PB LEINER

The Clear Solution

FREQUENTLY ASKED QUESTIONS

On Quality and Food Safety

This information bundle provides information about the **PB Leiner Argentina** Facility

FREQUENTLY ASKED QUESTIONS on Quality and Food Safety

This information bundle provides information about the PB LEINER Argentina facility and applies to all of its Solugel® products.

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PB Leiner Argentina S.A.
ROSANA MIÑO
Quality Assurance Manager

Last reviewed by: Rosana Miño
Function: Quality and Laboratory Manager
Date: 04.01.2024

SOLUGEL®
collagen peptides

FREQUENTLY ASKED QUESTIONS on Quality and Food Safety

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1. General information and contact details

SUPPLIER INFORMATION

Production site:
PB Leiner Argentina S.A
Ruta 11 Km 455 Parque Industrial
3017 Sauce Viejo –Santa Fe
Argentina
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Fax: +54 342 4501112
info@pbleiner.com

Head Quarters:
Tessenderlo Group
Troonstraat 130
1050 Brussel
Belgium
Tel: +32 2 639 18 11
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Custom tariff number:	35030010
EAN-code:	EAN 128
EU-registration number:	964
CAS Number:	68410-45-7
FDA registration number:	16699242530

HISTORY

PB Leiner is a well-established and renowned gelatin producer whose origins date back to more than a century ago. Operating as a global company, the company has decided in October 2018 to change its company brand name to PB Leiner.
The name was carefully chosen in order to reflect the combined 200 years of history of PB Gelatins and PB Leiner. PB stands for Pont Brûlé, the site in Vilvoorde, Belgium where the company started its operations in 1880. In Argentina the company started its operations in 1988. Since 2004 PB Leiner Argentina is a division of Tessenderlo Group.
For more information: www.pbleiner.com

SITE CONTACTS

QA/QC Manager	Rosana B. Miño	+54 342 5470926
Plant Operations Manager	Pablo Cerminato	+54 342 5673731

ACTIVITIES

Manufacturing and sales of standard and hydrolyzed gelatins for the food industry, gelatins for the pharmaceutical industry and gelatins for technical applications.

CERTIFICATION

PB Leiner Argentina is certified by Bureau Veritas for ISO 9001:2015
PB Leiner Argentina is certified by Bureau Veritas for FSSC 22000 (version 5.1)
PB Leiner Argentina is certified by Bureau Veritas for ISO 14001:2015

EMERGENCY CONTACT DETAILS

24 h emergency contact via site security: +54 342 4501128

EMPLOYMENT / PRODUCTION PATTERN

PB Leiner Argentina has approximately 180 employees of which 120 are production employees working in a rotating 4 shift pattern and a limited number of contracted staff. 9 people are involved in QA/QC functions. The number of contracted staff is depending on business requirements. Contractors are hired through named agencies if needed.

SAFETY AND FOOD SAFETY

PB Leiner Argentina operates a strict safety and food safety policy.

BUSINESS INTERRUPTION PREVENTION

We do have several plants producing the same type of products so one plant can back-up another in case of major interruptions. Minor interruptions can be covered by the well balanced stock of intermediate and final products. It is covered by an in company department with 24 hours support and scheduled backups of all programs.

OCCUPATIONAL SAFETY AND HEALTH

The company has a safety officer and global prevention plan. People are trained for emergencies on a regular basis. All workers received safety and food safety training (including needs and use of personal protection aids), temporary workers and contractors receive training before starting the job. Contractors are screened before they are hired.

ENVIRONMENT AND SUSTAINABILITY

The company has a dedicated person who takes care of environmental requirements and works conform to all national and regional requirements. This is checked on regular base and is part of an auto control program for wastewater and emissions with reporting to the authorities. The focus is to reduce all environmental impact, minimize the use of energy and auxiliaries, and emission of greenhouse gasses.

