COLLAGEN • PROTEIN • LEADER • SINCE 1922

SAFETY DATA SHEET: Collagen Hydrolysate

Based on Regulation EC No 1907/2006 (REACH) Article 31 and Annex II

REF:	GLGSDSCH	EDITION:	3
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1. IDENTIFICATION

1.1 Product Identifier

COLLAGEN HYDROLSYATE (GREAT LAKES GELATIN, CO.) Types: All Porcine types All Bovine types

1.1.1 Substances

Substance Name: Hydrolyzed Collagen CAS No.: 92113-31-0 EINIECS No.: 295-635-5 REACH Registration No.: NA

1.1.2 Other Means of Identification Protein hydrolysates, collagen hydrolysates.

1.2 Intended Use of the Product

Used in cosmetics, pharmaceuticals, feed, pet food, technical applications and as a nutritional fortifier in food and beverage health foods.

Collagen hydrolysate is a natural occurring biopolymer and for this reason, does not need a registration according regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as amended.

1.3 Company/Undertaking Identification

Great Lakes Gelatin 253 Commerce Drive Grayslake, IL 60030 Tel number: 847-223-8141 E-Mail: contactsales@greatlakesgelatin.com

1.4 Emergency Telephone Number

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2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture

Collagen Hydrolysate is not considered as a Hazardous Component as described in Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

It is 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, photographical and pharmaceutical gelatin are classified in Occupational Safety and Health Administration (OSHA) industry group 2899.

2.2 Label Elements

None required.

2.3 Other Hazards

Inhalation :	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.
Ingestion :	Because collagen hydrolysate can be used as a food ingredient, no detrimental effect
	would be expected as a result of moderate ingestion.
Skin Contact :	No detrimental effect.
Eye Contact :	Dust may cause irritation.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Name	Product Identifier	%	GHS Classification
Hydrolyzed Collagen	(CAS No.) 92113-31-0	100	Not Applicable

Synonyms	:	Hydrolyzed Collagen, Collagen peptides, Collagen protein hydrolysate, Hydrolyzed animal protein, Protein hydrolysate from collagen, Protein Hydrolysates.
Chemical Family		Protein hydrolysate derived from porcine or bovine bones, from cattle hides or from pigskins.
Molecular Formula	6	(-CO-CHR-NH-)n
Molecular weight	:	Not applicable
Hazard symbol	1	Not applicable
Risks (R phrases)	/:	Not applicable
CAS n°		92113-31-0
EINICS/ELINCS n°	:	295-635-5

*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 hydrolysates.

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4. FIRST AID MEASURES

4.1 First Aid Measures General

Product is edible and does not pose a risk to health.

4.2 First Aid Measures After Inhalation

If inhalation of dusts occurs causing coughing or discomfort, go to a fresh air environment until dust settles and irritation clears. A dust mask respirator may be used voluntarily to further reduce this risk.

4.3 First Aid Measures After Skin Contact

If contact occurs, wash the exposed area with water and dry skin completely before returning to work. Gloves and or long sleeve clothing can be used to minimize this risk.

4.4 First Aid Measures After Eye Contact

If eye irritation occurs, wash your eyes out with clean water for 15 minutes or until discomfort discontinues. If irritation persists, contact emergency personnel as required. Use of wrap around safety glasses or goggles can minimize this risk.

4.5 First Aid Measures After Ingestion

Drink 1-2 glasses of water. Get medical attention if symptoms occur.

4.6 Self-Protection of the First Aider

No special protective factors are required for first aid response.

5. FIRE-FIGHTING MEASURES

5.1 Suitable Extinguishing Media

Water, polyvalent foam, ABC dry chemical powder.

5.2 Unsuitable Extinguishing Media

No data available.

5.3 Special Exposure Hazards Arising from the Substance

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

5.4 Special Firefighting Procedures

Treat as "Class A" fire. Collagen Hydrolysate should be removed from the source of heat/ignition to reduce decomposition, if possible.

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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions

Handle as non-hazardous material. Wear 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 for Cleaning Up

Sweep up or vacuum, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and thoroughly wash spill site with warm water after material pick up is complete. An extreme slip hazard can develop if material spilled on the floor becomes wet.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling

7.1.1 Protective Measures

Advice on Safe Handling		Prolonged breathing of compound should be avoided.
Fire Preventions	:	Powdered material may form explosive dust-air mixtures. Minimize dust generation and accumulation. Use with adequate ventilation.
Aerosol and Dust Generating Preventions		Proper ventilation should be used when handling.
Environmental Precautions	:	Product is bio-degradable and possesses no increased environmental risks.

7.1.2 Advice on General Occupational Hygiene:

Voluntary use of safety glasses, dermal coverings and a dust mask will reduce the risk of irritation.

7.2 Conditions for Safe Storage

- Keep in tightly closed containers, away from extreme of temperature.
- Moisture should be excluded from opened bags. In closed facilities (like silos) avoid accumulation of electrostatic charges by earthing and prevent the proximity of any flame or spark created electrically or mechanically.
- Keep a good ventilation of warehouse.
- Avoid reactive vapors 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.

