



Maricol S

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Maricol S

Raw Material Documentation

- 1. Trade name:** Maricol S
- 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 Documentation

Chemical Name (IUPAC), Formula

Not applicable, as mixture.

Characterization

Maricol S contains fish skin derived native, soluble collagen with undamaged, i.e. skin identical, structure. Through special physico-technical process steps Maricol S has a minimized odour.

Origin

Tuna skin

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

INCI Name	EU Name	Range (FDA)
Soluble Collagen (the rest consisting of aqueous buffer)	./.	0.1 – 1.0 %



Maricol S

Raw Material Documentation

4. Registration

EINECS Designation:

Collagens

EINECS No.:

232-697-4

CAS No.:

9007-34-5

5. Pharmacopoeial Registration

.I.

6. Manufacturing Procedure

The native soluble collagen is gently extracted from fish skin and filtered. The collagen content then is adjusted to the desired value by means of ultrafiltration.

7. Raw Material Properties

Appearance, Odor

Water-clear, almost transparent, viscous liquid. Almost odorless.

Solubility

Soluble in water.

Recommended Use:

Maricol S as native soluble collagen is particularly suitable for the care of dry, UV-exposed and environmentally stressed skin as well as aging skin. Its nature identical structure helps to form a protective shield on the skin.

Maricol S can be used in emulsified and aqueous formulations designed to moisturize and protect the skin.



Maricol S

Raw Material Documentation

8. Analytical Data

Quality Control

Refractive index n_D^{20}	1.334 – 1.340
Density 20 °C	1.009 – 1.020 g/ml
pH value	3.0 – 4.5
Dry residue (2 h; 102 °C)	2.5 – 4.0 %
Hydroxyproline	470 – 540 µg/ml
Conductivity (20 °C)	4.4 – 10 mS/cm
Fibril Precipitation (15 % NaCl solution)	positive
Sodium Benzoate	0.20 – 0.26 %
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.

10. Contaminants/Reaction Intermediates occurring in the Raw Material

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		< 0.05 ppm	"
Pb		< 0.2 ppm	"



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Contaminants	not to be expected	Concentrations	Methods
Hg		< 0.05 ppm	"
Others	./.		
* no data available	** spot-checked	***DIN EN ISO 11885-E22	

11. Stabilizing Additives

Preservative: approx. 0.25% 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

Maricol S is obtained from the same raw material and using the same production procedure as that used for the existing product "Maricol CLR". Maricol S contains Sodium Benzoate whereas Maricol CLR contains Phenonip. The additional physico-technical process steps applied to minimize the odour of the product are not thought to affect its physiological safety. Sodium Benzoate can be considered as being safe in leave-on formulations up to a total concentration of 0.5% and rinse-off formulation up to a total concentration of 2.5% (SCCP/0891/05). Therefore, the data indicated below which reflect the results obtained with Maricol CLR are considered to be valid also for Maricol S:

Acute Toxicity

LD₅₀ oral: > 2000 mg/kg body

No toxicological significant effects were observed.

Primary Skin Irritation

Primary skin irritation/rabbit/Federal Register Test No. 187 (undiluted, 24 hours occlusive):

A primary cutaneous irritation index of 0.6 was found, which is within the lowest range and normal for products of this kind.



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Raw Material Documentation

Experienced Skin Tolerance under Use Conditions

Human Patch Test (primary skin irritation test):

A gel containing 10 % Maricol CLR was found to produce no reactions in 30 volunteers and therefore was classified as "harmless" as regards a potential skin irritating effect.

Primary Mucous Membrane Tolerance

Maricol CLR, undiluted, has undergone the 'Federal Register Eye Irritation Test': being "non irritant", it can be used in the eye area without hesitation.

Sensitization

In the 'Magnusson and Kligman Contact Maximisation Study' Maricol CLR, undiluted and applied topically, was shown to produce no sensitizing effects; the sensitization rate was 0 %.

