Elastin CLR

Elastin CLR

Raw Material Documentation

1. Trade name: **Elastin CLR**

Use: **Active for cosmetics**

Manufacturer: **Supplier:**

CLR – Chemisches Laboratorium
Dr. Kurt Richter GmbH
Sperenberger Straße 3
12277 Berlin / Germany
Tel.: +49 30 851026 – 0

Contact for information:
Sales Department

2. Raw Material Composition

Chemical Name (IUPAC), Formula
Not applicable, as mixture.

Characterization
Elastin partial hydrolysate in weakly acidic, aqueous buffer solution.

Origin
animal (bovine neck tendons)

3. INCI Name
(composition in percentages [ranges] according to FDA recommendations)

INCI Name	EU Name	Range (FDA)
Hydrolysed Elastin The rest consisting of buffer solution	./.	0.1 – 1 %

4. Registration

EINECS Designation:	*EINECS No.:*	CAS No.:
Elastins, cartilage, hydrolysates	309-148-3	100085-10-7

5. Pharmacopoeial Registration
./.

6. Manufacturing Procedure

Elastin CLR is obtained from bovine neck tendons using a special solubilisation procedure. The partial hydrolysate so obtained is characterized by the fact that the solution contains larger, typical structural units of elastin, such as α-elastin with a molecular weight of approx. 70000 Dalton.

7. Raw Material Properties

Appearance, odor
Yellowish, clear liquid. Almost odorless.

Solubility
Soluble in water in any proportion.

Recommended Use
Emulsified, aqueous or aqueous-alcoholic skin regenerating preparations designed for application to ageing skin to help prevent premature loss of elasticity.

8. Analytical Data

Quality Control

Refractive index n_D^{20}	1.334 – 1.336
Densitiy 20 °C	0.998 – 1.004 g/ml
pH value	3.8 – 4.2
Dry residue (2 hrs; 120 °C)	0.70 – 0.95 %
Protein (Biuret)	4.0 – 5.0 mg/ml
Total nitrogen	0.05 - 0.07 %
Preservative	0.15 – 0.25 % Sodium Benzoate
Colony forming units	
Total aerobic microbial count (TAMC)	< 100/ml
Total combined yeasts/moulds count (TYMC)	< 10/ml
	in absence of non conforming organisms

9. Methods of Identification

Total of quality control data.

Identification of higher molecular weight constituents in Elastin CLR is done by carrying out the coacervation test. On heating a sample of Elastin CLR to approx. 30 – 35 °C, turbidity will occur which is caused by aggregation of α-elastin molecules (formation of fibers). The temperature at which coacervation occurs depends on the pH. The process can be reversed by cooling down.

10. Contaminants/Reaction Intermediates occurring in the Raw Material or its Production Process:

Contaminants	not to be expected	Concentrations	Methods
Formaldehyde	x		
Nitrosamines	x		
1,4-Dioxane	x		
Free ethylene oxide	x		
Monochloroacetic acid	x		
Dichloroacetic acid	x		
Monomers	x		
Halogenous organic compounds	x		
Polycyclic aromatic hydrocarbons	*		
Pesticides	*		
Heavy metals			
As		< 0.15 ppm	ICP-OES** ***
Cd		< 0.01 ppm	"
Pb		< 0.2 ppm	"
Hg		< 0.05 ppm	"
Others	./.		

* no data available **spot-checked ***(DIN EN ISO 11885-E22)

11. Stabilizing Additives

Preservative: approx. 0.2 % Sodium Benzoate

12. Microbiology

Colony forming units (the total of aerobic, anaerobic and fungal colonies): < 100/ml.
Check for absence of characteristic pathogenic germs (Aspergillus niger, Candida albicans, Staphylococcus aureus, E. coli, Pseudomonas aeruginosa) is done using a sample of 10 ml.

13. Physiological Safety

Acute Toxicity
LD_{50} oral: > 5000 mg/kg body weight (rat): non-toxic

Primary Skin Irritation
Primary skin irritation/rabbit/Federal Register Test: mild irritant

Epicutaneous test/human/Patch Test: non-irritant

Experienced Skin Tolerance under Use Conditions
Product has been used in cosmetics for many years; negative effects have not been reported.

Primary Mucous Membrane Tolerance
Primary mucous membrane irritation test/rabbit eye/Federal Register Test: non-irritant

Sensitization
Sensitization test/guinea-pig/Magnusson & Kligman: non-sensitizing

14. Information on Percutaneous Permeation

no data available

15. Genotoxicity

Bacterial Testing
no data available

Non-Bacterial Testing
no data available

16. Human Experience (as far as available)

Product has been used in cosmetics for many years; negative effects have not been reported.

