Technical Information

TEGO® Xymenynic

The skin firmer

Intended use

Active for skin care

Benefits at a glance

- Is a highly purified, phytochemical compound extracted from Sandalwood seeds
- Is a unique, stabilized composition containing 20% Xymenynic Acid
- Xymenynic Acid, also known as Santalbic Acid, is extracted from the seeds of the sandalwood tree (Santalum album)
- Increases cellular detoxification and anti-oxidation capacity
- Leads to a strengthening of the extracellular matrix (ECM)
- Increases dermal strength
- Improves skin elasticity
- Is very effective against cellulite and reduces the appearance of orange peel skin
- Recommended usage level: 1.0-2.5%

INCI (PCPC name)

Caprylic/Capric Triglyceride; Xymenynic Acid

Chemical and physical properties (not part of specifications)

Form	yellowish solution
Active matter	approx. 20% Xymenynic Acid

Santalum album, the sandalwood tree, grows in the mountain regions of South India. All trees are owned by the government, and the harvest of the trees is strictly controlled. The seeds are collected by the Indian Government Forest Department in order to maintain the sustainability of the species. Traditionally, the plant is used in Arjuvedic treatments to make the skin smoother, tauter and more velvet.

Xymenynic Acid is extracted from the seeds of the sandalwood tree using a standardized process. It is a yellow, crystalline powder with the following structure:

Figure 1: Chemical structure of Xymenynic Acid

Due to the triple and double bond in the molecule, it is sensitive to oxidation. To stabilize Xymenynic Acid, it is solubilized in Caprylic/Capric Triglyceride (TEGOSOFT® CT). To guarantee color stability, Tocopherol is also present in this composition.

Properties

- ***in vitro* evaluation of ECM strengthening properties of TEGO® Xymenynic**

The extracellular matrix (ECM) is by volume the largest component of normal skin and gives the skin its unique properties of elasticity, tensile strength and compressibility. Therefore, an accurate composition of the ECM proteins, especially a proper

production of its major components, collagen and hyaluronic acid, is very important for strong and tight-looking skin.
The anti-hyaluronidase and anti-collagenase activities of Xymenynic Acid were analysed.

Method: For hyaluronidase inhibition assay, hyaluronic acid substrate (0.015% in phosphate buffer, pH 5.35) was incubated for 45 minutes at 37 °C with hyaluronidase enzyme solution (Sigma, 5 µg/ml in phosphate buffer, pH 7) and various concentrations (2-50 µg/ml) of Xymenynic Acid. Undigested hyaluronic acid was precipitated with 1% cetylpyridinum chloride. The absorbance of undigested hyaluronic acid was measured at 600 nm. A decrease in absorbance correlates with an increasing amount of digested hyaluronic acid.

For collagenase inhibition assay varying concentrations of Xymenynic Acid (3-50 µg/ml) were pre-incubated with fluorescein conjugated DQ gelatine substrate from pig skin (EnzChek collagenase assay kit). After 10 minutes Collagenase Type IV enzyme from Clostridium histolyticum (EnzChek collagenase assay kit) was added and fluorescence intensity was measured after 30 minutes of incubation at 485 nm (emission wavelength) and 520 nm (excitation wavelength). An increase in fluorescence is proportional to proteolytic activity, and fluorescence is quenched in the presence of an inhibitor.

Results: TEGO® Xymenynic inhibits hyaluronidase activity about 50% at a concentration of 23 µg/ml Xymenynic Acid. TEGO® Xymenynic inhibits collagenase activity about 50% at a concentration of 13 µg/ml Xymenynic Acid.

The inhibition of those enzymes by TEGO® Xymenynic prevents degradation of hyaluronic acid and collagen and leads to an overall strengthening of the ECM, which in turn leads to an improvement in skin elasticity and tighter looking skin.

- ***in vitro* evaluation of effects of TEGO® Xymenynic on cellular detoxification and anti-oxidation capacity**

The skin is highly susceptible to harmful external and internal influences causing cell damage. Free radicals and toxic molecules can accumulate in skin cells and interact with cellular macromolecules, such as DNA, lipids and proteins. As a consequence, the metabolic capacity of the cells is impaired, biosynthesis of macromolecules declines and severe structural alterations occur. This in turn leads to a loss of skin elasticity and strength. To protect the cells from those harmful effects, sophisticated anti-oxidation and detoxification mechanisms have been evolved by the skin.

