

SUN PROTECTION WITHOUT UV-FILTERS

PRODUCT DESCRIPTION:

Traditional sun protection products use products that absorb radiation in the range 290-360 nm (UV-A & UV-B). However, the formation of cell death (apoptosis) is caused by two major factors: genetic damage and excessive water loss. Those are the two pillars on which this formulation is based: to make genetic damage reversible and to avoid excessive water loss.

1. To avoid genetic damage on a cellular level so-called “repair enzymes” are active. These enzymes contain a blueprint of the genetic code, and as soon as a genetic mistake has been made the damaged part will be removed and replaced by a good sequence. Genetic mistakes due to exposure to UV radiation will also be handled in this way. Apigenin is an essential co-enzyme for a number of repair enzymes, and thus enables to reverse the genetic damage caused by UV radiation. A similar functionality can be allocated to the unsaponifiable fraction of shea butter (11-17%) and gamma-oryzanol. If the genetic damage cannot be sufficiently repaired the cell be subjected to apoptosis, but the number of events of this type is rather limited indeed.
2. In ordinary situations maintenance of the water balance is organised by the NMF (Natural Moisturising Factor). However, upon exposure to UV light the NMF factor is by far sufficient to avoid excessive water loss due the high energy loading of the radiation. In such a situation an osmo-protectant is required. Osmo-protectants are products that enable holding power for water in even the most extreme conditions. Betaine is an excellent example of an osmo-protectant.

Field test have shown that the efficacy of this formulation, that does not contain traditional UV filters, compares to products with a reported SPF value of 15-20. A significant contribution is also originating from the presence of panthenol (provitamin B5), tocopheryl linoleate and tocopheryl nicotinate. In both last products are elegant examples of the combinations of vitamins (vitamin E+F and vitamin E+B3). To protect sensitive ingredients a highly active rosemary extract has been applied.

As what should be a first boundary condition for sun care products, traditional registered preservatives should be avoided. For that reason pentylene glycol has been used, which also enables microbiological control. The use of a fragrance in sun care products is not particularly recommended, but if the a fragrance is required than the absence of allergens shall be guaranteed, relative to Directive 2002/34/EG.

COMPOSITION

AQUEOUS PHASE PART 1

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|---------------------|----------|-------------|
| Demineralised Water | 46,020 % | Aqua |
| Rhodicare D (1) | 0,300 % | Xanthan Gum |

AQUEOUS PHASE PART 2

| | | |
|---------------------|---------|------------------|
| Demineralised Water | 5,000 % | Aqua |
| Hydrolite 5 (2) | 4,000 % | Pentylene Glycol |
| Brij 721 (3) | 2,000 % | Steareth-21 |
| Panthenol, 75% (4) | 2,000 % | Panthenol |
| | | Aqua |
| Betafin BP20 (5) | 2,500 % | Betaine |
| Trisodium EDTA (6) | 0,030 % | Trisodium EDTA |

AQUEOUS PHASE PART 3

| | | |
|--------------------------|---------|----------------------|
| Glycerin 99,5 USPXXV (7) | 2,000 % | Glycerin |
| Butylene Glycol (8) | 2,000 % | Butylene Glycol |
| AMP 100 (9) | 0,150 % | Aminomethyl Propanol |
| Apigenin 90 (10) | 0,100 % | Apigenin |

AQUEOUS PHASE PART 4

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|-------------------------|---------|--------------------|
| Demineralised Water | 2,970 % | Aqua |
| Sodium Hyaluronate (11) | 0,030 % | Sodium Hyaluronate |

OIL PHASE

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|----------------------|---------|----------------------|
| Shea Butter RBD (12) | 6,000 % | Butyrospermum Parkii |
| Gamma Oryzanol (13) | 4,000 % | Oryzanol |
| Jobba Oil (14) | 3,000 % | Simmondsia Chinensis |
| Estol 1517 (15) | 3,000 % | Isopropyl Palmitate |
| Estol 3752 (16) | 2,000 % | PEG-8 Beeswax |
| Lanette 16 (17) | 2,000 % | Cetyl Alcohol |
| Brij 72 (18) | 2,000 % | Steareth-2 |
| Edenor L2SM (19) | 1,500 % | Stearic Acid |
| Arlacel 165 (20) | 1,000 % | Glyceryl Stearate |
| | | PEG-100 Stearate |



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|--------------------------------|---------|--------------------------------|
| Cholesterol NF (21) | 0,700 % | Cholesterol |
| Hydagen B (22) | 0,500 % | Bisabolol |
| Dow Corning Fluid 200/350 (23) | 0,500 % | Dimethicone |
| Vitenna L (24) | 0,300 % | Tocopheryl Nicotinate |
| Vitenna N (25) | 0,200 % | Tocopheryl Linoleate |
| Danox R-3204 (26) | 0,200 % | Rosmarinus Officinalis Extract |

