

SAFETY DATA SHEET

Gelatin hydrolysate

A safety data sheet is not required for this product under Regulation (EC) No 1907/2006 (REACH) Article 31.

This SDS, created on a voluntary basis, meets the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) requirements.

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PREVIOUS EDITION:	Edition 16 dated April 30, 2019		

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY

1.1 Product identifier:

Product name: **SOLUGEL®, COPRO** Types: All Porcine types
All Bovine types

Unique Formula Identifier (UFI): Not Applicable. The product is not a hazardous mixture.

SOLUGEL® and COPRO, gelatin hydrolysates from gelatin, are natural occurring biopolymer and for this reason, do not need a registration according to regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as amended.

1.2 Relevant identified uses of the substance and uses advised against

SOLUGEL® and COPRO are used as raw material in food, pharmaceutical, feed, petfood and technical applications. Bovine gelatin hydrolysate may not be used in feed for ruminants as specified in Regulation (EC) 999/2001 as amended.

1.3 Details of the supplier of the safety data sheet

Supplier of the data sheet

Tessenderlo Group N.V. Division PB Leiner
Marius Duchéstraat 260 B-1800 Vilvoorde - Belgium
Tel number: +32 2 255 62 60
Email address: sds.responsible@tessenderlo.com

Supplier of the product

PB Gelatins GmbH Große Drakenburgerstrasse 43 31582 Nienburg- Germany Tel: +49 5021 60 10 0 Fax: +49 5021 60 10 60	PB Leiner USA 7001 Brady Street - Davenport, IA, 52806 - United States of America Tel: +1 563 386 80 40 Fax: +1 563 391 11 38
PB Leiner Argentina S.A. Casilla de Correo 108 Parque industrial Sauce Viejo S3016 WAC Santo Tomé- Santa Fe Argentina Tel: +54 342 4501100 Fax: +54 342 4501112	Tessenderlo Group N.V. Division PB Leiner Marius Duchéstraat 260 B-1800 Vilvoorde – Belgium Tel.: +32 2 255 62 60



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PB Gelatins UK Ltd Unit A6, Severn Road Treforest Industrial Estate, Pontypridd, CF37 5SQ - United Kingdom Tel.: +44 144 384 93 06	PB Leiner Brazil Indústria e Comércio de Gelatinas LTDA Acorizal – Mato Grosso – Brazil Estrada Vicinal Acorizal-Aldeia, km 03, Acorizal, MT, 78480-000 Tel.: +55 65 99339 9505 or +55 65 99934 6506
PB Gelatins (Heilongjiang) Co.,Ltd. Xinyi Industry Park, Kongguo Town Nehe City 161311 Heilongjiang Province, P. R. China Tel.: + 86 452 380 1188	

1.4 Emergency telephone number

PB Gelatins GmbH - Germany Emergency tel number: +49 5021 60 10-0	PB Leiner USA - United States of America Emergency tel number: +1 563-386-8040 Monday to Friday 8.00 to 16.00 Central Time
PB Leiner Argentina S.A. - Argentina Emergency tel number: +54 342 4995622 or + 54 342 4501128	PB Leiner Brazil Indústria e Comércio de Gelatinas LTDA - Brazil Emergency Tel. number: +55 65 99339 9505 or +55 65 99934 6506
Tessenderlo Group N.V., Division PB Leiner - Belgium Emergency tel. number (24h/24): +32 2 255 62 11	PB Gelatins UK Ltd - United Kingdom Emergency tel number: +44 1443 849 300
PB Gelatins (Heilongjiang) Co., Ltd P. R. China Emergency tel number: +86452 3800 577	

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance

Gelatin hydrolysates are not considered as Hazardous Components as described in Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures.

See Section 16 for the hazard statements.

Gelatin hydrolysates are also not listed in the FDA draft list of Potentially hazardous contaminants in animal feed and feed ingredients.

Establishments primarily engaged in manufacturing edible, technical, photographic and pharmaceutical gelatins are classified in Occupational Safety and Health Administration (OSHA) industry group 2899.

Gelatin hydrolysates are listed as UVCB in the EPA's non-confidential chemical substance listings on the TSCA Inventory 042018. Gelatin hydrolysates are defined as Enzymatic digest produced by hydrolysis of gelatin.



