Phytosan™ K

Table of Contents

Phytosan K

Raw Material Documentation

1. Trade name: **Phytosan K**

Use: **Active for cosmetics**

Manufacturer **Supplier:**

CLR – Chemisches Laboratorium
Dr. Kurt Richter GmbH
Bennigsenstraße 25
D-12159 Berlin / Germany
Tel.: +49 (30) 85 10 26 – 0

Contact for information:
Sales Department

2. Raw Material Composition

Chemical Name (IUPAC), Formula
not applicable, as mixture

Characterization
Phytosan K contains proteins, glycoproteins and polysaccharides isolated from soybeans. By stimulating synthesis of extracellular matrix constituents and providing comprehensive photoprotection, Phytosan K counteracts the signs of biological and UV-induced premature skin aging (such as formation of wrinkles).

Origin
plant-derived

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

INCI Name	EU Name	Range (FDA)
Water (Aqua)	Aqua	> 50 %
Glycerin	Glycerin	10 – 25 %
Glycine Soja (Soybean) Seed Extract	Glycine Soja Extract	1 - 5 %

4. Registration

EINECS Designation:	*EINECS No.:*	*CAS No.:*
Water	231-791-2	7732-18-5
1,2,3-Propanetriol	200-289-5	56-81-5
Glycine Soja	./.	84776-91-0

5. Pharmacopoeial Registration

./.

6. Manufacturing Procedure

The proteins, glycoproteins and polysaccharides are extracted from soybeans under gentle conditions, using a weakly acidic, aqueous buffer. After filtration, an amount of approx. 20 % glycerin is added to stabilize the extracted components.

7. Raw Material Properties

Appearance, Odour

Yellowish, transparent liquid. Characteristic odour.

Solubility

Miscible with water in any proportion, but yields no clear solution.
A clear solution is obtainable by dissolving, for example, 5% Phytosan K in deionized water with added 0.5% EDTA.

Recommended Use:

In emulsified and gel-type skin care preparations designed to reestablish the physiological balance of aging skin or skin stressed by environmental influence.

8. Analytical Data

Quality Control

Refractive index n_D^{20}	1.365 - 1.375
Density 20 °C	1.060 - 1.090 g/ml
pH value	4 - 5
Dry residue (2 h, 102 °C)	18.0 - 25.0 %
Total protein (Sigma TP0200)	0.4 - 1.0 %
Phenoxyethanol	0.8 - 1.0 %
Potassium sorbate	0.2 - 0.3 %
Colony forming units	< 100/ml in absence of pathogenic germs

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		< 0.01 ppm	"
Pb		< 0.2 ppm	"
Hg		< 0.1 ppm	"
Allergenic substances (acc. to 2003/15/EC)	x		
Diethylene glycol		< 0.1 %	GC (Glycerin)

Contaminants	not to be expected	Concentrations	Methods
Ethylene glycol		< 0.1 %	GC (Glycerin)
Others	./.		

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

11. Stabilizing Additives

Preservatives: approx. 1% Phenoxyethanol
approx. 0.25% Potassium sorbate

12. Microbiology

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

13. Physiological Safety

Acute oral Toxicity

Phytosan K is made from food grade, non-genetically modified soybeans. Since the manufacturing procedure does not chemically alter the raw material and no toxic substances are used to produce Phytosan K, oral toxicity testing in the rat was not conducted with this product. Phytosan K is considered to be non-toxic.

Primary Skin Irritation

cf. Sensitization"

Experienced Skin Tolerance under Use Conditions

cf. "Sensitization"

Primary Mucous Membrane Tolerance

The eye irritancy potential of Phytosan K was tested in the chorioallantoic membrane at a 100 % concentration using an alternative preservation (parabens) under the product name "Phytosan". Phytosan, undiluted, was classified as non-irritant.

Sensitization

Repeated Insult Patch Test on humans (RIPT according to Shelanski):
An O/W cream containing 10 % Phytosan, preserved with parabens, was applied repeatedly to 50 volunteers with dry, sensitive skin (among them, 9 persons suffering from eczemas) for

a duration of 4 weeks. The cream containing Phytosan did not produce any skin irritating effects nor signs of skin sensitization.

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)

cf. "Sensitization"

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

Phytosan K does not imply any risk of BSE since it contains neither animal nor animal-derived raw materials.

18. Potential Risks presented by UV Exposure and on Inhalation

Phototoxicity
Phytosan (undiluted) has been tested *in vitro* using the 3T3 Neutral Red Uptake Phototoxicity Assay. No phototoxic effects have been observed.
Note: Differently to the current preservation system, this test has still been run with a phenoxyethanol/paraben preservation.

Photosensitization
no data available

Toxicity on Inhalation
no data available

19. Ecology

Biodegradability
The proteins and glycerin contained are easily biodegradable.