Method: 1) To initially identify the biological activity of TEGO® Xymenynic, reconstructed human epidermis models (SkinEthic) were topically treated with a formulation containing 0.5% Xymenynic Acid for 48 h. RNA from vehicle- and verum-treated skin models was extracted and reversely transcribed into cDNA, labelled with fluorescent dyes and analyzed by DNA-Chip technology to characterize genome wide gene expression (Affymetrix® HGU133 GeneChips). The results of this study were then verified by quantitative real-time PCR (qRT-PCR) in an independent experiment.

2) To extend the application range and to confirm the analysed activity of TEGO® Xymenynic, a second study with UVB-stimulated cells was performed. Primary human epidermal keratinocytes were cultivated in medium containing 2.8 ppm Xymenynic Acid resp. in medium without any test substance for 24 h. After this pre-incubation, the cells were exposed to a dose of 160 J/m2 UVB radiation, which previously was found to be optimal to induce gene expression without affecting viability in this cell type. After irradiation, cells were cultivated for another 24h, either in the presence or in the absence of Xymenynic Acid. Subsequently cells were harvested and total RNA was extracted, reversely transcribed into cDNA and applied for qRT-PCR to analyze expression of genes involved in the glutathione pathway. The results were normalized to 18S rRNA and compared to vehicle control.

Results: DNA-Chip analysis suggested a stimulatory effect on the glutathione system. This hypothesis was confirmed independently by qRT-PCR measurements. In particular, the genes encoding glutamate cystein ligase, which is the first rate limiting enzyme of glutathione synthesis, were found to be induced. Both subunits of this enzyme (GCLM & GCLC) were significantly up-regulated. In addition, the genes coding for glutathione peroxidise 2 (GPX2)

and glutathione transferase (MGST1) were also found to be induced by Xymenynic Acid. Both enzymes play key roles in the elimination of hydrogen peroxide and detoxification of other substances.

UVB irradiation of human keratinocytes induced the expression of all major components of the glutathione system. This protective cellular response was extremely boosted by the application of Xymenynic Acid.

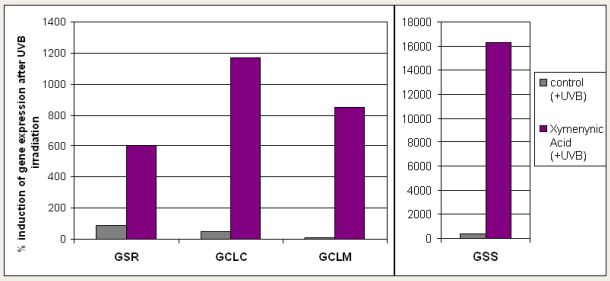

Figure 1: Expression of different genes involved in glutathione metabolism

TEGO® Xymenynic increases cellular detoxification under unstressed conditions, as well as under physiological stress. Mediated by the improvement of the physiological anti-oxidation mechanisms it reduces inflammation and alleviates symptoms of impaired skin.

- ***Ex vivo* skin penetration analysis of TEGO® Xymenynic**

In order to have the optimal performance, it is important that the active ingredient reaches the proper site of action. The bioavailability of the active ingredient was investigated by a dermal absorption assay based on porcine skin.

Method: Prior to the study the integrity of the used porcine skin was verified by both the measurement of the transepidermal water loss (TEWL), and caffeine penetration.

A skin layer of defined thickness, 1000 µm, was cut off with a dermatome (containing the stratum corneum, epidermis, and a part of the dermis). The skin samples were mounted onto Franz' diffusion cells with the epidermis side up. The dermis side was completely covered with the receptor medium (PBS buffer, pH 7.0). Afterwards approx. 20 – 40 mg/cm² of the test formulation were applied on the skin and spread evenly by rubbing the formulation on the skin. The diffusion cells were placed in a climatic chamber (32 °C, 50% relative humidity). During the experiment the receptor medium was stirred with a magnetic stirrer at 300 rpm.

After 24 ± 1 h, the residual test formulation on the porcine skin was rinsed off with a cotton swab, and the skin samples were cut into small pieces for extraction overnight. Finally, the amount of Xymenynic Acid in the receptor medium, the rinse-off medium, and the skin extract was analysed by GC.