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2.2 Label elements:

Gelatin hydrolysates are not classified as dangerous according to the criteria of Regulation (EC) No 1272/2008.

Gelatin hydrolysates are exempted from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

2.3 Other hazards

Gelatin hydrolysates are not persistent, not bioaccumulative and not toxic (PBT) and are also not very persistent and not very bioaccumulative (vPvB) according to Regulation (EC) 1907/2006.

The product was not included in the candidate list for having endocrine disrupting properties. The product is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 and Commission Regulation (EU) 2018/605.

3. COMPOSITION / INFORMATION ON INGREDIENTS

CAS name : Gelatin hydrolysate
Synonyms : Collagen hydrolysate, Collagen peptides, Collagen protein hydrolysate, Hydrolyzed collagen, Hydrolyzed Gelatin, Gelatin Hydrolysate, Hydrolyzed animal protein, Protein hydrolysate from collagen, Protein hydrolysate, SOLUGEL®, COPRO (Remark: In P.R. China, "Collagen peptides" is the only synonym accepted)
Composition : min. 91% hydrolysed protein, < 8% water, inorganic ash < 2% (Ca, Na, SO₄....)

Chemical Family : Protein hydrolysate derived from beef hides, from pigskins or from porcine or bovine bones.

Molecular Formula : (-CO-CHR-NH-)_n

Molecular weight : Not applicable

Hazard symbol : Not applicable

Risks (R phrases) : Not applicable

CAS n° : 68410-45-7

Specific concentration limits and M-factors for substances included in the list of harmonised classification and labelling of substances under the CLP Regulation (EC) 2008/1272: Not Applicable for this product.

For the production of gelatin hydrolysates, raw materials are sourced from healthy animals slaughtered in registered slaughterhouses and declared *fit for human consumption* after ante- and post-mortem inspection by the official veterinary officer. Bovine specified risk material, as specified in Regulation (EC) 999/2001 and in 21 CFR Sec. 189.5 - Prohibited cattle materials, are not used for the production of gelatin.



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4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation : Remove from source of gelatin hydrolysate into fresh air.
Seek medical assistance if necessary
Skin contact : Rinse with water, soap may be used
Eyes contact: Flush contaminated eye/s with clean lukewarm water.
Ingestion : Edible product

4.2 Most important symptoms and effects, both acute and delayed

No acute or delayed effects known after inhalation, skin contact, eyes contact and/or ingestion

4.3 Indication of any immediate medical attention and special treatment needed

No information known on clinical testing or medical monitoring of delayed effects or contraindications.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: water, polyvalent foam, ABC dry chemical powder.

5.2 Special hazards arising from the substance

May form flammable dust in the finely divided and air suspended state.
Under fire conditions, may emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and lower amounts of sulphur oxides.

5.3 Advice for firefighters

Treat as "class A" fire.

Gelatin should be removed from the source of heat/ignition to reduce decomposition, if possible.

Wear protecting equipment including overalls, boots, gloves, eye and face protection and compressed air/oxygen apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Handle as non hazardous material. Wear protective clothing, a dust mask type P1, chemical safety goggles and rubbery boots (type Wellington boots).

6.2 Environmental precautions

Unlikely to present environmental hazard.

Do not flush to drain, surface waters or ground waters. In function of circumstances, inform competent authorities.



6.3 Methods and material for containing and cleaning up

Plug the leak, cut off the supply. Sweep up or vacuum, place in a bag or container and hold for waste disposal. Avoid raising dust. An extreme slip hazard could develop if material spilled on the floor becomes wet. Ventilate area and wash thoroughly spill site with warm water after material pick up is complete. Wash clothing and equipment after handling.

In function of circumstances, inform competent authorities.

6.4 Reference to other sections

See heading 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid dust formation. Do not smoke. Keep away from burning products or heat sources. Avoid release of the substance to the environment. Avoid spills. Keep away from drains. Do not eat, drink or smoke in work areas. Remove contaminated clothing and protective equipment and wash hands before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Keep in tightly closed containers, away from extremes of temperature. Moisture should be excluded from opened bags. Keep a good ventilation of warehouse.

