

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Biogel AG, Haldenstrasse 11, 6006 Luzern** with its site **Biogel AG, Gewerbering 6, 6105 Schachen, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) restricted to gelatine, the manufacturing licence excluding sterile API

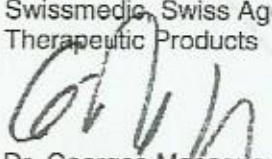
that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention /Co-operation Scheme (PIC/S) and the Directives of the European Commission;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **August 6, 2014**;

that the requirements regarding manufacture and quality control for active pharmaceutical ingredients for export are identical to those applicable to APIs sold in Switzerland.

Berne, November 17, 2014
No. 14-2163

Swissmedic, Swiss Agency for
Therapeutic Products


Dr. Georges Meseguer





Certificate



The Food Safety Management System of



Biogel AG
Tailor-made Gelatine
Haldenstrasse 11
6006 Luzern
Switzerland

has been assessed and complies with the requirements of
FSSC 22000

Certification scheme for food safety systems
including ISO 22000:2005, ISO/TS 22002-1 and
additional FSSC 22000 requirements.

This certificate is applicable for

Headquarter: Luzern / Operation: Schachen

Category C

Production of edible gelatin and collagen hydrolysates

This certificate is provided based on the FSSC 22000 certification
scheme, version 3, published 10 April 2013. The certification system
consists of an annual audit of the food safety management systems
and an annual verification of the PRP elements and additional
requirements as included in the scheme and the ISO/TS 22002-1.

Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
First issue: June 16, 2011
Issue date: June 26, 2015

This SQS Certificate is valid up to
and including June 15, 2017
Scope numbers 3, 13
Registration number 38256



Trusted Cert

X. Edelmann

X. Edelmann, President SQS



R. Glauser

R. Glauser, CEO SQS



Swiss Made





Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the standard specified below.

B I O G E L

Tailor-Made Gelatin

6006 Luzern
Switzerland

Certified area

Headquarter: Luzern/Operation: Schachen

Field of activity

Production of edible gelatin
and collagen hydrolysates

Standard

ISO 9001:2008

Quality Management System

Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: June 26, 2015

This SQS Certificate is valid up to
and including October 27, 2017
Scope numbers 3, 13
Registration number 11804



Trusted Cert

X. Fiedlmann

X. Fiedlmann, President SQS



R. Glauser

R. Glauser, CEO SQS





Suisse - Schweiz - Svizzera

CERTIFICADO DE EXPORTACION

Declaración del exportador



| | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-------------------------------|--------------------------------------------------------------------|
| Exportador : BIOGEL AG (Reg.Nr.: CH-GL-1) Gewerbering 6, CH-6105 Schachen, Suiza | | País de producción : Suiza | |
| Destinatario : A quien le interese | | País de destino : Chile | |
| Medio de transporte : Envío por mar / aire | | Número de cuenta : | |
| Descripción del producto : Proteína hidrolizada en polvo "VITAGEL" (in SECURIPACK recipiente de polietileno de 310 g 410 g 450 g peso neto o bolsitas de 10 g peso neto; Incluye cuchara dispensadora blanca Polymerics 97% Poliestireno 124N, 3% color blanco PS. Para dosificar 10 gr) | | | |
| Peso bruto (kg) : | Peso neto (kg) : | Tipo y cantidad de unidades : | Identificación numérica de lotes de producción : |
| El firmado confirma que : <ul style="list-style-type: none">- los productos corresponden a las exigencias legales de Suiza- los productos son de venta libre en Suiza- son adecuados para el consumo humano- según los conocimientos actuales no resultan peligrosos para la salud- la empresa ha establecido un método de autocontrol | | | |
| Anexos : | | | |
| Nombre y cargo : Roland Fischer Director general | Lugar : CH-6105 Schachen | Fecha : 25.09.2017 | Firma : BIOGEL AG Gewerbering 6, CH-6105 Schachen |

Confirmación de las autoridades oficiales

El control oficial de alimentos firmando confirma, que todos los alimentos e ingredientes puestos en venta en Suiza deben ser producidos según las normas de las leyes alimentarias suizas. Según estas leyes no solo deben ser producidas bajo condiciones higiénicas impecables sino que tampoco deben contener sustancias que podrían ser de riesgo de salud por sus cantidades y propiedades. La empresa exportadora está bajo control periódico de las autoridades de inspección