Result: The bioavailability of Xymenynic Acid in porcine skin has been shown to be approx. 40% depending on the oil.

This demonstrates a high bioavailability of TEGO® Xymenynic in the skin which is in line with the theoretical $\log P_{O/W}$ value of Xymenynic Acid of 5.7.

- ***In vivo* evaluation of TEGO® Xymenynic: skin elasticity (Cutometer)**

With the above mentioned *in vitro* studies, it was shown that TEGO® Xymenynic strengthens the ECM. From this result it can be deduced that TEGO® Xymenynic should improve skin elasticity. The aim of the following *in vivo* study was to verify this hypothesis.

Method: For the study 20 volunteers were recruited. They received two formulations; one containing 0.5% Xymenynic Acid, the other one containing no active ingredient (vehicle). They applied one test formulation on the left inner forearm and the other on the right inner forearm twice daily over a period of 8 weeks.

At the beginning of the study, and after 8 weeks, skin elasticity was assessed using a Cutometer (Courage & Khazaka, Cologne). The difference of the elasticity parameters R1, R2, R5 and R6 compared to vehicle was calculated after 8 weeks application.

The measurements were performed in a climatic room at 21 – 22 °C and 50% relative humidity. Before the measurement started the volunteers had to acclimatize for at least 15 min.

After 8 weeks skin that was treated with Xymenynic Acid showed considerably improved skin elasticity compared to the skin treated with the vehicle (figure 2-5).

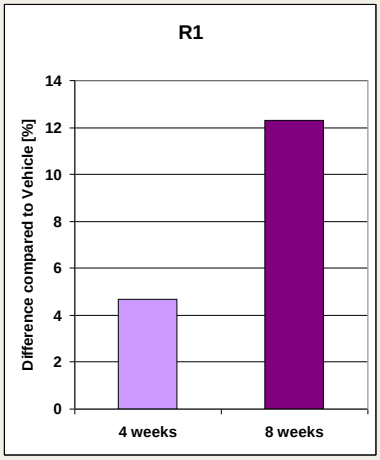

Figure 2: R1 = remaining deformation after first stretching cycle

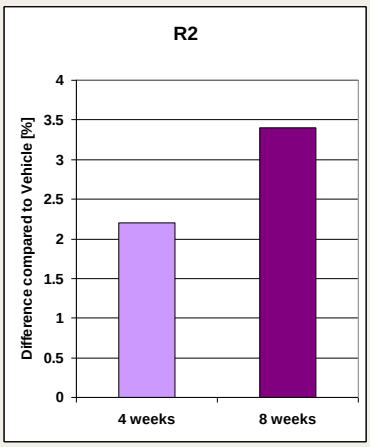

Figure 3: R2 = overall elasticity

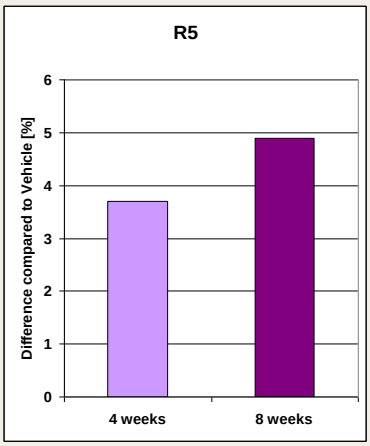

Figure 4: R5 = net elasticity

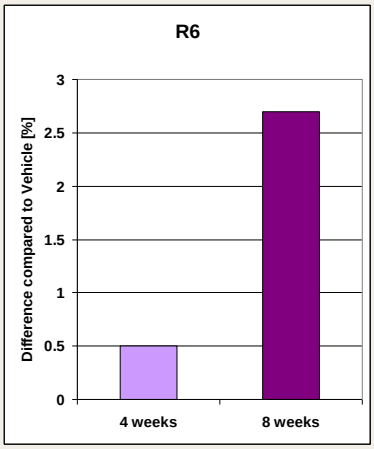

Figure 5: R6 = ratio of viscous and elastic deformation

- ***In vivo*** **evaluation of TEGO® Xymenynic: anti-cellulite study**

The appearance of cellulite is the consequence of different interacting impacts: increased fat accumulation in the adipocytes, reduced dermal strength and reduced microcirculation. In addition to this, cellulite is usually accompanied by a constant inflammation.