17. Other Information

Chronic Toxicity
no data available

Subchronic Toxicity
no data available

Teratogenicity
no data available

Toxicokinetics
no data available

Additional Genotoxicological Tests (as far as required)
no data available

Mutagenicity
no data available

BSE Hazard
Origin of raw material: bovine
Material used: neck tendons

Classification and resultant factorial sum for Elastin CLR according to the "Guidelines on safety requirements for cosmetic products containing ingredients derived from bovines, sheep or goats to avoid the risk of transmission of BSE or Scrapie dated 9th May 1994 [Bundesministerium für Gesundheit (German Ministry of Health)]: 24 (the recommended minimum sum is 20).

This risk analysis relates to an anticipated dosage of 10 % of this product in a cosmetic preparation and a daily dosage of 1 g of the cosmetic product when used on a regular basis. Information on how the factorial sum is generated by the individual factors is available on request.

18. Potential Risks presented by UV Exposure and on Inhalation

Phototoxicity
Under the test conditions applied, Elastin CLR was found to be non-phototoxic.

Photosensitization
Under the test donations applied, Elastin CLR was found to be non-photosensitizing.

Toxicity on Inhalation
no data available

19. Ecology

Biodegradability
As carrier of a partial hydrolysate of animal protein in aqueous buffer solution, Elastin CLR is easily biodegradable.

Acute Aquatic Toxicity
- Bacteria
- Algae
- Daphnia
- Fish

no data available

Water Pollution Hazard Class:
1 [Classification according to the Regulations for Water Pollutants ("VwVwS") of May 17, 1999, Annex 2 / Ident No. 1431, "Protein hydrolysate"]

authorized by:

W. Reinhold
(Director Quality Assurance)
– valid without signature –

Elastin CLR

Product Specification

Characteristics

Elastin CLR is obtained from bovine neck tendons. Its manufacturing process secures that the partial hydrolysis necessary for the solubilization only proceeds to such an extent that in Elastin CLR elastin typical protein structures could be detected – such as α-elastin with a molecular weight of about 70.000. This is important for the tested, efficacy of this product,

INCI Name	**CAS No.**	**EINECS No.**
Hydrolyzed Elastin	100085-10-7	309-148-3

Analytical Data

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Total Nitrogen (Kjeldahl)	0.05 – 0.07 %
Preservative	0.15 – 0.25 % Sodium benzoate
Colony forming units	
Total aerobic microbial count (TAMC)	< 100/ml
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Quantitative Determination of Elastin CLR

The elastin content in Elastin CLR is to be determined by means of the Biuret reaction.

1. Biuret reagent
   1.5 g Cu $SO_4 \cdot 5\ H_2O$ and 6 g sodium potassium tartrate (Rochelle salt, Na K $C_4H_4O_6 \cdot 4\ H_2O$) are dissolved in 500 ml water. Whilst stirring 300 ml of a 10 % (W/V) NaOH solution as well as 1 g KJ are added. This solution is filled up to the marking in a 1000 ml measuring flask with distilled water and thereafter transferred in a plastic container for the storage.

2. Determination
   To determine the elastin content 4 ml of the Biuret reagent and 1 ml of the Elastin CLR solution are thoroughly mixed and allowed to stand at room temperature for 30 minutes. Analogous to this, a blank value is prepared with 1 ml water instead of the elastin solution. The absorbance of the sample is determined at 540 nm.

3. Calibration
   For the calibration Elastin CLR has been separated from the preservative by chromatography on a P-2-column (Bio-Gel P2, Messrs. BIO-RAD) and the pure elastin content has been lyophilised. Calibration solutions of different concentrations have been prepared with the lyophilisate and the absorbance has been determined according to the method described under point 2

Content [mg Elastin/ml H_2O]	Absorbance [540 nm]
0.5	0.030
1.0	0.055
5.0	0.265
10.0	0.512

   The calibration curve results from the absorbance as function of the content.

Physiological Safety

Acute oral toxicity

LD_{50} in rats: greater than 5000 mg/kg body weight.
No toxicological effects could be observed.

Eye irritation potential

Elastin CLR, undiluted, has undergone the 'Federal Register Eye Irritation Test'. The result 'non irritant' suggests the unobjectionable use of Elastin CLR in the vicinity of the eye.

Skin tolerance and sensitization

The 'Federal Register Skin Irritation Test' in the rabbit revealed a primary irritation index of 0.6 for Elastin CLR, applied undiluted, which is within the lowest and, thus, normal range for this type of product.

In the 'Magnusson and Kligman Maximisation Study' no sensitizing properties could be observed for Elastin CLR, applied undiluted.