Administración competente :

| | | | |
|-----------------------------------------|----------------------------|-----------------------|-------------------------------------------------------------------------------------|
| Número del certificado : BIO189 - 17 | Lugar : CH-6002 Lucerna | Fecha : 25.09.2017 | Firma y sello : veterinärdienst Luzern Kantonstierarzt Dr. O. Ineichen |
|-----------------------------------------|----------------------------|-----------------------|-------------------------------------------------------------------------------------|



APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. País: Confederación Suiza, Cantón de Lucerna

El presente documento público

2. ha sido firmado por

S. Menéndez i.a. O. Ineichen

3. actuando en calidad de

Veterinario

4. se halla provisto de sello

Food / Veterinary Office Lucerna

Certificado

5. en Lucerna

6. el *27.09.2017*

7. por la Cancillería de Estado del Cantón de Lucerna

con el número *6867/2017*

10. Firma



Claudia Achermann

Schachen, 12 de Julio 2017

COLLAMIN "Natur'active" Collagen Peptide
COLLAMIN Péptido de Colágeno "Natur'active"

Reporte de datos de estabilidad

| | |
|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Nombre del Producto: COLLAMIN Péptido de Colágeno "Natur'active" | Tamaño del lote: 2'850 kg |
| Forma: Polvo | Lote: 780005 |
| Tipo de envejecimiento: bacteriología | Material de envase y empaque: HD-PE SECURIPAC Containers with LD-PE JAYCAPS caps (310 g, 410 g, 450 g y 10g sachets) |
| Descripción del Material: COLLAMIN Péptido de Colágeno "Natur'active" | Condiciones ambientales del sitio de prueba: 28 °C / 80 % HR |
| Fecha de inicio del estudio: 20.10.2010 | Fecha del terminación del estudio: 20.10.2014 |

| Parámetros Descripción | Referencias Métodos | Especificaciones | Resultados | | | | | |
|---------------------------------|---------------------|------------------|-----------------|-------|-------|-------|-------|-------|
| | | | Tiempo en meses | | | | | |
| | | | 6 | 12 | 24 | 36 | 48 | 60 |
| Viscosidad a 20 % at 25°C | PA4-2 | 2.2 – 3.7 MpA.S | 3.31 | 3.31 | 3.31 | 3.31 | 3.31 | 3.31 |
| Color | PA4-4 | max. 1.5 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 |
| Claridad | PA4-5 | max. 12 F/TE | 11 | 11 | 11 | 11 | 11 | 11 |
| Valor de pH | PA4-3 | 5.0 – 6.4 | 5.7 | 5.7 | 5.7 | 5.7 | 5.6 | 5.6 |
| Humedad | PA4-7 | max. 7.0 % | 6.8 | 6.8 | 6.7 | 6.6 | 6.7 | 6.6 |
| Punto isoelectrico (IEP) | PA4-6 | 7.0 – 9.0 | 8.0 | 7.9 | 7.9 | 8.0 | 8.0 | 7.9 |
| Proteína | GME | 91.00 – 96.00 % | 93.05 | 93.05 | 93.15 | 93.25 | 93.15 | 93.25 |
| Contenido de Ceniza | PA4-10 | max. 2.0 % | 0.15 | 0.15 | 0.15 | 0.15 | 0.15 | 0.15 |
| Metalos pesados (plomo) | GME | max. 1 ppm | <1 | <1 | <1 | <1 | <1 | <1 |
| Hierro (Fe) | GME | max. 30 ppm | <1 | <1 | <1 | <1 | <1 | <1 |
| Cromo (Cr) | GME | max. 2 ppm | <1 | <1 | <1 | <1 | <1 | <1 |
| Cinc (Zn) | GME | max. 50 ppm | 1 | 2 | 1 | 1 | 1 | 1 |
| Arsénico (As) | GME | max. 0.3 ppm | <0.1 | <0.1 | <0.1 | <0.1 | <0.1 | <0.1 |
| Mercurio (Hg) | GME | max. 0.1 ppm | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 |
| Dióxido de sulfuro (SO2) | PA4-11 | max. 10 ppm | 3 | 0 | 3 | 4 | 4 | 2 |
| Peróxido (H2o2) | PA4-12 | max. 10 ppm | 0 | 0 | 2 | 0 | 0 | 0 |
| Densidad a granel | PA4-8 | 250 – 350 g/l | 320.5 | 320.0 | 321.0 | 323.5 | 320.0 | 323 |
| Peso promedio molecular | GME | 2 mill – 3mill | 2.10 | 2.10 | 2.10 | 2.10 | 2.10 | 2.10 |
| Conductividad | PA4-9 | max. 1 mS/cm | 0.2 | 0.3 | 0.3 | 0.3 | 0.2 | 0.2 |
| Fenólicos agentes conservantes | EP4 | ausente | 0 | 0 | 0 | 0 | 0 | 0 |
| Total cuenta microorg. aerobios | GME | max. 1'000 CFU/g | 0 | 0 | 0 | 0 | 0 | 0 |
| Staphylococcus aureus | GME | ausente en 1g | 0 | 0 | 0 | 0 | 0 | 0 |
| Escherichia Coli (per 1 g) | GME | ausente en 10g | 0 | 0 | 0 | 0 | 0 | 0 |
| Salmonelas (per 10 g) | GME | ausente en 25g | 0 | 0 | 0 | 0 | 0 | 0 |