To fight against all these signs of cellulite, usually a combination of different actives is used in cosmetic anti-cellulite formulations.

Caffeine is a commonly-used active with a well known lipolytic activity. In the following *in vivo* study, it was combined with Xymenynic Acid because as shown before, Xymenynic Acid is able to fight against another mechanism of cellulite: decreased dermal strength and skin elasticity.

Method: For this study 30 volunteers were recruited. They received two test formulations; one containing 1.0% Caffeine (vehicle), the other contained a combination of 1.0% Caffeine and 0.2% Xymenynic Acid. They applied one test formulation on the left thigh and the other on the right thigh twice daily over a period of 8 weeks.

At the beginning of the study, and after 4 and 8 weeks, the following analyses were performed:
- the orange peel skin degree was assessed by dermatologists (expert grading),
- determination of skin thickness using ultra sound (Dermascan C, Cortex Technology),
- digital photos were taken.

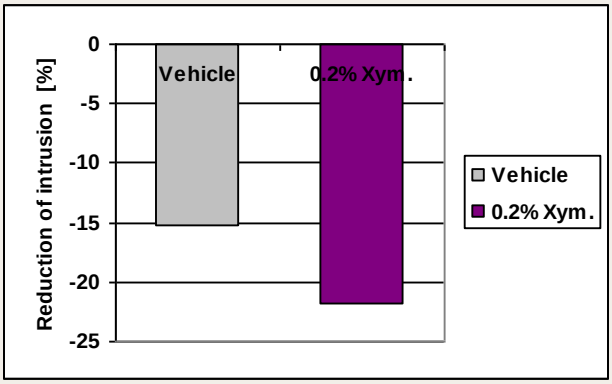

Figure 6: Skin Thickness: reduction of intrusion of subcutaneous fat tissue into the dermis

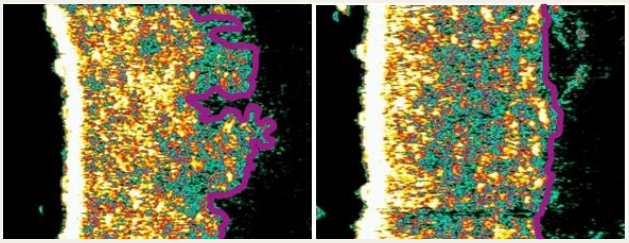

Figure 7: Ultra sound pictures of the skin structure before the application started and after 8 weeks.

Results: Skin thickness was reduced by Caffeine alone. A further, significant reduction of skin thickness can be achieved by the addition of Xymenynic Acid.

The ultra sound pictures clearly demonstrate that Xymenynic Acid led to a significantly improved, better structured dermis. This improved dermal structure minimized the invasion of fat cells into the connective tissue, visually leading to reduced bumps and a reduced appearance of orange peel skin. The body imperfections due to cellulite are minimized.

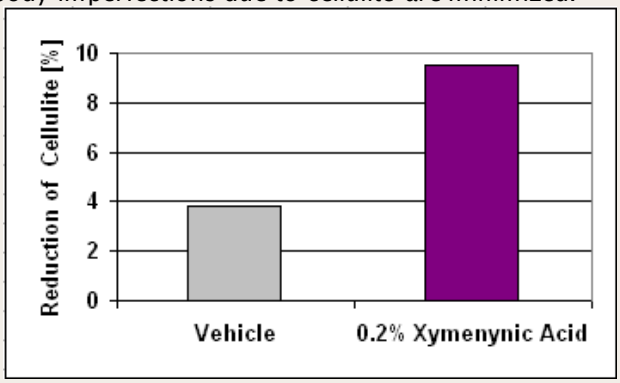

Figure 8: Expert grading of orange peel skin degree

Figure 9: left photo: before application started, right photo: after 8 weeks of application.

It can be seen that already Caffeine alone (vehicle) reduced the appearance of cellulite slightly. By the addition of Xymenynic Acid, a nearly 10% improvement can be achieved. This success is confirmed by the digital pictures.

Formulation hints

TEGO® Xymenynic is oil soluble and can be added directly to the oil phase of an emulsion. Then the emulsion (O/W or W/O) is prepared as usual.