Phototoxicity and Photosensitization

No phototoxicity or photosensitization could be ascertained under the conditions of the study after application of Elastin CLR to guinea pig skin.

Elastin CLR

Product Specification

Mode of action

Elastin is the main protein in the elastic fibres, tendons and ligaments. In the connective tissue of the skin, however, it is present with 2 - 4 % only, whilst the collagen portion is about 70 %. From the interwinding of the elastic fibres with those of the collagen result the mechanical properties of the connective tissue. In the course of the aging process an advanced cross-linking of the collagen takes place whereby the flexibility of the connective tissue decreases whilst, at the same time, the elastin fibres get thicker and become brittle and thus forfeit their rubber-like properties. The reason is, on the one hand, an addition of lipides to the hydrophobic groups of the elastin, and, on the other hand, an increase of its content of calcium and magnesium. These processes which take place in the cutis lead to a loss of elasticity and moisture of the tissue which, in turn, results in formation of wrinkles of the skin.

In clinical tests on human beings as well as in animal tests, in the course of which creams with Elastin CLR were to some extent applied daily over a period of one year, an increase of elastic fibres in the skin could be determined histologically which were, against controls, at the same time finer structured and more regularly arranged.

Application

Due to the subepidermal interwinding of collagen with elastin, preparations with Elastin CLR represent for the regenerating skin care a convenient supplement to cosmetics containing Collagen CLR as carrier of native soluble collagen.

Elastin CLR can be used in emulsified, aqueous and aqueous-alcoholic skin regeneration preparations.

Dosage

5 - 10 %.

Appearance/Odor

Yellowish clear liquid. Almost odorless.

Solubility

Clearly soluble in water, water-alcohol mixtures and alcohol.

Elastin CLR

Product Specification

Processing

Elastin CLR is thermo-stable. Nevertheless, we recommend to add this active agent in the manufacture of emulsified preparations only to the creams and liquid emulsions after these have cooled down to about 35 °C. The reason for this recommendation is that in the course of warming Elastin CLR – depending on the pH value of the aqueous phase – a turbidity may occur which is caused by a reassociation of the α-elastin contained in Elastin CLR to fibres (coacervation). This process is reversible by cooling down, however, this might be disturbed by other components of the water phase.

Elastin CLR does not affect the colour of cosmetic preparations.

Cosmetics with Elastin CLR may be perfumed without difficulties.

Storage

At cellar to room temperature (10 - 20 °C), in well closed containers, protected from light. Protect from frost.
When possible, Elastin CLR should not be stored for longer than 2 years before processing.

Packing

Available pack sizes: 1 kg; 5 kg; 25 kg
Sample size: 50 g

Safety Data Sheet
according to Regulation (EC) No. 1907/2006 (REACH)

Trade name :	Elastin CLR		
Revision date :	17.06.2019	**Version (Revision) :**	3.3.1 (3.3.0)
Print date :	23.06.2021		

SECTION 1: Identification of the substance/mixture and of the company/ undertaking

1.1 Product identifier
Elastin CLR (150)

1.2 Relevant identified uses of the substance or mixture and uses advised against
Relevant identified uses
PC 39 - Cosmetics, personal care products
Uses advised against
No information available.
Remark
The product is intended for professional use.

1.3 Details of the supplier of the safety data sheet
Supplier (manufacturer/importer/only representative/downstream user/distributor)
CLR Chemisches Laboratorium
Dr. Kurt Richter GmbH

Street : Sperenberger Strasse 3

Postal code/city : D-12277 Berlin

Telephone : +49 30 851026-0

Telefax : +49 30 851026-85

Information contact : Info@clr-berlin.com

1.4 Emergency telephone number
+49 30 851026-0 (Available at: Mon.-Thu. 8.00 am - 4.30 pm; Fri. 8.00 am - 3.30 pm)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008 [CLP]
None

2.2 Label elements
According to EC directives or the corresponding national regulations the product does not have to be labelled.

2.3 Other hazards
None

SECTION 3: Composition/information on ingredients

3.2 Mixtures
Description
Elastin partial hydrolysate in weakly acidic, aqueous solution.

Hazardous ingredients
None

This mixture contains the following substances of very high concern (SVHC) which are included in the Candidate List according to Article 59 of REACH
None

This mixture contains the following substances of very high concern (SVHC) which are subject to authorisation according to Annex XIV of REACH
None

Additional information
All ingredients of this mixture are (pre)registered according to REACH regulation.

SECTION 4: First aid measures

4.1 Description of first aid measures

Following inhalation
Provide fresh air.

In case of skin contact
Water and soap

After eye contact
After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion
Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed
No information available.