Conclusiones:

De acuerdo con el estudio realizado se indica que el producto COLLAMIN Péptido de Colágeno "Natur'active" es estable física y químicamente a 28°C y 80 % HR durante un periodo de vida útil de 60 meses.

APROBADO POR: Roland Fischer Gerente General



BIOGEL AG

Gewerbering 6, CH-6105 Schachen, Switzerland, Phone +41 41 418 40 50, Fax +41 41 418 40 51

Veterinary Control Nr.: CH-GL-1 / ISO 9001:2015 / ISO 22000:2005 / SWISSMEDIC CERTIFICATE OF GMP COMPLIANCE

BIOGEL AG
 Gewerbering 6, CH-6105 Schachen

COLLAMIN

| | | | |
|--------------------|------------------------------------------|-------------------------|-------------------------------|
| Product: | COLLAMIN Natur'Active Collagen | Packaging: | 310 g HD-PE containers |
| Lot Nr.: | 898911-4 | Production date: | September / 2017 |
| Net weight: | 8'596 kg | Expiry date: | September / 2022 |

Certificate of Analysis

| Physical and chemical properties | Specifications | Analysis methods references | Analysis results |
|-----------------------------------------------------|-------------------------------|-----------------------------|------------------|
| Typical average Molecular Weight (Mw) | 2000 Da | COLLASWISS | 2020 Da |
| Protein Content | ≥ 92 % | COLLASWISS | 92.4 % |
| Viscosity (20% at 25°C) | 2.2 - 3.7 mPa.s | GME* | 3.3 |
| pH value | 5.0 - 6.4 | GME* | 5.8 |
| Color | ≤ 1.5 | COLLASWISS | 0.9 |
| Clarity | ≤ 12 | COLLASWISS | 11 |
| Isoelectric point | 7.0 - 9.0 | COLLASWISS | 8.6 |
| Loss on drying | ≤ 8.0 % | GME* | 7.5 % |
| Bulk density | 0.25 - 0.35 g/cm ³ | COLLASWISS | 0.33 |
| Conductivity | ≤ 1.0 mS/cm | EP 4.5 | 0.46 mS/cm |
| Solubility | Cold water soluble | COLLASWISS | 48 seconds |
| Organoleptical properties (re-constituted solution) | Specifications | Analysis methods references | Analysis results |
| Odor | < 2 | COLLASWISS | 1-2 |
| Taste | < 2 | COLLASWISS | 1 |
| Residue limits | Specifications | Analysis methods references | |
| Ash content | ≤ 1.5 % | COLLASWISS | 0.20 % |
| Heavy Metals | ≤ 50 ppm | USP | 1 ppm |
| Arsenic | ≤ 0.3 ppm | GME* | absent |
| Cadmium | ≤ 0.5 ppm | GME* | absent |
| Chromium | ≤ 2 ppm | GME* | absent |
| Copper | ≤ 5 ppm | GME* | absent |
| Mercury | ≤ 0.1 ppm | GME* | absent |
| Lead | ≤ 1.0 ppm | GME* | absent |
| Zinc | ≤ 50 ppm | GME* | absent |
| Sulphur dioxide (SO ₂) | ≤ 10 ppm | GME* | 4 ppm |
| Peroxide (as H ₂ O ₂) | ≤ 10 ppm | COLLASWISS | 2 ppm |
| Fat | absent | COLLASWISS | absent |
| Microbiological Properties | Specifications | Analysis methods references | |
| Total aerobic count | ≤ 1000 CFU/g | GME* | <10 |
| Yeast and moulds | absence in 1 g | GME* | absent |
| E. coli | absence in 10g | GME* | absent |
| Anaerobic sulfite-reducing sp. | ≤ 10 CFU/g | GME* | absent |
| Salmonella | absence in 25g | GME* | absent |
| Staphylococcus aureus | absence in 1g | GME* | absent |

GME* = Gesellschaft für Mikrobiologie und Hygiene Diagnostik

Lyss, September 10, 2016, Head of Quality Control:

BIOGEL AG

Gewerbestr. 6, CH-6105 Schachen
 Veterinary Control No.: CH-GI.1 / ISO 9001:2015 / ISO 22000:2005 / SWISSMEDIC CERTIFICATE OF GMP COMPLIANCE

Veterinärdienst

Meyerstrasse 20
Postfach 3439
6002 Luzern
Telefon 041 228 61 35
Telefax 041 228 53 57
veterinaerdienst@lu.ch
www.veterinaerdienst.lu.ch

Bio188 - 17

To whom it may concern

Confirmation

The undersigned Official Veterinary Officer is herewith confirming that VITAGEL and COLLAGEN Collagen Peptides I Type B supplied by BIOGEL AG, Gewerbering 6, CH-6105 Schachen / Switzerland (Swiss Plant-Reg.Nr.: CH-GL-1) has been provided from bovine skins only. Afterwards the concentrated Gelatin was sterilised during 4 - 8 seconds at 138 - 140°C. The goods have been manufactured in hygienical safe processing facilities and in conformity with the European Regulations (EC) No 999/2001, (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 for the production of gelatin. The HACCP-methods as well as the company's quality-system according to ISO 9001:2015 / FSSC 22000:2010 / SWISSMEDIC GMP are implemented.

The goods are bacteriologically controlled and fit for human consumption. The gelatin has exclusively been manufactured from impeccable raw materials. The products do not contain any specified risk-material (BSE) nor was it produced out of such material. The used raw material (skins) is not considered BSE risk material by the OIE.

Lucerne, 26 September 2017

CANTONAL VETERINARY OFFICE, CH-Lucerne

A. S. Meisler

Dr. Otto Ineichen, Cantonal Veterinary Officer



APOSTILLE

(Convention de la Haye du 5 octobre 1961)

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Food / Veterinary Office Lucerna

Certificado

5. en Lucerna

6. el 27.09.2017

por la Cancillería de Estado del Cantón de Lucerna

8. con el número 6868/2017-10, Firma

9. Sello



.....
Claudia Achermann

BIOGEL

Pharmaceutical Division

COLLAMIN® Natur'active Collagen Peptide

Naturally derived food grade collagen peptides made out of bovine skins. Applied as bio-active components in versatile nutraceutical and OTC products but also highly nutritional food products. COLLAMIN Natur'active Collagen Peptides avail of excellent dispersibility and solubility characteristics in combination with most neutral organoleptic properties. The perfect choice for multiple added-value nutraceuticals, dietary beverages and functional supplements.

Nutritional Benefits

| Nutrients | Typical quantity |
|---------------------|--------------------|
| Protein | 92 g |
| Fat | absent |
| Fibres | absent |
| Carbohydrates | absent |
| Sodium Salt (calc.) | 120 mg 0.3 g |
| Vitamins | absent |
| Potassium | absent |
| Calcium | 40 mg |
| Magnesium | absent |
| Energy value | 366 kcal / 1544 kJ |

Amino Acids Composition

*essential amino acids

| Amino-acids | Typical G AA/100 g Protein |
|----------------|----------------------------|
| Alanine | 7.8 |
| Arginine | 8.2 |
| Asparagine | 6.5 |
| Cysteine | Traces |
| Glutamine | 12.6 |
| Glycine | 20.6 |
| Histidine | 1.1 |
| Hydroxylysine | 1.3 |
| Hydroxyproline | 11.4 |
| Isoleucine | 1.3 |
| Leucine | 2.9 |
| Lysine | 3.7 |
| Methionine | 0.8 |
| Phenylalanine | 2.0 |
| Proline | 11.2 |
| Serine | 3.8 |
| Threonine | 1.9 |
| Tryptophane | 0.0 |
| Tyrosine | 6.6 |
| Valine | 2.5 |

Recommended daily dosage

10 g consumed with ample liquids

Storage and shelf life

COLLAMIN Natur'active Collagen Peptide will maintain their original properties for 243 months if kept protected from heat and humidity in unopened original packaging.

Packaging

310 g and 450 g sealed PE-cans

10 g sticks packed in cartons of 12 and 30 units each

Regulatory Affairs

COLLAMIN® Natur'active Collagen Peptide is complying with major international regulations presently implemented in most countries comprising also the EU regulations (EC) 853/2004 as well as 2073/2005, 629/2008 (in view of contaminants for dietary supplements) and QB2732 standards. Nevertheless it is recommended that its usage and applications are being adapted to meet compliance with national / local regulations.