In closed facilities (like silos) avoid accumulation of electrostatic charges and prevent the proximity of any flame or spark created electrically or mechanically.

In case of auto combustion, take appropriate measures in order to avoid contact with air of the burning material.

In order to avoid auto inflammation by chemical reactivity: Do not smoke. Keep away from ignition sources and flame.

Keep a good ventilation of warehouse

Avoid reactive vapours like formaldehyde, which can compromise the products functionality.

In order to avoid auto inflammation by chemical reactivity: Do not smoke

Keep away from ignition sources and flame.

7.3 Specific end use(s)

Good Manufacturing Practice hygiene measures should be applied at all times.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Exposure limit values

Not Applicable. Gelatin is Generally Recognised as Safe (GRAS)

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

No risk known to the safety and health of workers arising from the presence of the substance

8.2.2. Individual protection measures, such as personal protective equipment

Avoid raising dust : Ventilate area.



Respiratory protection : Wear a dust mask type P1 when handling.
Hand protection : Wear safety gloves when manipulating hot gelatin hydrolysate solutions.
Eye protection : Wear safety goggles when handling.
Skin protection : None.
Facilities storing or utilizing this material should be equipped with an eye wash facility and a safety shower.

8.2.3. Environmental exposure controls

Gelatin, from which the gelatin hydrolysate is obtained, is a natural occurring biopolymer and as such does not present a risk for the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance (physical state and colour): Pale yellow free flowing powder.

Odour: slight characteristic "bouillon-like".

pH	:	4.0 - 7.0 in 12.5% aqueous solution at 40 °C.
Melting point/Freezing point	:	Not applicable (with dry product)
Boiling point/Boiling range	:	Not applicable
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability	:	Not applicable
Dust explosion risk	:	Low ATEX risk (Dust explosion class risk class St 1)
Combustibility	:	Not applicable
Vapour pressure	:	Not applicable
Relative density	:	300 - 500 g/l (as packed).
Solubility	:	Highly soluble in water, insoluble in fat (solvent or oil).
Partition coefficient n octanol / water:	Not applicable	
Oxidizing properties	:	none.

9.3 Other information:

Moisture : < 8%

10. STABILITY AND REACTIVITY

10.1 Reactivity

Avoid reactive like formaldehyde, which can compromise the products functionality.

10.2 Chemical stability

10.2 Chemical Stability
Gelatin hydrolysates are stable for at least 5 years when suitably stored in sealed containers under typical warehouse conditions, to prevent ingress or loss of moisture. After 5 years, Bloom gel strength and moisture should be re-tested to establish that no significant change has occurred.

10.3 Possibility of hazardous reactions/ Hazardous decomposition products

May cause toxic fumes of CO, CO₂ and NO_x in case of burning.



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10.4 Conditions to avoid:

Excessive moisture could induce fermentation
Heat that could initiate auto inflammation.

10.5 Incompatible materials

Strong oxidising agents

10.6 Hazardous decomposition products

Growth of Moulds in the case of storage in high moisture conditions.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

No acute toxicity (ingestion, inhalation, skin and eye contact or other routes).
Not classified as inducing skin corrosion/irritation.
Eye damage/irritation: Dust may cause irritation
Respiratory sensitisation: Dust may cause irritation. At very high concentration for prolonged periods could cause blockages of the respiratory tract due to swelling of the dust as it absorbs body moisture.
No skin sensitisation.
Ingestion: Because gelatin hydrolysate can be used as a food ingredient, no detrimental effect would be expected as a result of moderate ingestion.
Germ cell mutagenicity, carcinogenicity, reproductive toxicity: No (test) data available, Not classified as mutagenic, carcinogenic or teratogenic.
No Single Target Organ Toxicity (STOT) - single exposure and repeated exposure
No aspiration hazard
Potential for accumulation: Not likely to accumulate. Easily metabolised.
Gelatin hydrolysate does not cause occupational disease.
Gelatin is not listed in the National Toxicology Program (NTP) Report on Carcinogens and has not been found as a potential carcinogen in the International Agency for Research on Cancer (IARC) Monograph latest edition, the OSHA or the California Prop 65 list.
Not classified as endocrine disruptor.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Not hazardous in water (WGK or WHC = 0). Susceptible to microbiological decomposition.
Not toxic to fish, aquatic invertebrates, aquatic plants (e.g. algae) nor microorganisms (e.g. bacteria).