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)

The product "Gel with 10 % Maricol CLR" was tested in the epicutaneous patch test (24 h; 30 individuals) and found to be well tolerated by the skin from a dermatological point of view.

17. Other Information

Chronic Toxicity

no data available

Subchronic Toxicity

no data available

Teratogenicity

no data available



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Toxicokinetics

no data available

Additional Genotoxicological Tests (as far as required)

no data available

Mutagenicity

no data available

BSE Hazard

No BSE risk analysis required because animal-derived raw material used is tuna skin.

18. Potential Risks presented by UV Exposure and on Inhalation

Phototoxicity

no data available

Photosensitization

no data available

Toxicity on Inhalation

no data available

19. Ecology

Biodegradability

As carrier of fish protein in weakly acidic buffer solution. Maricol S is readily biodegradable.

Acute Aquatic Toxicity

- Bacteria	}	no data available
- Algae		
- Daphnia		
- Fish		

Water Pollution Hazard Class:

Product presents no water pollution hazard (self-classification).

authorized by:



Maricol S

Raw Material Documentation

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



Maricol S

Product Specification

Characteristics

Maricol S contains fish skin derived native, soluble collagen with undamaged, i.e. skin identical, structure. Through special physico-technical process steps Maricol S has a minimized odour.

INCI Name	CAS No.	EINECS No.
Soluble Collagen	9007-34-5	232-697-4

Analytical Data

Refractive index n_D^{20}	1.334 – 1.340
Density 20 °C	1.009 – 1.020 g/ml
pH value	3.0 – 4.5
Dry residue (2 h; 102 °C)	2.5 – 4.0 %
Hydroxyproline	470 – 540 µg/ml
Conductivity 20 °C	4.4 – 10 mS/cm
Fibril precipitation (15 % NaCl solution)	positive
Sodium Benzoate	0.20 – 0.26 %
Colony forming units	
Total aerobic microbial count (TAMC)	< 100/ml
Total combined yeasts/moulds count (TYMC)	< 10/ml
	in absence of non conforming organisms

Physiological Safety

Maricol S is obtained from the same raw material and using the same production procedure as that used for the existing product "Maricol CLR". Maricol S contains Sodium Benzoate whereas Maricol CLR contains Phenonip. The additional physico-technical process steps applied to minimize the odour of the product are not thought to affect its physiological safety. Sodium Benzoate can be considered as being safe in leave-on formulations up to a total concentration of 0.5% and rinse-off formulation up to a total concentration of 2.5% (SCCP/0891/05). Therefore, the data indicated below which reflect the results obtained with Maricol CLR are considered to be valid also for Maricol S:

Acute oral toxicity

LD₅₀ in rats: greater than 2000 mg/kg body weight.

No significant toxicological effects could be observed.



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Product Specification

Eye irritation potential

Maricol CLR, undiluted, has undergone the 'Federal Register Eye Irritation Test': being "non irritant", it can be used in the eye area without hesitation.

Skin compatibility

Human Patch Test (primary skin irritation test):

A gel containing 10 % Maricol CLR was found to produce no reactions in 30 volunteers and therefore was classified as "harmless" as regards a potential skin irritating effect.

Sensitization

In the 'Magnusson and Kligman Contact Maximisation Study' Maricol CLR, undiluted and applied topically, was shown to produce no sensitizing effects; the sensitization rate was 0 %.

In the 'Federal Register Skin Irritation Test' Maricol CLR, applied undiluted (24 hours; occlusive), was found to produce a primary cutaneous irritation index of 0.6, which is within the lowest range and normal for products of this kind.

Mode of action

The collagen fibrils which are twisted together with elastin fibers are responsible for tensile strength and elasticity of the skin. Triple helical basic units of the collagen are linked to form long-chain fibril bundles. Structure and functionality are unique among proteins and can be found in all polycellular organisms, but not in plants.