BIOGEL

HYDROLYZED COLLAGEN PEPTIDE

HYDROLYZED
Naturally Active
Collagen Peptide



Product Specification

| Physical and chemical properties | Specifications | Analysis methods references |
|----------------------------------------------|-------------------------------|-----------------------------|
| Typical average Molecular Weight (Mw) | 2000 Da | GME |
| Protein Content | ≥ 92 % | GME |
| Viscosity (20% at 25°C) | 2.2 - 3.7 mPa.s | GME |
| pH value | 5.0 - 6.4 | GME |
| Color | ≤ 1.5 | GME |
| Clarity | ≤ 12 | GME |
| Isoelectric point | 7.0 - 9.0 | GME |
| Loss on drying | ≤ 8.0 % | GME |
| Bulk density | 0.25 - 0.35 g/cm ³ | GME |
| Conductivity | ≤ 1.0 mS/cm | EP 4.5 |
| Residue limits | Specifications | Analysis methods references |
| Ash content | ≤ 1.5 % | GME |
| Heavy Metals | ≤ 50 ppm | USP |
| Arsenic | ≤ 0.3 ppm | GME |
| Cadmium | ≤ 0.5 ppm | GME |
| Chromium | ≤ 2 ppm | GME |
| Copper | ≤ 5 ppm | GME |
| Mercury | ≤ 0.1 ppm | GME |
| Lead | ≤ 1.0 ppm | GME |
| Zinc | ≤ 50 ppm | GME |
| Sulphur dioxide (SO ₂) | ≤ 10 ppm | GME |
| Peroxide (as H ₂ O ₂) | ≤ 10 ppm | GME |
| Fat | absent | GME |
| Microbiological Properties | Specifications | Analysis methods references |
| Total aerobic count | ≤ 1000 CFU/g | GME |
| E. coli | absence in 10g | GME |
| Anaerobic sulfate-reducing sp. | ≤ 10 CFU/g | GME |
| Salmonella | absence in 25g | GME |
| Staphylococcus aureus | absence in 1g | GME |

Spezifikation
COLLAMIN

Natur active Collagen Peptide

 Version Nr. 1
 Datum 17.05.17

Seite 1

| Beschreibung | Bedingung | Methode | Spezifikationen |
|-----------------------------------------------|-----------|------------|-----------------------------|
| Chemisch- physikalische Eigenschaften | | | |
| Viskosität bei 25°C | 20 % | B-10.9.30 | 2.2 - 3.7 mPa.s |
| Farbe | 6,67 % | B-10.9.13 | max. 1.5 |
| Klarheit | 6,67 % | B-10.9.4 | max. 12 TE/F |
| pH- Wert | 1 % | B-10.9.5 | 5.0 - 6.4 |
| Feuchtigkeit | 105 °C | B-10.9.6 | max. 8.0 % |
| Isoelektrischer Punkt IEP | | B-10.9.7 | 7.0 - 9.0 |
| Protein | | Kjeldahl | min. 92.00 % |
| Aschegehalt | 550 °C | B-10.9.8 | max. 1.5 % |
| Schwermetall | | USP | max. 50 ppm |
| Arsen (As) | | LFGB:AAS | max. 0.3 ppm |
| Blei (Pb) | | LFGB:AAS | max. 1 ppm |
| Eisen (Fe) | | LFGB:AAS | max. 30 ppm |
| Chrom (Cr) | | LFGB:AAS | max. 2 ppm |
| Zink (Zn) | | LFGB:AAS | max. 50 ppm |
| Kupfer (Cu) | | LFGB:AAS | max. 5 ppm |
| Cadmium (Cd) | | LFGB:AAS | max. 0.50 ppm |
| Quecksilber (Hg) | | LFGB:AAS | max. 0.1 ppm |
| Schwefeldioxid (SO ₂) | | B-10.9.10 | max. 10 ppm |
| Fett | | B-10.9.30 | max. 0.01 % |
| Peroxide (als H ₂ O ₂) | | B-10.9.20 | max. 10 ppm |
| Schüttdichte | | B-10.9.16 | 250 - 350 g/cm ³ |
| Mittl. Molekulargewicht | | Formol Ti. | 2'000 - 3'000 |
| Leitfähigkeit | | EP 8.1 | max. 1 mS/cm |
| Mikrobiologie | | | |
| Gesamtkeimzahl | in 1 g | GME | max. 1'000 |
| Sulfitred. anaerobe Sporen | in 1 g | GME | < 10 |
| E.Coli | in 10 g | GME | abwesend |
| Staphylococcus aureus | in 1 g | GME | abwesend |
| Salmonella | in 25 g | GME | abwesend |