The company is member of SEDEX to emphasize our commitment regarding social responsibility.

2. Product Information

FAQ 2.1 What is the product's name?

For all intents and purposes, the product's name is "Solugel".

FAQ 2.2 What is the product's legal name?

The product's legal name is "hydrolyzed gelatin".

FAQ 2.3 What is the designation of the goods?

Product obtained by the partial hydrolysis of the collagen from animal origin.

FAQ 2.4 How to describe Solugel® ?

Solugel® can be commonly described as a "hydrolyzed gelatin".

FAQ 2.5 Is the hydrolyzed gelatin fit for human consumption?

Yes, PB Leiner's Solugel® is fit for human consumption, unless stated differently.

FAQ 2.6 What is the origin of the raw materials?

Raw materials, used by PB Leiner Argentina, come from animals that have been declared fit for human consumption after ante- and post-mortem inspection by the official veterinarian authorities and coming from registered slaughterhouses or from registered tanneries (in case of bovine hides) in Argentina, Uruguay or Paraguay. Suppliers are audited by PB Leiner and the veterinary authorities.

FAQ 2.7 What is the full ingredient list?

All Solugel® produced at PB Leiner Argentina is 100% hydrolyzed gelatin.

FAQ 2.8 What is the Solugel's legal status?

The product complies with the requirements for finished products established by the importer country´s
legislation. For exports to the EU, the gelatin complies with the specific requirements described in Regulations (EC) No. 853/2004 and amendments, 2073/2005 and amendments, 2023/915 and amendments and the "GME Standard Code Bacteriological Specification" for food grade gelatin.

FAQ 2.9 What are the Solugel's sensory qualities?

Solugel® comes in the shape of white to slightly yellowish, free flowing powder or agglomerate powder, free from any visible contamination.

FAQ 2.10 What odor does the hydrolyzed gelatin have?

Our hydrolyzed gelatin smells almost neutral, free of foreign odors.

FAQ 2.11 What taste does the Solugel have?

Typical taste, free of foreign taste.

FAQ 2.12 What are the Solugel's chemical characteristics?

Please see the product specifications for details.

FAQ 2.13 What are the Solugel's microbiological characteristics?

Please see the product specifications for details.

FAQ 2.14 Are there any heavy metals present in the hydrolyzed gelatin?

Please see the product specifications for details.

FAQ 2.15 Are there any pesticides or antibiotics present in the hydrolyzed gelatin?

Analyzed on a statistical basis, there are no detectable pesticides or antibiotics to be found in the hydrolyzed gelatin.

FAQ 2.16 Are there any mycotoxins present in the hydrolyzed gelatin?

Mycotoxins are not applicable for Solugel®. There is no potential for mycotoxines in the hydrolyzed gelatin manufactured by PB Leiner, provided that the low water activity of those products, which doesn't permit the development of yeast and moulds, is maintained.

FAQ 2.17 Is the hydrolyzed gelatin irradiated?

No, our Solugel® is not irradiated in any way.

FAQ 2.18 Are there any allergens present in the hydrolyzed gelatin?

Please refer to the annex for a statement on allergens and full list of allergens under current regulations.

3. Site Organization & Lay-Out

FAQ 3.1 What is the size of the site's premises?

The site's total dimensions are approximately 43310 m², 16275 m² of which are covered surface.

FAQ 3.2 Are the production areas generally in a good state of repair?

Yes, we keep our production areas in a good state of repair.

FAQ 3.3 Are the buildings generally in brick/metal?

Yes, all buildings are constructed in brick/metal.

FAQ 3.4 Do any adjoining premises cause a danger to the product?

No, the site is located in an industrial area. All site boundaries are road inside an industrial area.

FAQ 3.5 Is the site perimeter fenced?

Yes, the entire site's perimeter is fenced.

FAQ 3.6 Do production workers enter the production areas through specific, clearly marked entrances?