PRE-MIX 1

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|---------------------|---------|---------------|
| Demineralised Water | 1,980 % | Aqua |
| Schizophyllan (27) | 0,020 % | Schizophyllan |

INCI List: Aqua, Butyrospermum Parkii, Glycerin, Oryzanol, Pentylene Glycol, Isopropyl Palmitate, Simmondsia Chinensis, Betaine, Butylene Glycol, Cetyl Alcohol, PEG-8 Beeswax, Steareth-2, Steareth-21, Panthenol, Stearic Acid, Cholesterol, Glyceryl Stearate, Bisabolol, Dimethicone, PEG-100 Stearate, Tocopheryl Nicotinate, Xanthan Gum, Rosmarinus Officinalis, Tocopheryl Linoleate, Aminomethyl Propanol, Apigenin, Sodium Hyaluronate, Trisodium EDTA, Beta Glucan.

SUPPLIERS:

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|--------------------------|-------------------------------|
| (1) Rhodia | (2) Symrise |
| (3) Uniqema | (4) GOVA |
| (5) Danisco Cultor | (6) Eastman Kodak |
| (7) Uniqema | (8) Eastman Kodak |
| (9) Angus Chemie | (10) MMP Inc. |
| (11) CPN | (12) Jan Dekker International |
| (13) Tsuno Rice | (14) Floratech |
| (15) Uniqema | (16) Uniqema |
| (17) Cognis | (18) Uniqema |
| (19) Cognis | (20) Uniqema |
| (21) Dishman Netherlands | (22) Cognis |
| (23) Dow Corning | (24) Ennagram |
| (25) Ennagram | (26) IFSC |
| (27) CPN | |

MANUFACTURING PROCEDURE:

1. The equipment is sterilised with alcohol and thoroughly dried to remove all residual alcohol. The equipment is then further dried with purified hot air, including the piping system and all taps & auxiliaries. The use of other disinfectants such as chlorhexidine digluconate shall be avoided.

2. Xanthan Gum is dispersed in demineralised water using a low shear rotor stator agitator. The opaque, slightly stringy dispersion shall be free of aggregates and fully homogeneous. Phase A1.

The use of demineralised water is essential as apigenin used in phase A3 forms complexes with calcium and/or magnesium that are detrimental to the efficacy of the final product.

3. The ingredients of phase A2 are combined while stirring with a planetary mixer. Although the mutual solubility of all ingredients is excellent, moderate heating while stirring is recommended. Phase A2.
4. Subsequently phase A2 is added to phase A1 and the mixture is stirred with a planetary mixer until a homogeneous, low viscous gel structure has been obtained.
5. Apigenin is dissolved in the mixture of glycerin and butylene glycol. The solubility of apigenin is good, but the speed of dissolution is low. Moderate heating is recommended. Finally aminomethyl propanol is added. The salts of aminomethyl propanol and apigenin are easily soluble in the mixture of glycerin and butylene glycol; the colour of the medium-viscous solution is yellowish. Phase A3.
Phase A3 is added to the combined phase {A1+A2} and stirred until homogeneous. The pH of phase {A1+A2+A3} is gently alkaline (7,8-8,6).
6. Sodium hyaluronate is dissolved in demineralised water using a low shear rotor stator agitator. A viscous, homogeneous solution will be obtained. Phase A4 is added to phase {A1+A2+A3+A4} and stirred until homogeneous. Phase {A1+A2+A3+A4} is heated to 70°C while mixing with a planetary mixer. A low/medium viscous water phase will be obtained.
7. The oil phase is made by heating the ingredients to 70°C while mixing with a planetary mixer. At 70°C a homogeneous, opaque solution will be obtained. The oil phase is added to the water phase while mixing gently. Spontaneous emulsification will be observed. As soon the addition is completed the pre-emulsion is homogenised with a rotor stator mixer at high velocity. A low viscous emulsion will be obtained. The emulsion is cooled with forced cooling during 1 hour to 30°C.
8. Schizophyllan is dissolved in water; a medium viscous solution will be obtained. The schizophyllan solution is added to the emulsion at 30°C. Subsequently the emulsion will be stirred during two hours.
9. The emulsion is allowed to age during 24 hours before the emulsion is analysed on the basis of the specifications. If the analytical data satisfy the specifications the emulsion can be committed for confectioning.

SPECIFICATIONS:

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| Appearance: | Glossy emulsion, with a characteristic rheology |
| Colour: | Off-white, slightly yellowish |
| Odour: | Odourless |
| pH: | 5,7-6,4 (Typical 5,91) |
| Viscosity: | 21.000-24.000 cPs (Brookfield DV-II+ Programmable; S6, 20°C, 20 rpm) (typical: 22.900 cPs) |
| Microbiology: | <10 CFU/g |