TEGO® Xymenynic might decrease the viscosity of an O/W-emulsion. In this case it is recommended to increase the concentration of waxes like fatty alcohols or Glyceryl Stearate (TEGO® Alkanol 16, TEGO® Alkanol 1618, TEGO® Alkanol 18, TEGIN® M Pellets) or adjust the viscosity by increasing the concentration of hydrocolloids like Carbomer (TEGO® Carbomer) or Xanthan Gum.

Recommended usage concentration

1.0–2.5% of TEGO® Xymenynic

Applications

- Anti-cellulite applications
- Body firming products
- Contouring treatments
- Bust firming lotions
- Skin tightening face creams
- Anti-sagging eye creams

Processing hint

TEGO® Xymenynic can show crystallization which is reversible. In this case it has to be heated to 30–40 °C and homogenized before use. After that it is again ready for use.

Packaging

4 kg

Hazardous goods classification

Information concerning

- classification and labelling according to regulations for transport and for dangerous substances
- protective measures for storage and handling
- measures in accidents and fires
- toxicity and ecological effects

is given in our material safety data sheets.

Guideline formulations

Moisturizing Anti-Cellulite cream gel MAC 685/3/1	
Phase A	
TEGOSOFT® DC (Decyl Cocoate)	8.0%
TEGOSOFT® OP (Ethylhexyl Palmitate)	5.0%
TEGOSOFT® CR (Cetyl Ricinoleate)	2.0%
TEGO® Alkanol 1618 (Cetearyl Alcohol)	1.0%
TEGO® Xymenynic (Caprylic/Capric Triglyceride; Xymenynic Acid)	**2.5%**
Tocopheryl Acetate	0.5%
Phase B	
TEGOSOFT® PSE 141 G (Sucrose Stearate)	2.0%
TEGO® Care CG 90 (Cetearyl Glucoside)	0.5%
HyaCare® (Sodium Hyaluronate)	0.1%
Caffeine	1.0%
Propylene Glycol	4.0%
Glycerin	4.0%
Water	40.9%
Phase C	
TEGO® Carbomer 341 ER (Acrylates / C10-30 Alkyl Acrylate Crosspolymer)	0.45%
Water	29.55%
Phase D	
Sodium Hydroxide (10%)	q.s.
Phase Z	
Preservative, Perfume	q.s.

Preparation:

1. Heat phase A and B separately to 75–80 °C.
2. Add phase A to phase B with stirring[1)].
3. Homogenize.
4. Cool with gentle stirring.
5. Add phase C at approx. 45 °C with stirring.
6. Homogenize for a short time.
7. Add phase D at 40 °C while stirring.

[1)] Important: If phase A has to be charged into the vessel first, phase B must be added without stirring.

Energizing & firming body lotion MAC 650/3/3	
Phase A	
TEGO® Care LTP (Sorbitan Laurate; Polyglyceryl-4 Laurate; Dilauryl Citrate)	1.5%
TEGOSOFT® CI (Cetearyl Isononanoate)	5.0%
TEGOSOFT® DEC (Diethylhexyl Carbonate)	3.5%
TEGOSOFT® OP (Ethylhexyl Palmitate)	1.1%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	2.5%
TEGO® Carbomer 140 (Carbomer)	0.15%
TEGO® Carbomer 141 (Carbomer)	0.15%
Xanthan Gum	0.1%
TEGO® Xymenynic (Caprylic/Capric Triglyceride; Xymenynic Acid)	**2.5%**
Phase B	
TEGO® Cosmo C 100 (Creatine)	0.5%
Glycerin	3.0%
Water	80.0%
Phase C	
Sodium Hydroxide (10%)	q.s.
Phase Z	
Preservative, Perfume	q.s.

Preparation:

1. Mix ingredients of phase A.
2. Combine phase A and B without stirring.
3. Homogenize.
4. Adjust the pH with Sodium Hydroxide (phase C).
5. Add phase Z and stir well.