Yes, we have specific entrances for production workers to enter the production areas.

FAQ 3.7 What's the product sales distribution?

PB Leiner Argentina's products are sold worldwide.

FAQ 3.8 What is the range of products available?

PB Leiner Argentina produces standard and hydrolyzed gelatins for the food industry, gelatins for the pharmaceutical industry.

FAQ 3.9 Do you use off site stores for your products?

All products are stored on-site.

FAQ 3.10 Are stores audited and approved by QA prior to use?

Yes, stores are audited and approved by QA on a regular basis.

FAQ 3.11 Are certificates of analysis available for all products?

Yes, these certificates are readily available upon request.

FAQ 3.12 Are responsibilities clearly defined and delimited?

Yes, the organization chart shows all dependencies.

FAQ 3.13 Is Quality Assurance / Control Unit independent from production?

Yes, the QA / QC department is absolutely independent.

4. Control of Raw Materials & Processing Aids

FAQ 4.1 Which raw materials (RM) are used?

All gelatin produced on the PB Leiner Argentina site comes from bovine hides.

FAQ 4.2 Is your raw material (RM) sourced from pre-audited suppliers?

Yes, PB Leiner Argentina purchases raw materials for from an approved supplier list is in place based on supplier evaluation and periodic audits.

FAQ 4.3 Are all RM fit for human consumption?

Yes, all purchased RM are subject to veterinary inspection (post + ante mortem) by local authorities and are conform to SENASA Decree 4238 (Argentine regulation) and Regulation EC No. 853/2004.

FAQ 4.4 Are all RM inspected?

Yes, every delivery is inspected prior to unloading. A well documented system for incoming goods inspection is in place.

FAQ 4.5 Do specifications exist for purchased RM?

Yes, we apply clear specifications for purchased RM.

FAQ 4.6 Are RM sampled upon receipt?

Yes, we perform an organoleptic control of each delivery, completed with random sampling and analysis.

FAQ 4.7 Are all RM GMO free?

Yes, all RM used by PB Leiner Argentina are 100% GMO free.

FAQ 4.8 Are processing aids purchased from approved suppliers?

Yes, all suppliers must be approved.

FAQ 4.9 Are processing aids certificated and checked for conformance?

Yes, all processing aids are supplied with a certificate of analysis or conformance.

FAQ 4.10 Are processing aids stored in designated areas?

Yes, the site has designated areas for storage of processing aids.

5. Production Process

FAQ 5.1 Is production a 24h a day, 7 days a week process?

Yes, PB Leiner Argentina applies continuous production, 24/7.

FAQ 5.2 Are process manuals available to all operational employees?

Yes, process manuals are readily available.

FAQ 5.3 Is the equipment maintained in a good state of repair?

Yes, all equipment is maintained in a good state of repair to ensure the quality of the end product.

FAQ 5.4 Is critical equipment identified and calibrated?

Yes, calibration procedures and schedules are available for laboratory and process equipment.

FAQ 5.5 Is all process water used fit for food production?

Yes, PB Leiner Argentina uses only potable water for production of hydrolyzed gelatin.

FAQ 5.6 Is the water quality monitored?

Yes, the water quality is monitored by an accredited lab according to EC 98/83 “quality of water fit for human consumption", in addition to in-house inspections of the water quality by the on-site laboratory.

FAQ 5.7 Are food grade lubricants used where necessary?

Yes, wherever there is a potential for food or feed products to come into contact with lubricants, food grade products are used.

FAQ 5.8 Is a preventative maintenance program in place?

Yes, we have a preventative maintenance program at the PB Leiner Argentina site.

FAQ 5.9 Are periodic internal inspections performed according to a self-inspection system?

Yes, we have several operational controls in place which are mainly performed by the quality department.

6. Products, Specifications and Shelf Life

FAQ 6.1 Are all products suitable for Coeliacs, diabetics and lacto-intolerants?