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8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1 Control Parameters

Exposure Limit Values: Not Applicable. Collagen hydrolysate is Generally Recognized as Safe (GRAS)

8.2 Exposure Controls

8.2.1 Occupational Exposure Controls:

Avoid Raising Dust	:	Ventilate area.
Respiratory Protection	:	Voluntary use of a type P1 dust mask can be used to reduce the risk of inhalation.
Hand Protection	:	None.
Eye Protection	$\langle \cdot, \cdot \rangle$	Voluntary use of safety goggles can be used to prevent ocular exposure.
Skin Protection	$\left \cdot \right\rangle$	None.

8.2.2. Environmental Exposure Controls

Compound does not create an environmental hazard.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General Information

Appearance : Pale yellow granular powder.

Odor : Slight characteristic "bouillon-like".

9.2 Important Health, Security and Environmental Information:

pH	:	5.0 - 6.5 in 6.67% aqueous solution at 60°C.
Melting Point	: (Not applicable (with dry product).
Boiling Point	:	Not applicable.
Flash Point	:	Not applicable.
Dust Explosion Risk	:	Low ATEX risk (St 1)
Combustibility	:	Not applicable.
Oxidizing Properties	:	None.
Vapor Pressure	:	Not applicable.
Relative Density		300 - 500 g/l (as packed).
Solubility	:	Highly soluble in water, insoluble in fat (solvent or oil).
Partition Coefficient in Octanol /Water	:	Not applicable.

9.3 Other Information:

Moisture	: < 15%
Dioxine	: < 2,5 ng WHO TEQ/kg (88% D.S.)
Dioxine + DL-PCB's	: < 7 ng WHO TEQ/kg (88% D.S.)

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10. STABILITY AND REACTIVITY

10.1 Reactivity

Not known to be chemically reactive with other substances causing a hazardous reaction.

10.2 Chemical Stability

Chemical is stable. Fine powder material may form explosive dust-air mixtures.

10.3 Possibility of Hazardous Reactions

Unknown.

10.4 Conditions to Avoid

Unknown.

10.5 Incompatible Materials

Not known to be incompatible with other substances creating a hazardous reaction.

10.6 Hazardous Decomposition Products

Carbon dioxide, carbon monoxide, oxides of nitrogen. Powdered material may form explosive dust-air mixtures.

11. TOXICOLOGICAL INFORMATION

- No acute toxicity (ingestion, inhalation, skin and eye contact or other routes).
- No skin or eye irritation
- No corrosivity
- No sensitization.
- No chronic hazards have been identified. Collagen hydrolysate does not cause Asthma or any occupational disease.
- No repeated dose toxicity
- No CMR effects i.e. No carcinogenicity, no teratogenicity and no embryo toxicity, no reproductive toxicity and no mutagenicity
- Potential for accumulation: Not likely to accumulate. Easily metabolized as protein.
- Carcinogenicity: Not listed as a carcinogen by ACGIH, IARC, NTP or California prop 65.

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12. ECOLOGICAL INFORMATION

12.1 Eco Toxicity

Not hazardous in water (WGK or WHC = 0). Susceptible to microbiological decomposition. In large quantities in watercourse, would raise the B.O.D. level.

Not toxic to fish, aquatic invertebrates, aquatic plants (e.g. algae) nor microorganisms (e.g. bacteria).

12.2 Persistence and Degradability

No bioaccumulation. Decomposed in soil, biodegradable. Not photodegradable.

13. DISPOSAL CONSIDERATIONS

Small Quantities :	Wash to waste with warm water.
Large Quantities	Dispose as municipal or commercial waste, according to local regulations.
Packaging :	Recycle, according to local regulations.

14. TRANSPORT INFORMATION

Collagen hydrolysate is not subject to transport regulations for dangerous substances.

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 accordance with Commission Regulation (EC) No 1069/2009 and 142/2011 and amendments, gelatin and their Hydrolysates, when used for technical applications should be dispatched from one Member State to another Member State in containers or vehicles which are prominently and, at least for the period of transport, indelibly color-coded using the color green with a high content of blue. During transport, a label attached to the container or vehicle must clearly indicate the category of the animal by-products from which the processed products were derived and bear the words: "not for human consumption".

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15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations / Legislation Specific for the Substance or Mixture

The regulation (EC) 1907/2006 of December 18, 2006 concerning the Registration, Evaluation Authorization and Restriction of Chemicals (REACH) does not apply to Gelatine / Collagen and their hydrolysates as they are natural polymers and/or chemically modified natural polymers. The amino acids are regarded as non-isolated intermediates and therefore do not have to be registered. The exemption of the registration of Gelatine / Collagen, their hydrolysates and their monomers is confirmed by ECHA and the German REACH help desk.

15.2 Chemical Safety Assessment:

Compound is an organic, stable, edible food grade product made from animal by-products. The compound is not classified as a hazardous chemical / substance and does not adversely affect the environment or human health as defined in the GHS.

*In the USA, collagen hydrolysate 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 and by 9 CFR 94.18.
- Restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy and FDA Guidance note for industry on bovine gelatin dated September 1997.

*Food grade collagen hydrolysate meets the specifications of most recent edition of Food Chemical Codex; Pharmaceutical grade collagen hydrolysate meets the specifications of the European and US Pharmacopoeia except that it has no gel strength.

16. OTHER INFORMATION

Hazard Symbol: Not Applicable Safety Phrases: S16 Keep away from sources of ignition

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.