# ASES CHEMICAL WORKS

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SINCE 1942

## Ceramide Complex CLR™ PE-F

**Product Specification**

**Characteristics**

Ceramide Complex CLR™ PE-F contains phyto lipids in lamellar, liquid crystalline form. The plant-derived lipid mixture consists of phospholipids and sphingolipids (ceramides, glycoceramides = cerebrosides).

| **INCI Name** | CAS No. | EC No. |
|---|---|---|
| Water (Aqua) | 7732-18-5 | 231-791-2 |
| Pentylene Glycol | 5343-92-0 | 226-285-3 |
| Phospholipids | 123465-35-0 | ./. |
| Sphingolipids | 85116-74-1 | 285-526-0 |

**Analytical Data**

| | |
|---|---|
| Refractive index $n_D^{20}$ | 1.340 – 1.345 |
| Density 20 °C | 0.999 – 1.006 g/ml |
| pH value | 5.0 – 6.0 |
| Dry residue | (2 h, 102 °C) 2.0 – 2.5 % |
| p-Anisic Acid | 0.05 – 0.10 % |
| Colony forming units | < 100/ml |
| Total aerobic microbial count (TAMC) | < 10/ml |
| Total combined yeasts/moulds count (TYMC) | in absence of non-conforming organisms |

**Physiological Safety**

The toxicological results listed below were obtained with the product “Ceramide Complex CLR™ (P)”, which differs from Ceramide Complex CLR™ PE-F only by the ingredients used for microbiological stabilization (Pentylene Glycol/p-Anisic Acid vs. Phenonip/Methylparaben), with the exception of skin tolerance patch testing.

Acute oral toxicity LD50 in rats: greater than 2000 mg/kg body weight.
No significant toxicological effects were observed.

Eye Irritation Test
Ceramide Complex CLR™ (P) was tested with the EytexTM system which is an in vitro alternative test to replace the standard ocular Draize rabbit test.

The Eytex system involves the use of an organized macromolecular matrix which is exposed to irritants of known Draize classification that serve as calibrators to determine Eytex/Draize equivalents. The resulting calibration curve is used to classify the test substances. Eytex allows reproducible and most precise determination of the ocular irritation level.

The ocular irritation level of Ceramide Complex CLR™ (P) according to Eytex classification was found to be "mild" (predicted in vivo classification: minimal). Therefore, Ceramide Complex CLR™ (P) can be applied to the eye area without hesitation.

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**Product Specification**

Skin tolerance

Ceramide Complex CLR™ PE-F was tested at a 50% concentration on 50 volunteers (among these 29 individuals with normal skin, 3 sufferers from eczema, 2 allergic and 16 individuals with sensitive skin). None of the subjects showed any reaction to the test product. On the basis of the test results and under the test conditions, Ceramide Complex CLR™ PE-F can be classified as harmless as regards the possibility of skin irritation.

Skin compatibility

In terms of dermal safety assessment, too, the conventional dermal rabbit test was replaced with an in vitro alternative test, i.e. the SkintexTM system, in the case of Ceramide Complex CLR™ (P).

Testing is done by exposing a biomembrane and an organized macromolecular matrix to irritants of known dermal in vivo classification as calibrators (cf. EytexTM test) with subsequent and reproducible determination of the dermal irritation level of the test substance.

The dermal irritation level of Ceramide Complex CLR™ (P) according to Skintex classification was found to be "mild".

**Mode of action**

Ceramides are the most important structural elements of the lipid barrier. They are orderly arranged in lamellar form to act as a membrane and fill the intercellular space in the stratum corneum (SC). Apart from the important barrier function, this membrane also controls cohesionof dead cells, the corneocytes. In dry and fissured skin this lipid barrier is largely destroyed and the skin suffers increased desquamation of corneocytes and high transepidermal water loss. Especially loss of water from deeper epidermal layers will affect functioning of the cells which decisively depend on their hydrated environment. Therefore, restoration of the lipid barrier, apart from removing the real cause of dry skin conditions, will also restore the physiological cell functions, thus improving the entire condition of the skin.

In in vivo tests ceramide-containing formulations were shown to produce the desired effect only when the ceramides were present in lyotropic form, i.e. as lamellar liquid crystals. Topically applied preparations containing ceramides in non-arranged form did not produce any effect.

The lipids contained in Ceramide Complex CLR™ PE-F are present in a membranous and thus active structure.

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## Ceramide Complex CLR™ PE-F

**Application**

Ceramide Complex CLR™ PE-F restores the lipid barrier of the SC of dry and fissured skin and provide a well-balanced moisture content. An epidermis that is intact also at the outermost boundary is crucial for a well functioning physiological interaction between the individual skin layers.

Ceramide Complex CLR™ PE-F can be used in aqueous and emulsified skin care preparations, especially gels.

**Dosage**

5 – 10 %

**Appearance / Odor**

Yellowish-beige, clear to slightly opalescent liquid

Almost odorless.

**Solubility**

Miscible with water

**Processing**

Do not exceed processing temperatures above 35 °C. Shearing forces produced by stirring too vigorously may partially destroy the lamellar structure. Emulsified preparations can be checked by means of electron microscopy after freeze fracturing in order to find out whether they contain intact membranes.

**Storage**

Cellar to room temperature (15 to 25 °C), protected from light, in well-closed containers. Protect from frost. Ceramide Complex CLR™ PE-F should not be stored for longer than 1 year before processing. When properly stored in accordance with the above conditions, the material in the unopened container retains its specifications during the specified shelf life. After opening the container, the material should be used as soon as possible.