Yes, all PB Leiner Argentina products are suitable for the related dietary restrictions.

FAQ 6.2 Are all products suitable for vegans and vegetarians?

No. As hydrolyzed gelatin is by definition a product of animal origin, it does not suit a vegan or vegetarian lifestyle.

FAQ 6.3 Are all products Kosher suitable?

Kosher certification is available for all PB Leiner Argentina's products.

FAQ 6.4 Are all products Halal suitable?

PB Leiner Argentina is in line with Halal requirements. Halal certification is available for all PB Leiner Argentina 's products. Halal certificates can be issued based on a specific batch and available on demand. They are valid only for this batch.

FAQ 6.5 Are specifications and MSDS available for all products?

Yes, a specification sheet and MSDS (Material Safety Data Sheet) is available for every product.

FAQ 6.6 Is specialist help available if required?

Yes, our applications specialists team is ready to help and provide the necessary assistance.

FAQ 6.7 Do all food products have an expiry date?

All hydrolyzed gelatin produced by PB Leiner Argentina has a shelf life of 5 years, when stored under dry and ambient conditions in the original packaging and in an environment with no specific odor.

FAQ 6.8 Are all products fully traceable in compliance with EU law?

Yes, we ensure full upstream and downstream traceability, according to all applicable EU and Argentine laws.

FAQ 6.9 Does PB Leiner Argentina have a Product Liability Insurance?

Yes, a Product Liability Insurance is in place.

7. Personal Facilities, Hygiene and Cleaning

FAQ 7.1 Does all operational personnel undergo basic food hygiene training as part of site introduction?

Yes. Next to an introductory training there is a yearly refresher training on the training platform.

FAQ 7.2 Are separate changing and washroom facilities available to all staff?

Yes, and personal belongings can be stored in individual lockers in the changing room.

FAQ 7.3 Are separate eating and drinking facilities available to all staff?

Yes. Eating and drinking is not allowed in the production areas, only in dedicated areas.

FAQ 7.4 Is protective clothing available to all staff?

Clothing is provided, laundered and maintained by an approved supplier. Different types of clothing are used for different production areas.

FAQ 7.5 Is smoking allowed in production areas?

No, a strict “no smoking” policy applies to the entire site.

FAQ 7.6 Do all employees undergo a medical examination prior to employment?

Yes, all employees are required to undergo a medical examination before employment, and annual check-up medical examinations are in place.

FAQ 7.7 Is there a jewelry policy for the site?

Yes, in the production areas no jewelry is allowed .

FAQ 7.8 Are contract cleaners used on site?

Contract cleaners are used on site but never used in the production area.

FAQ 7.9 Does QC monitor the effectiveness of the site cleaning?

Yes, periodic hygiene audits are performed on a regular basis.

FAQ 7.10 Are cleaning and disinfecting chemicals stored separately?

Yes, they are stored in segregated areas or in designated lockers.

FAQ 7.11 Are all disinfectants approved?

Yes, only products approved to use in Food Industries are used.

FAQ 7.12 Which precautions do you take to prevent hairs from contaminating the product?

Hair nets are compulsory in our production facilities.

8. GMP and HACCP

FAQ 8.1 Is a HACCP study available for all production processes?

Yes. Please refer to the annex for a full overview of the identified CCP's.

FAQ 8.2 Is the HACCP study performed by a multidisciplinary team?

Yes. Moreover there is also an annual review of the HACCP study.

FAQ 8.3 Are all members of the HACCP team trained?

Yes, training records are available.

FAQ 8.4 Is there a formal system for change control?

Yes, PB Leiner Argentina has a formal change control system in place. In case of a significant change the customers will be informed without being requested to do.

FAQ 8.5 Is the HACCP system separately certified?

No, the HACCP system is a part of the FSSC 22000 v5.1 certification.

FAQ 8.6 Does an approved contractor undertake pest control activities?

