

Technical Product Data

FORTIBONE®

Product description:

FORTIBONE® are highly purified Bioactive Collagen Peptides¹ from bovine bone. The average molecular weight is approx. 5,000 g/mol.

¹BIOACTIVE COLLAGEN PEPTIDES® is a Trademark of GELITA AG

Characteristics:

Light ivory colored, agglomerated powder with a bulk density between 200 and 350 g/L. Specifically neutral in taste and odor and excellently soluble in cold and warm water and liquids.

FORTIBONE® is pure collagen protein with low mineral content and is free of fat, cholesterol, carbohydrates, and dietary fibers.

Bioactivity is monitored according to GELITA's monitoring plan, assured by our quality system.

Amino acid composition⁵

| Amino acid | Weight (%) |
|----------------|------------|
| Alanine | 8.6 |
| Arginine | 7.3 |
| Aspartic acid | 5.8 |
| Glutamic acid | 10.2 |
| Glycine | 22.2 |
| Histidine | 1.0 |
| Isoleucine | 1.4 |
| Leucine | 2.7 |
| Lysine | 3.6 |
| Hydroxylysine | 1.6 |
| Methionine | 0.9 |
| Phenylalanine | 2.1 |
| Proline | 12.7 |
| Hydroxyproline | 11.9 |
| Serine | 3.2 |
| Threonine | 1.8 |
| Tyrosine | 0.8 |
| Valine | 2.4 |

Application and Service:

FORTIBONE® is scientifically proven to stimulate bone matrix synthesis and mineralization. It also could be demonstrated that bone degradation processes can be reduced. Supplementation of **FORTIBONE®** supports the body's own mechanisms for maintaining healthy bones.

Shelf life:

Under dry and odorless conditions **FORTIBONE®** can be stored in the original unopened packaging at ambient temperatures (< 30°C) for 5 years without loss of quality.

Packages:

Multi-ply paper bags with PE-liner containing 15 kg net.

Chemical/Physical Data:

| Parameter | Test Method | Value |
|---|---------------------|-------------------|
| Protein content | Kjeldahl (N x 5.55) | 91 – 95 % |
| Protein content based on dry substance | GELITA method | ≥ 95 % |
| Dry substance (105 °C, 16 h) | GME ³ | 91 – 96 % |
| Ash (550°C)² | USP/GME | ≤ 1.5 % |
| pH (10 %, RT) | Potentiometer | 5.5 – 6.5 |
| Viscosity (10 %, 25°C) | GELITA method | 1.50 – 3.50 mPa s |
| Peroxides | Ph. Eur./GME | ≤ 10 mg/kg |
| Sulphur dioxide² | Ph. Eur./GME | ≤ 10 mg/kg |
| Arsenic² | ICP-OPS | ≤ 0.7 mg/kg |
| Cadmium² | ICP-OPS | ≤ 0.1 mg/kg |
| Chromium² | ICP-OPS | ≤ 5.0 mg/kg |
| Copper² | ICP-OPS | ≤ 2.0 mg/kg |
| Mercury² | AAS | ≤ 0.02 mg/kg |
| Lead² | ICP-OPS | ≤ 0.5 mg/kg |
| Zinc² | ICP-OPS | ≤ 10 mg/kg |

²Reduced frequency testing in accordance to an internal quality program.

The values given are based on average GELITA monitoring data at the time of printing. These values are for information only.

³GME, Gelatine Manufactures of Europe

⁴determined due to national regulations and requirements – not standard

⁵Average score for typical collagen peptides derived from mammals.

The amino acid composition was determined by amino acid analysis as described in Ph.Eur. 2.256 (Version 8).

Nutritional profile (per 100g):

| Nutrient | Typical value |
|----------------------------------|--------------------------|
| Energy value (average) | 1,530 kJ (360 kcal) |
| Fat² | 0 g |
| <i>of which</i> | |
| -saturates² | 0 g |
| -trans fat | 0 g |
| Cholesterol | 0 g |
| Carbohydrates² | 0 g |
| <i>of which</i> | |
| -sugars² | 0 g |
| Protein⁶ | 90.0 g |
| Salt | 0.5 g |
| Sodium | 0.2 g |
| Vitamin D | Not a significant source |
| Calcium | Not a significant source |
| Iron | Not a significant source |
| Potassium | Not a significant source |

⁶The protein is calculated from the nitrogen content by using the factor 5.55 as described in Jones, D.B. (1941) US. Dept. Agric. Circ. 183 (revised).

Regulatory Issues:

FORTIBONE® is pure collagen protein with an extremely low mineral content and is free of fat, cholesterol, carbohydrates, dietary fibers and GMO. The product is in accordance with FDA regulations, HACCP, ISO9001:2015 and FSSC22000:2010. Classified as GRAS (Generally Regarded As Safe). Furthermore, the product is in compliance with regulation (EC) No. 852/2004 on the hygiene of foodstuffs and with regulation (EC) No. 853/2004, laying down specific hygiene rules for food of animal origin. According to regulation (EC) No. 1829/2003 and regulation (EC) No. 1830/2003 the product has not to be labelled as "GMO".

Depending on the application and on the country where the product is to be consumed additional regulatory requirements may apply, therefore it needs to be ensured by the customer/user that the product is used in compliance with national legal requirements. Statements are made to the best of our knowledge at the time of issuing the data sheet. **The values given in the data sheet are for information only and are not to be considered as specifications.** User shall be responsible for the commercialization of this GELITA ingredient also if applied into finished or semi-finished product formulations.

Microbiological limits:

| Parameter | Test Method | Value |
|----------------------------------|-------------------|-----------------|
| Total aerob. micro. count | Ph. Eur./USP | < 1000 cfu/g |
| Total yeast/mould count | Ph. Eur./USP | < 100 cfu/g |
| Sulfite re. anaer. spores | AFNOR NF V59-106 | < 10 cfu/g |
| Escherichia coli | Ph. Eur./USP mod. | negative / 10 g |
| Salmonella | ISO 6579 | negative / 25 g |

Allergen information

| Allergens (REG (EU) No 1169/2011) / USDA | contains |
|--|------------|
| Cereals containing gluten, namely wheat (such as spelt and Khorasan wheat), rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof | No |
| Crustaceans and products thereof | No |
| Eggs and products thereof | No |
| Fish and products thereof | No |
| Peanuts and products thereof | No |
| Soybeans and products thereof | No |
| Milk and products thereof (including lactose) | No |
| Nuts, namely almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts, and products thereof | No |
| Celery and products thereof | No |
| Mustard and products thereof | No |
| Sesame seeds and products thereof | No |
| Sulphur dioxide and sulphites (E220 - E228) at concentrations of > 10 mg/kg or > 10 mg/l expressed as SO₂ | ≤ 10 mg/kg |
| Lupin and products thereof | No |
| Molluscs and products thereof | No |

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