Structural changes caused by hydrolysis or denaturation destroy the nature identical, i.e. native structure of the collagen. As a result it loses its special feature, namely, its natural affinity for the skin.

Due to its intact triple helical structure, the fish skin derived Maricol S has preserved both the characteristic water-binding capacity and its affinity for skin keratin, thus providing the skin with a protective moisturizing shield.

Application

Maricol S as native soluble collagen is particularly suitable for the care of dry, UV-exposed and environmentally stressed skin as well as aging skin. Its nature identical structure helps to form a protective shield on the skin.



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Product Specification

Maricol S can be used in emulsified and aqueous formulations designed to moisturize and protect the skin.

Dosage

3.0 – 10.0 %

Appearance/Odor

Water-clear, almost transparent, viscous liquid.
Almost odorless.

Solubility

Dissolves in water to give clear solutions.

Processing

As native collagen, Maricol S is sensitive to heat and therefore should be added to emulsified preparations only after cooling down to 25 °C. Then the emulsion will act as a protective matrix which prevents the collagen from denaturing. Keep the formula at an acid pH in the range 4.5 – 6.5.

Storage

If kept in a cool place (10 – 20 °C), protected from light, in well-closed containers, Maricol S should not be stored for longer than 2 years. Protect from frost.

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 : Maricol S
Revision date : 17.06.2019
Print date : 17.06.2019

Version (Revision) : 3.3.1 (3.3.0)

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

1.1 Product identifier

Maricol S (352)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

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

Native soluble fish skin collagen in a weakly acidic buffer 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

Safety Data Sheet

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



Trade name : Maricol S
Revision date : 17.06.2019
Print date : 17.06.2019

Version (Revision) : 3.3.1 (3.3.0)

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

Safety Data Sheet

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



Trade name : Maricol S
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Print date : 17.06.2019

Version (Revision) : 3.3.1 (3.3.0)

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/DMEL and 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 health and safety measures

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 : colourless

Odour

Safety Data Sheet

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



Trade name : Maricol S
Revision date : 17.06.2019
Print date : 17.06.2019

Version (Revision) : 3.3.1 (3.3.0)

Almost odourless.

Safety relevant basis data

Physical state :			Liquid
Initial boiling point and boiling range :	(1013 hPa)	approx.	100 °C
Flash point :		>	100 °C
Vapour pressure :	(50 °C)	approx.	123 hPa
Density :	(20 °C)		1.009 - 1.02 g/cm ³
Solvent separation test :	(20 °C)		No data available
pH :			3 - 4.5
Viscosity :	(20 °C)	approx.	40 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

Maricol S is obtained from the same raw material and using the same production procedure as that used for the existing product "Maricol CLR". Maricol S contains Sodium Benzoate whereas Maricol CLR contains Phenonip. The additional physico-technical process steps applied to minimize the odour of the product are not thought to affect its physiological safety. Sodium Benzoate can be considered as being safe in leave-on formulations up to a total concentration of 0.5% and rinse-off formulation up to a total concentration of 2.5% (SCCP/0891/05). Therefore, the data indicated below which reflect the results obtained with Maricol CLR are considered to be valid also for Maricol S:

Acute effects

Acute oral toxicity

Parameter :	LD50
Exposure route :	Oral
Species :	Rat
Effective dose :	> 2000 mg/kg
Test result :	not toxic

Irritant and corrosive effects

Primary irritation to the skin

Parameter :	Primary irritation to the skin
Species :	Human

Safety Data Sheet

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



Trade name : Maricol S
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Exposure time : 24 h
Result : Not irritant
Method : Federal Register Test :

Irritation to eyes

Parameter : Irritation to eyes
Species : Rabbit
Result : Not irritant
Method : Federal Register Test :

Sensitisation

In case of skin contact

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.

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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

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/NDL 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

Safety Data Sheet

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



Trade name : Maricol S
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Print date : 17.06.2019

Version (Revision) : 3.3.1 (3.3.0)

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.