Yes. Our pest control activities are subcontracted to ISA, who is responsible for interventions for rodents (1 every two weeks), crawling insects (1 every week) and flying insects (1 by week). On an annual basis, a review of a biologist is performed.

FAQ 8.7 Does the plant operate a closed-door policy to prevent pest access?

Yes, including insect screens on windows that can be opened.

FAQ 8.8 Are training records available for all pest control company employees on site?

Yes, these records are readily available.

FAQ 8.9 Are MSDS maintained for all pest control chemicals used on site?

Yes, these are maintained and available.

FAQ 8.10 Are toxic baits used in final product areas for pest control?

No, these are never used in final product areas.

FAQ 8.11 Does a site plan exist indicating each bait station and the bait in use at each location?

Yes, PB Leiner Argentina uses such a plan/map.

FAQ 8.12 Does the plant have a foreign body control system in place?

Yes. Permanent magnets are used for intermediate products. Metal detection is applied on final packed products:

- non-ferrous: 1.2 mm
- ferrous: 1.2 mm
- stainless steel: 1.8 mm

FAQ 8.13 Does the site have a glass policy?

Yes, we have a policy in place for glass and hard plastics.

9. Laboratory and Product Analysis

FAQ 9.1 Does the plant have its own laboratory on site?

Yes. On site laboratories allow the majority of in-process and finished products to be analyzed.

FAQ 9.2 Is this laboratory externally accredited?

No, the on-site laboratories are not accredited. To be compliant to relevant European regulations, samples are sent out to an external accredited laboratory with long time relationship.

FAQ 9.3 Are all laboratory methods incorporated within the site Quality System?

Yes, all methods are incorporated.

FAQ 9.4 Do you use external laboratories for more specialized analyses?

Yes. Although most of the analyses can be done in-house, we use external accredited laboratories if and when needed.

FAQ 9.5 Are external laboratories approved?

Yes, all external laboratories are certified according to ISO 17025 and part of supplier evaluation system.

FAQ 9.6 Are QC records kept for >5 years?

Yes, QC records are stored for the shelf life plus 5 years.

FAQ 9.7 Are retain samples from each delivery kept for at least the shelf life of each product?

Yes, all samples are stored for the product's shelf life +1 year.

FAQ 9.8 Are training records available for all employees undertaking analysis of final products?

Yes, these records are readily available.

FAQ 9.9 Are results taken from production processes and finished end products able to show conformance to internal/external specification?

Yes. Samples are taken both during production and from finished products. The frequency of sampling is defined. Records of analysis are handled by an ERP system including release of intermediate and final products by dedicated responsible persons.

FAQ 9.10 Are all products released against specifications agreed with customers?

Yes. Final batch release using an ERP system is in place.

10. Traceability, Complaints and Recall

FAQ 10.1 Are reference samples of all products leaving site retained?

Yes, reference samples are retained for at least their minimum shelf life + 1 year, identified by a unique lot number.

FAQ 10.2 Is traceability maintained from final product back to the supplier?

Yes, PB Leiner Argentina ensures full traceability.

FAQ 10.3 Is the traceability system audited with results kept on file?

Yes, a test recall is undertaken on a yearly basis, including trace forward and backward.

FAQ 10.4 Is a record of customer complaints and rejections maintained?

Yes. Complaints are received by the customer services department and recorded on a computerized system designated for this purpose. To all customer complaints a root cause analysis in performed.

FAQ 10.5 Is QA responsible for the investigation of each complaint or rejection?

Not necessarily. QA and customer services co-ordinate the investigation of each complaint. The responsible for investigation depends on the cause.

FAQ 10.6 Does QA inform customers on the results of the investigation based on a complaint?

Yes. For PB Leiner complaints are opportunities for improvement, and customers are informed by the sales representatives about the root cause analysis. The final report sent to the customer is the responsibility of QA.

FAQ 10.7 Are all products leaving site given an individual load number?