Skin tightening cream for mature skin MAC 650/4/3	
Phase A	
ABIL® Care XL 80 (Bis-PEG/PPG-20/5 PEG/PPG-20/5 Dimethicone; Methoxy PEG/PPG-25/4 Dimethicone; Caprylic/Capric Triglyceride)	2.5%
TEGIN® M Pellets (Glyceryl Stearate)	1.0%
TEGO® Alkanol 18 (Stearyl Alcohol)	2.0%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	4.9%
TEGOSOFT® OP (Ethylhexyl Palmitate)	4.5%
TEGOSOFT® DEC (Diethylhexyl Carbonate)	4.0%
TEGOSOFT® APS (PPG-11 Stearyl Ether)	3.0%
Avocado (Persea Gratissima) Oil	1.0%
TEGO® Xymenynic (Caprylic/Capric Triglyceride; Xymenynic Acid)	**1.0%**
Phase B	
SKINMIMICS® (Ceteareth-25; Glycerin; Cetyl Alcohol; Behenic Acid; Cholesterol; Ceramide NP; Ceramide NS; Ceramide EOS; Ceramide AP; Caprooyl Phytosphingosine; Caprooyl Sphingosine)	5.0%
Glycerin	3.0%
Water	66.0%
Phase C	
TEGO® Carbomer 134 (Carbomer)	0.2%
TEGOSOFT® OP (Ethylhexyl Palmitate)	0.8%
Phase D	
Sodium Hydroxide (10%)	q.s.
Phase Z	
Preservative, Perfume	q.s.

Preparation:

1. Heat phase A and B separately to approx. 80 °C.
2. Add phase B to phase A without stirring[1)].
3. Homogenize.
4. Cool with gentle stirring to approx. 60 °C and add phase C.
5. Homogenize for a short time.
6. Cool with gentle stirring and add phase D below 40 °C.

[1)] Important: If phase A has to be charged into the vessel first, phase B must be added without stirring.

Anti-Cellulite body lotion MAC 685/1/1	
Phase A	
TEGO® Care LTP (Sorbitan Laurate; Polyglyceryl-4 Laurate; Dilauryl Citrate)	1.5%
TEGOSOFT® CI (Cetearyl Isononanoate)	10.0%
TEGOSOFT® DEC (Diethylhexyl Carbonate)	3.5%
TEGOSOFT® OP (Ethylhexyl Palmitate)	1.1%
TEGO® Xymenynic (Caprylic/Capric Triglyceride; Xymenynic Acid)	**2.0%**
TEGO® Carbomer 140 (Carbomer)	0.15%
TEGO® Carbomer 141 (Carbomer)	0.15%
Xanthan Gum	0.1%
Phase B	
Caffeine	1.0%
Glycerin	3.0%
Water	77.5%
Phase C	
Sodium Hydroxide (10%)	q.s.
Phase Z	
Preservative, Perfume	q.s.

Preparation:

1. Mix ingredients of phase A.
2. Combine phase A and B without stirring.
3. Homogenise.
4. Adjust the pH with Sodium Hydroxide (phase C).

Add phase Z and stir well.

D 06/12

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Product specification

TEGO®XYMENYNIC

Substance No:	306803
Spec.Code:	S00: STANDARD
Version:	1
Version from:	24.03.2010
Print-out date:	07.08.2012

Insp. Characteristic	Method	Limits	Unit	
Identification	GM_1559_01	OK		C
Content	GM_1562_05	> = 20	%	X
Total Plate Count	GM_1553_01	< = 100	CFU/g	X

Identification	OK

Print on inspection document:
X = Actual measured value reported.
C = 'Conforms' is printed as characteristic value.

Appearance @ 25°C : slightly yellow liquid with specific odour

TEGO®Xymenynic can show crystallization which is reversible. In this case it has to be heated to 30-40 °C and homogenized before use. After that it is again ready for use.

This print-out is valid unsigned.

Edition 8
13 June 2014
Mat. Number G306803

TEGO® Xymenynic

Product data record

1. General information

1.1 Manufacturer/Supplier

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1.2 Product Description

1.2.1 Raw material category Skin Repair Active

1.2.2 Ingredients according to INCI

Caprylic/Capric Triglyceride; Xymenynic Acid

1.2.3 Composition

Components	Source	Ratio
Caprylic/Capric Triglyceride	vegetable	approx. 77.5 %
Xymenynic Acid	vegetable	approx. 20 %

1.2.4 Solvents, preservatives and other additives

	CAS No.	EINECS / EC No.	content	Function
Tocopherol	119-13-1	204-299-0	0.5 %	antioxidant

No components which are listed in Annex II of the Regulation (EC) No 1223/2009 and its modifications and updates are added to and are not to be expected in the above mentioned product due to the raw materials used and the production process.