Acute Aquatic Toxicity
- Bacteria
- Algae
- Daphnia
- Fish

} no data available

Water Pollution Hazard Class:
1 (self-classification)

authorized:

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

Phytosan K

Product Specification

Characteristics

Phytosan K contains proteins, glycoproteins and polysaccharides isolated from soybeans. By stimulating synthesis of extracellular matrix constituents and providing comprehensive photoprotection, Phytosan K counteracts the signs of biological and UV-induced premature skin aging (such as formation of wrinkles).

INCI Name	**CAS No.**	**EINECS No.**
Water (EU name: Aqua)	7732-18-5	231-791-2
Glycerin	56-81-5	200-289-5
Glycine Soja (Soybean) Seed Extract (EU name: Glycine Soja Extract)	84776-91-0	./.

Analytical Data

Refractive index n_D^{20}	1.365 - 1.375
Density 20 °C	1.060 - 1.090 g/ml
pH value	4 - 5
Dry residue (2 h, 102 °C)	18.0 - 25.0 %
Total protein (Sigma TP0200)	0.4 - 1.0 %
Phenoxyethanol	0.8 - 1.0 %
Potassium sorbate	0.2 - 0.3 %
Colony forming units	< 100/ml in absence of pathogenic germs

Physiological Safety

Acute oral toxicity

Phytosan K is made from food grade, non-genetically modified soybeans. Since the manufacturing procedure does not chemically alter the raw material and no toxic substances are used to produce Phytosan K, oral toxicity testing in the rat was not conducted with this product. Phytosan K is considered to be non-toxic.

Eye irritation potential

The eye irritancy potential of Phytosan K was tested in the chorioallantoic membrane at a 100 % concentration using an alternative preservation (parabens) under the product name "Phytosan". Phytosan, undiluted, was classified as non-irritant.

Human Repeated Insult Patch Test (HRIPT according to Shelanski):
An O/W cream containing 10 % Phytosan (preserved with parabens) was applied repeatedly to 50 volunteers with dry, sensitive skin (among them, 9 persons suffering from eczemas) for a duration of 4 weeks. The cream containing Phytosan did not produce any skin irritating effects nor signs of skin sensitization.

Phototoxicity
Phytosan (undiluted) has been tested *in vitro* using the 3T3 Neutral Red Uptake Phototoxicity Assay. No phototoxic effects have been observed.
Note: Differently to the current preservation system, this test has still been run with a phenoxyethanol/paraben preservation.

Mode of action

Cell-cell communication is essential for all functions of the human body. Via cell receptors and appropriate signaling molecules metabolic and catabolic reactions can be controlled in the cell. Environmental influences such as UV light interfere with metabolic processes in human skin by modulating signaling pathways between the cells. Cell receptors not only recognize endogenous signaling molecules; defined classes of substances derived from plants are also able to influence cell responses by interacting with cell receptors.

By both in vitro experiments conducted with human skin cells and in vivo tests on humans it could be demonstrated that the ingredients of Phytosan K can influence cell responses. The biological activity of Phytosan K shows in a significant increase in total protein synthesis as a result of signal transduction as well as in an induction of collagen biosynthesis.

Apart from a resultant improvement of the microrelief of the skin, Phytosan K was found to have extraordinary anti-stress activity after UV irradiation. Phytosan K clearly prevents decrease in ATP levels in keratinocytes after UV exposure, thus enabling cell mechanisms for prevention of DNA damage to produce a more efficient protective effect.

Phytosan K significantly increases the DNA repair rate after UV exposure, with resultant decrease in the number of reparable DNA single strand breaks and less irreparable DNA damage. Furthermore, formation of sunburn cells is reduced by modulation of UV-induced apoptosis.

Phytosan K

Product Specification

By interfering with protective mechanisms of skin cells, Phytosan K possesses a high photoprotective potential. As a "biological sun protection factor" Phytosan K thus counteracts UV-induced premature skin aging. Since it simultaneously stimulates skin regenerative cell functions, it improves skin elasticity and the microrelief of the skin.

Application

Phytosan K is suitable for the regenerative skin care and for the care of stressed skin. It especially counteracts UV-induced premature skin aging.

It can be u sed in emulsified and gel-type skin care products. Use of emulsifiers and/or gel builders which are non-sensitive to electrolytes is recommended.

Dosage

2 - 5 %

Appearance/Odor

Yellowish, transparent liquid. Characteristic odor.

Solubility

Miscible with deionized water, but yields no clear solution. A clear solution is obtainable by dissolving, for example, 5% Phytosan K in deionized water with added 0.5% EDTA (1/10 of the use level of Phytosan K).