4.3 Indication of any immediate medical attention and special treatment needed
None

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media
Water Carbon dioxide (CO2) Foam

Unsuitable extinguishing media
None

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products
The product itself does not burn.

5.3 Advice for firefighters
Do not inhale explosion and combustion gases.

5.4 Additional information
Do not allow run-off from fire-fighting to enter drains or water courses.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
No special measures are necessary.

6.2 Environmental precautions
Do not allow to enter into surface water or drains.

6.3 Methods and material for containment and cleaning up
Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

6.4 Reference to other sections
None

SECTION 7: Handling and storage

7.1 Precautions for safe handling

None

7.2 Conditions for safe storage, including any incompatibilities

Hints on joint storage

Storage class (TRGS 510) : 10

Further information on storage conditions

Protect against : UV-radiation/sunlight Frost

Storage temperature : 10 - 20 °C (50 - 68 °F)

7.3 Specific end use(s)

None

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

DNEL-/PNEC-values

DNEL/DMEL

No substance related limit value derivable.

PNEC

No substance related limit value derivable.

8.2 Exposure controls

Personal protection equipment

Eye/face protection

Suitable eye protection

Eye glasses with side protection

Skin protection

Hand protection

Suitable gloves type : Disposable gloves.

Suitable material : PE (polyethylene) NR (natural rubber, natural latex) NBR (Nitrile rubber)

Thickness of the glove material : > 0.1 mm

Respiratory protection

Usually no personal respirative protection necessary.

General information

When using do not eat, drink, smoke, sniff. Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Liquid

Colour : Yellowish

Odour

Almost odourless.

Safety characteristics

Physical state :			Liquid	
Initial boiling point and boiling range :	(1013 hPa)	approx.	100	°C
Flash point :		>	100	°C
Vapour pressure :	(50 °C)		No data available	
Density :	(20 °C)		0,998 - 1,004	g/cm³
Solvent separation test :	(20 °C)		No data available	
pH :			3,8 - 4,2	
Viscosity :	(20 °C)	approx.	1	mPa*s

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

No information available.

10.2 Chemical stability

No information available.

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Acute oral toxicity

Parameter :	LD50
Exposure route :	Oral
Species :	Rat
Effective dose :	> 5000 mg/kg
Result :	not toxic

Corrosion

Skin corrosion/irritation

Parameter :	Skin corrosion/irritation
Species :	Rabbit
Result :	Minimal irritant
Method :	Federal Register Test :
Parameter :	Skin corrosion/irritation
Species :	Human
Result :	Not irritant
Method :	Patch test

Serious eye damage/eye irritation

Parameter :	Serious eye damage/eye irritation
Species :	Rabbit
Result :	Not irritant
Method :	Federal Register Test :

Respiratory or skin sensitisation

Skin sensitisation

Parameter :	Sensitation
Species :	Guinea pig
Result :	Not sensitizing
Method :	OECD 406

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

The ingredients in this mixture do not meet the criteria for classification as CMR category 1A or 1B according to CLP.

SECTION 12: Ecological information

12.1 Toxicity

No information available.

12.2 Persistence and degradability

Biodegradation

Biodegradable.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

12.6 Other adverse effects

No information available.

12.7 Additional ecotoxicological information

None

SECTION 13: Disposal considerations

13.1 Waste treatment methods

No information available.

SECTION 14: Transport information

14.1 UN number

No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

Land transport (ADR/RID)

No dangerous good in sense of these transport regulations.

Class(es) : -

Sea transport (IMDG)

No dangerous good in sense of these transport regulations.

Class(es) : -

Air transport (ICAO-TI / IATA-DGR)
No dangerous good in sense of these transport regulations.
Class(es) : -

14.4 Packing group
No dangerous good in sense of these transport regulations.

14.5 Environmental hazards
No dangerous good in sense of these transport regulations.

14.6 Special precautions for user
None

14.8 Additional information
Transport temperature: 4 – 20 °C / 39 – 68 °F, protect from frost.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
National regulations
Technische Anleitung Luft (TA-Luft)
Weight fraction (Number 5.2.5. I) : < 5 %
Water hazard class (WGK)
Class : nwg (Non-hazardous to water) Classification according to AwSV
Additional information
Substance/product listed in the following inventories
EINECS/ELINCS DSL/NDSL IECSC

15.2 Chemical safety assessment
No information available.

SECTION 16: Other information

16.1 Indication of changes
15. Water hazard class (WGK)

16.2 Abbreviations and acronyms
None

16.3 Key literature references and sources for data
None

16.4 Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]
No information available.

16.5 Relevant H- and EUH-phrases (Number and full text)
None

16.6 Training advice
None

16.7 Additional information
None

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily

valid for the new made-up material.