2. Information on production process

General description of production process:
TEGO® Xymenynic a mixture of Xymenynic acid in Caprylic/Capric Triglyceride.

The product is not irradiated.

TEGO® Xymenynic is produced in the strictest absence of any animal derived material of any type.

TEGO® Xymenynic does not contain any remains of micro-organism which have been genetically modified.

2.1 By products

		method
Residual solvents	n-Hexane max. 60 ppm	
Free amines	not applicable	
1,4-Dioxane	not applicable	
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides	
Heavy metals	max. 20 ppm	AAS-ICP
As	< 2 ppm	AAS-ICP
Latex	not to be expected in the product due to the raw materials used and the production process	
VOC	< 3 % according to SR (Swiss Right) 814.018	

2.2 CMR (Carcinogenic, Mutagenic or Reprotoxic)

The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.

Further Information:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

Some of the CMR substances mentioned below and listed in Annex VI to Regulation (EC) No 1272/2008 are used as starting materials or solvents for the production of our cosmetic raw materials and may require reporting under California Proposition 65 or the Safe Cosmetics Act, SB 484.

The presence of these prohibited substances has to be seen as non-intended. It is stemming from impurities of the starting materials or the manufacturing process which is technically unavoidable in good manufacturing practice.

CMR substance	Starting material	max. concentration	method
Ethylene Oxide	no		
Propylene Oxide	no		
Octamethylcyclotetrasiloxane (D4)	no		
2-Ethylhexanoic Acid	no		
n-Hexane	yes	60 ppm	
Methyl Chloride	no		
Dimethyl Sulphate	no		

2.3 "Allergens" according to the Regulation (EC) No 1223/2009

The presence of substances, the mentioning of which is required under the column 'Other' in Annex III, shall be indicated in the list of ingredients in addition to the terms parfum or aroma.

The cosmetic raw materials and the cosmetic actives supplied by Evonik Personal Care are manufactured without the use of perfumes and fragrances. An analytical proof for the absence in traces of the substances to be mentioned in addition to the terms parfum or aroma is not performed in cosmetic raw materials, which are chemically produced.

None of these substances have been intentionally added to our cosmetic raw materials or are formed during the manufacturing process according to our knowledge of the chemistry.

2.4 Food Ingredients listed in Annex IIIa of Commission Directive 2007/68/EC.

None of these substances have been intentionally added to our cosmetic raw materials or are formed during the manufacturing process according to our knowledge of the chemistry.

3. Microbiological status

Total Viable Count	max. 100 cfu/g
Pathogens*	absent/g

*Pathogens are: Enterobacteria, Pseudomonas, Enterococci, Candida albicans, Staphylococci

4. Shelf life / storage conditions

Stable for at least 12 months after production when stored at room temperature (approx. 20 °C, unopened original packaging)

5. Regulatory Status

5.1 Customs tariff number 38249097

5.2 Regulatory status (chemical regulations)

Europe

Components	REACH status	CAS No.	EINECS / EC No.
Caprylic/Capric Triglyceride	Reg. No. 01-2119492306-35	73398-61-5	277-452-2
Xymenynic Acid	pre-registered	557-58-4	209-179-1

Other countries

Country		yes / no	Remark
Caprylic/Capric Triglyceride			
Australia	AICS:	yes	
China	IECSC:	yes	
Canada	DSL: NDSL:	yes	
Xymenynic Acid			
Australia	AICS:	no	
China	IECSC:		registration in progress
Canada	DSL: NDSL:	yes	

In the following countries the relevant authorities currently do not require pre-market approval for cosmetic raw materials:

Brazil, Japan, South Korea, Philippines, USA

5.2.1 Regulatory status (cosmetic regulation)

Country		yes / no	Remark
Caprylic/Capric Triglyceride			
China	CFDA:	yes	
Japan	JSQI:	yes	JSQI No. 111164, but specifications not controlled
Xymenynic Acid			
China	CFDA:	yes	
Japan	JSQI:	no	

6. Toxicology and Ecotoxicology

Refer to summary of ecotoxicological and toxicological data