTANT LEGAL WARNING - READ CAREFULLY

Some applications of this product may be regulated or restricted by national or international standards (i.e. for food additives, the pharmaceutical industry, etc.). The buyer and the eventual user, in his sole and entire liability, shall respect those standards, orders of any relevant authority and all existing patents and intellectual properties rights; and shall comply with the laws and the regulations applicable to the product and/or to his activity. The buyer and the eventual user must independently determine the suitability of this product for any particular purpose and its manner of use. To our present knowledge, the information contained herein is accurate as of the date of this document. However, we do not make any warranty, express or implied, or accepts any liability in connection with this information or its use. This information is for use by technically skilled persons at their own discretion and risk and does not relate to the use of this product in combination with any other substance or any other process. This is not a license under any patent or other proprietary right. The user alone must finally determine suitability of any information or material for any contemplated use, the manner of use in compliance with relevant legislations and whether any patents are infringed. We reserve our right to make additions, deletions, or modifications to the information at any time without prior notification.

Specification

Parameter	Specification
Product Name	Lactoferrine
Appearance	Red fine powder (with some variations)
Assay (HPLC) LF (%) of protein	≥95% Min
Identity	NMR conforms to structure
Protein	≥95%
Moisture	≤1.5%
Ash	≤1.5%
Iron Saturation	10-20%
Melamine	≤0.50ppm
Calcium	0.0083 mg/100g
Chloride	1000 mg/100g
Phosphorous	0.0053 mg/100g
Potassium	1.2 mg/100g
Sodium	210 mg/100g
Lead	≤0.03ppm
Heavy metals (as Lead)	≤5ppm
Arsenic (as)	≤0.01ppm
Nitrate	≤100ppm
Nitrite	≤2ppm
Solubility (ml/10ml@5%sol)	<0.1
pH solution 2%@20°C	5.5-6.5
Foreign matter	Absent (Class I)
Sediment ADMI/5g	A
Aerobic plate count/g	≤50
Bacillus cereus/g	≤50
Coliforms	Absent
E. Coli	Absent
Enterobacter sakazakii/100g	Absent (ESAK020405)
Clostridium perfringens/g	Absent
Shigella/g	Absent
Sulphite reducing clostridia spores/g	≤25
Enterobacteriaceae/g	Absent
Yeast and Moulds/g	<1
Coagulase+ve staoh aureus/g	Absent
Inhibitory substance ug/ml	<0.003
Salmonella/25g	Absent
Listeria/25g	Absent
Residual Pesticides	absent
Storage Temp	Room Temperature (under 30°C)
Conclusion	Meets requirements of this Specification

ND Pharma & Biotech · Regulatory Statement

LACTOFERRINE 95®

LACTOFERRINE 95 is manufactured in strict accordance with COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

EU REGULATION · SPECS

Bovine Lactoferrin (bLF) is a protein that occurs naturally in cows' milk. It is an iron-binding glycoprotein of approximately 77 kDa and consists of a single polypeptide chain of 689 amino acids.

Production process: Bovine Lactoferrin is isolated from skimmed milk or cheese whey via ion exchange and subsequent ultrafiltration steps. Finally it is dried by freeze drying or spraying and the large particles are sieved out.

It is a virtually odorless, light pinkish powder.

Physical-Chemical properties of Bovine Lactoferrin (bLF):

Moisture: < 4,5 %

Ash: < 1,5 %

Arsenic: < 2,0 mg/kg

Iron: < 350 mg/kg

Protein: > 93 % of which bovine Lactoferrin (bLF): > 95 % of which other proteins: < 5,0 %

pH (2 % solution, 20 °C): 5,2-7,2

Solubility (2 % solution, 20 °C): complete

Information given corresponds to the current state of our knowledge (May 2019)

LEGAL STATEMENT

The information contained within this brochure is provided for our customer's use only and We accept no liability to any third parties, reflecting our current knowledge and experience of the product. All products are supplied in accordance within our general terms and conditions of sale. We can accept no liability for the effects of any chemical combinations or mixtures of the product which are carried out by customers or third parties. In using the product our customers are reminded to comply with all relevant legal, administrative and regulatory requirements and procedures relating to its use and the protection of the environment.

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DTS · Dairy Tech Solutions S.A.U.

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LACTOFERRINE⁹⁵ ND Pharma



ND Pharma & Biotech

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For more information, please write to:
info@ndpharmabiotech.com (Ref:Lactoferrine 95)

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