Processing

When formulating Phytosan K it must be noted that electrolyte sensitive raw materials of formulations might be influenced. Small amounts of EDTA can stabilize the emulsion. Ionic emulsifiers should not be used. Electrolyte sensitive rheology modifiers and hydrocolloids might lose some efficacy when Phytosan K is added. This impact can be overcome when EDTA is added (1/10 of the used Phytosan K quantity). The development of W/O formulations is possible without any difficulties. The temperature should not exceed 40 °C during the production process, precipitations could be observed in the case of higher temperatures. The pH range of formulations with Phytosan K is wide and allows formulations between 3.0 – 7.5.

Storage

If kept at 10 - 20 °C, protected from frost and light, in well-closed containers, Phytosan K is stable for at least 2 years. Product packs should be fully used once opened.

Phytosan K

Product Specification

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 :	Phytosan K		
Revision date :	05.06.2015	**Version (Revision) :**	3.2.0 (3.1.0)
Print date :	05.06.2015		

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

1.1 Product identifier
Phytosan K (417)

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 : Bennigsenstrasse 25

Postal code/city : D-12159 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.
Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Special rules for supplemental label elements for certain mixtures

EUH210 Safety data sheet available on request.

2.3 Other hazards
None

SECTION 3: Composition / information on ingredients

3.2 Mixtures
Description

Phytosan K contains proteins, glycoproteins and polysaccharides isolated from soybeans. By stimulating synthesis of extracellular matrix constituents and providing comprehensive photoprotection, Phytosan K counteracts the signs of biological and UV-induced premature skin aging (such as formation of wrinkles).

Hazardous ingredients

CALCIUM CHLORIDE ; EC No. : 233-140-8; CAS No. : 10043-52-4

Weight fraction : ≥ 1 - < 5 %

Classification 1272/2008 [CLP] : Eye Irrit. 2 ; H319

Additional information

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

Full text of H- and EUH-phrases: see section 16.

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 : 10

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 : Yellowish clear

Odour

characteristic

Safety relevant basis data

Physical state :			liquid	
Initial boiling point and boiling range :	(1013 hPa)	ca.	100	°C
Flash point :		>	100	°C
Vapour pressure :	(50 °C)		No data available	
Density :	(20 °C)	ca.	1,073	g/cm^3
Solvent separation test :	(20 °C)		No data available	
PH :		ca.	5	
Viscosity :	(20 °C)	ca.	5	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

Phytosan K is made from food grade, non-genetically modified soybeans. Since the manufacturing procedure does not chemically alter the raw material and no toxic substances are used to produce Phytosan K, oral toxicity testing in the rat was not conducted with this product. Phytosan K is considered to be non-toxic.

Irritant and corrosive effects

The irritancy potential of Phytosan K was tested using an alternative preservation (parabens) under the product name "Phytosan".

Primary irritation to the skin

Parameter :	Primary irritation to the skin
Species :	Human
Result :	Not irritant
Method :	Patch test (10% in o/w-cream)

Irritation to eyes

Parameter :	Irritation to eyes
Species :	hen's egg
Result :	Not irritant
Method :	HET-CAM

Sensitisation

The sensitation potential of Phytosan K was tested using an alternative preservation (parabens) under the product name "Phytosan".

In case of skin contact

Parameter :	Sensitation
Species :	Human
Result :	Not sensitizing
Method :	Repeated Human Patch Test(10%, acc. to Shelanski)

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.

Phototoxicity

The photoxicity potential of Phytosan K was tested using an alternative preservation (parabens) under the product name "Phytosan".

In vitro phototoxicity

Parameter :	In vitro phototoxicity
Species :	Mouse Fibroblast cells
Test result :	No acute phototoxic potential - in-vivo phototoxicity unlikely.
Method :	OECD 432

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

Product/Packaging disposal

Waste treatment options

Appropriate disposal / Product

Dispose of waste according to applicable legislation.

Appropriate disposal / Package

Completely emptied packages can be recycled.

SECTION 14: Transport information

14.1 UN number
No dangerous goods in sense of this transport regulation.

14.2 UN proper shipping name
No dangerous goods in sense of this transport regulation.

14.3 Transport hazard class(es)
Land transport (ADR/RID)
No dangerous goods in sense of this transport regulation.
Class(es) : -

Sea transport (IMDG)
No dangerous goods in sense of this transport regulation.
Class(es) : -

Air transport (ICAO-TI / IATA-DGR)
No dangerous goods in sense of this transport regulation.
Class(es) : -

14.4 Packing group
No dangerous goods in sense of this transport regulation.

14.5 Environmental hazards
No dangerous goods in sense of this transport regulation.

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 : 1 (Slightly hazardous to water) Classification according to VwVwS
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
None

16.2 Abbreviations and acronyms
None

16.3 Key literature references and sources for data
None

16.4 Relevant H- and EUH-phrases (Number and full text)
H319 Causes serious eye irritation.

16.5 Training advice
None

16.6 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.