12.2 Persistence and degradability

Susceptible to microbiological decomposition.
In large quantities in watercourse, would raise the B.O.D. level.
Not photodegradable

13. DISPOSAL CONSIDERATIONS

Small quantities: wash to waste with warm water.
Large quantities: as municipal or commercial waste, according to local regulations.
Packaging: recycle, according to local regulations.



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14. TRANSPORT INFORMATION

14.1 UN Number and 14.2 UN Shipping name

Not applicable

14.3 Transport Hazard class(es)

Gelatin hydrolysates are not subject to transport regulations for dangerous substances:

- European REACH regulation: gelatin is exempted from REACH regulation
- Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180): not applicable
- United States Department of Transportation (USDOT or DOT): not applicable
- Canadian Transportation of Dangerous Goods (TDG): not applicable
- International Air Transport Association (IATA): not applicable

14.4 Packing group: No data available

14.5 Environmental hazard : Not a marine pollutant

14.6 Special precautions for user

Food, pharmaceutical product should be transported according to GMP. Transport in unopened original containers away from extremes of temperature; keep in dry condition to avoid moisture pick up.

In the US, import and transport of products of animal origin are regulated by 9 CFR part 94 and 95.

In Brazil, import and transport of products of animal origin are regulated by RISPOA articles 851 – 869.

15. REGULATORY INFORMATION

In Europe:

Gelatin hydrolysates for human consumption, are regulated by Commission 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 and by Commission Regulation (EC) No 2073/2005 and amendments on microbiological criteria for foodstuffs.

Gelatin and its hydrolysates used for technical applications, are regulated by Regulations (EC) No 1069/2009 and (EU) 142/2011.

This SDS is compliant with Commission Regulation (EU) 2020/878 amending Annex II to REACH Regulation

In the USA, gelatin for human consumption is regulated by:

- FDA 21 CFR 189 and 700 concerning the record keeping requirements for human Food and Cosmetics manufactured from, processed with or otherwise containing Material from Cattle
- FDA 9 CFR parts 309, 310, 311, 318 and 319 concerning the prohibition of the use of specified risk material for human food
- FDA Guidance note for industry on bovine gelatin dated September 1997.
- 9 CFR Parts § 94.23, 94.24 and 94.26.



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In Argentina, gelatin for human consumption is regulated by SENASA (National Health Service and Food Quality) Decree nº 4238/68 on inspection of animal products and by-products and animal derivatives chapter 18.

In Brazil, gelatin for human consumption is regulated by RISPOA article 433.
(RIISPOA = Regulation of industrial and sanitary inspection of products of animal origins)

In China, gelatin for human consumption must comply with the Food Safety Law of the People's Republic of China and the National Standard for gelatin GB 6783- 2013.

Food grade gelatin hydrolysates meets the specifications of most recent edition of Food Chemical Codex. Pharmaceutical grade gelatin hydrolysates meet the specifications of the harmonised European, US and the Japanese Pharmacopeia as well as the Argentina, Brazil and the Chinese Pharmacopoeia.

15.1. Safety, health and environmental regulations/ Legislations: not applicable

15.2. Chemical safety assessment: No chemical Assessment known for gelatin

16. OTHER INFORMATION

Hazard statements: Not applicable

Precautionary statements according to Annex IV of Regulation (EC) No 1272/2008:

- P232: Protect from moisture
- P306+351+338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing

Modifications for revision 17:

Revision of all sections of the SDS to ensure compliance with Commission Regulation (EU) 2020/878 amending Annex II to REACH Regulation.

The above information is believed to be correct at the date of issue but does not pretend to be exhaustive. It shall only be used as a guideline for correct manipulation, storage, use, transport and disposal of the product, but it is not intended as a guarantee or indication of quality. It is relative to the above-mentioned product and loses its validity when used together with other products, except if otherwise indicated in the text.