Yes, every lot receives an individual number enabling traceability. Batch code consists of a letter L + number of 9 digits given in sequence by SAP system.

FAQ 10.8 Is a product recall plan in place?

Yes, PB Leiner Argentina has a product recall plan.

FAQ 10.9 Is the product recall system tested and documented?

Yes, the recall system is tested and documented on a twice by year basis.

11. Packaging

FAQ 11.1 Do written specifications exist for all packaging materials?

Yes, these specifications are available.

FAQ 11.2 Is packaging material only sourced from approved suppliers?

Yes, a list of approved suppliers is available.

FAQ 11.3 Is the packaging used compliant to EU regulation?

Yes. The packing complies with : Argentina CAA Cap 5, SENASA Disp 1021 and EU regulation 1935/2004 and the amending regulations articles intended to come into contact with food.

FAQ 11.4 Is the weighing equipment used during packing conform to local legislation?

Yes, our weighing equipment is audited and calibrated on a 2-years basis. To ensure accuracy and functionality, the balances are regularly checked internally.

FAQ 11.5 Are vehicles sealed to ensure product integrity?

No, only full loads are sealed.

FAQ 11.6 Are vehicles used for transport inspected prior to loading?

Yes. An inspection and registration is required before loading.

FAQ 11.7 Are products identified?

Yes, every product has a unique incremental number of minimum 9 digits. Also see FAQ 10.7.

FAQ 11.8 Which type of packaging is used?

PB Leiner Argentina uses paper bags 15-20 kg or polypropylene big bags

FAQ 11.9 Are all packaging units labeled?

Yes, all units are labeled with:

- Product name
- Weight
- Lot number
- Expiry date

12. Regulatory Information

FAQ 12.1 Is the product compliant with EU Regulations?

Gelatin manufactured by PB Leiner, intended for dispatch inside or outside the European Community are produced in compliance with :

- Regulation (EC) No 178/2002 of the European Parliament and of the council 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
- Regulation (EC) No 853/2004 of the European Parliament and of the Council and amendments laying down specific hygiene rules for food of animal origin
- Commission Regulation (EC) No 2073/2005 and amendments on microbiological criteria for foodstuffs

Gelatin for technical applications is regulated by EC Regulation No 1069/2009 and 142/2011.

Argentina :

- Decree 4238/68 SENASA
- CAA Argentine Food Code

FAQ 12.2 Is the product compliant with the Food Chemical codex?

Food grade hydrolyzed gelatin meets the specifications of most recent edition of the Food Chemical Codex.

FAQ 12.3 Is the product compliant with the European and US pharmacopeia?

Pharmaceutical grade hydrolyzed gelatin meets the specifications of the harmonized European, US and Japanese Pharmacopoeia.

FAQ 12.4 Is food contact material compliant with EC Regulations?

Yes. Food contact materials in production and packaging material are compliant with

- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

FAQ 12.5 Does the product contain nanoparticles?

No, PB Leiner does not produce engineered nanomaterial as defined in chapter 1 article 2 of Regulation (EC) 1169/2011 on the provision of food information to customers.

FAQ 12.6 Is the producto made from genetically modified organisms?

No, hydrolyzed gelatin is not concerned by EC Regulation 1829/2003, EC Regulation 1830/2003 and EC Directive 2001/18/EC because gelatin does not consist of, does not contain and is not derived from Genetically Modified Organisms (GMOs).

FAQ 12.7 Is an EDQM certificate available for bovine gelatin?

For bovine gelatin an EDQM certificate is available.

13. Attachments

Additional information

The information within this information bundle will be periodically updated. Updated versions of this bundle will be available upon request.

Standard attachments

- ISO 9001:2015 certificates
- FSSC 22000 (version 5.1) certificate
- GMO free statement
- MSDS
- HACCP process flow diagram
- List of allergens
- List of CCP's
- Nutritional data sheet