Technical Information

AXOL® C 62 Pellets MB & dermofeel® GSC SG

Emulsifier for the formulation of cosmetic O/W creams and lotions

Intended use

O/W emulsifier

Benefits at a glance

- PEG-free emulsifier based on vegetable raw materials
- Stable emulsions from pH 5 8
- Easy to handle

INCI (PCPC name)

Glyceryl Stearate Citrate

Chemical and ph	Chemical and physical properties (not part of specifications)			
Form		Pellets		
HLB value		Approx. 12		

* Note: conglomerates can occur due to filling temperature and packaging pressure.

Properties

- AXOL® C 62 Pellets MB and dermofeel® GSC SG are anionic, PEG-free emulsifier based on vegetable raw materials.
- They are suitable for the hot emulsification process of O/W creams and lotions.
- They are easy to handle due to the pelletized product form.
- The emulsifiers form stable emulsions with all commonly used oils for skin care products, e. g. mineral oils, vegetable oils and synthetic esters.
- Substances with specific properties, such as UV filters and moisturisers are well tolerated by the emulsion based on the emulsifiers.
- Emulsions based on AXOL® C 62 Pellets MB and dermofeel® GSC SG show a good application and stability profile, if creams contain 20 35% and lotions 10 25% oil phase.

- The emulsions are distinguished by high stability towards heat and freezing stress; stability between -25 °C and +45 °C is attainable.
- The amount of AXOL® C 62 Pellets MB or dermofeel® GSC SG used, referred to the emulsion, is 1.5 2.0%.
- AXOL® C 62 Pellets MB and dermofeel® GSC SG behave very similar in most formulations regarding the stabilization potential. Due to different raw material grades of the stearic acid, AXOL® C 62 Pellets MB can generate higher emulsion viscosities compared to dermofeel® GSC SG depending on the specific formulation.
- As consistency enhancers components such as TEGO® Alkanol 1618 (Cetearyl Alcohol) as well as TEGIN® M Pellets MB (Glyceryl Stearate) or Stearic Acid proved to be most effective.
- Water-swelling organopolymers may improve the freeze stability.
- The pH value of the emulsions based on the emulsifiers can be adjusted from 5.0 to 8.0.
- For buffering the pH value of emulsions, e. g. 0.1% Disodium Phosphate is recommended, especially in the case of higher concentrations of the emulsifiers.

Application

The emulsifiers are especially suitable for O/W creams, lotions and wipes for:

- Facial and body care
- Baby care
- Sunscreens
- After sun care

Preparation

Processing

It is suggested to add AXOL® C 62 Pellets MB and dermofeel® GSC SG to the oil phase. We recommend to heat oil phase and water phase separately to approx. 80 °C. Furthermore, we recommend adding the hot oil phase to the hot water phase while stirring. The coarsely dispersed pre-emulsion is then homogenized.

If the above-mentioned processing is not possible, we recommend to combine the hot water and oil phase without stirring (to avoid the formation of a water-in-oil emulsion) and to start afterwards with the homogenization.

During cooling, a constant horizontal and vertical movement of the emulsion has to be ensured. The viscosity of the liquid emulsion increases to a creamy consistency, as the hydrated consistency promoters solidify.

The dispersion of TEGO® Carbomer 141 or other carbomer types in oil is added at 60°C. Then the emulsion is homogenized again for a short time.

Perfume or temperature–sensitive substances are added at 35 - 45 °C.

Neutralization of the emulsion is done at approx. 35 $^{\circ}$ C.

Suggested usage concentration

1.5 - 2.5% AXOL® C 62 Pellets MB or **dermofeel®** GSC SG

Hazardous goods classification

Information concerning

- classification and labelling according to regulations for transport of chemicals
- protective measures for storage and handling
- measures in case of accidents and fire
- toxicological and ecotoxicological effects

is given in our safety data sheets.

Guideline formulations

Phase A	
AXOL® C 62 Pellets MB (Glyceryl Stearate Citrate)	1.50%
TEGO® Alkanol 1618 (Cetearyl Alcohol)	1.00%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	9.50%
TEGOSOFT® MM MB (Myristyl Myristate)	4.00%
TEGO® Feel C 10 (Cellulose)	1.00%
Tocopheryl Acetate	1.00%
Xanthan Gum (Keltrol CG-SFT, CPKelco)*	0.50%
Phase B	
Water	77.50%
Glycerin	3.00%
Phase C	
Sodium Hydroxide (10% in water)*	0.20%
Phase D	
Benzyl Alcohol; Glycerin; Benzoic Acid; Sorbic Acid (Rokonsal BSB-N, Asland)*	0.80%

Preparation

- 1. Heat phase A and phase B separately to approx. 70 75 °C.
- 2. Add phase A to phase B with stirring. 1)
- 3. Homogenize.
- 4. Cool with gentle stirring to approx. 40 °C.
- 5. Add phase C and phase D and stir well.
- 6. Adjust the pH to 5.0 5.5.
- 1) Important: If phase A has to be charged into the vessel first, phase B must be added without stirring.

Remarks

Viscosity (Brookfield DV-I prime, sp. 4/5 rpm): 16 Pas

Microbiological safety: challenge test not performed

Natural content c_n (incl. water, ISO 16128): 80.7% Natural origin content c_{no} (incl. water, ISO 16128): 100.0%

*Not considered for calculation of c_n and c_{no} Stability between -5 °C and 45 °C

Phase A	
Water	70.15%
Glycerin	5.00%
dermofeel® PA-3 (Sodium Phytate; Aqua; Alcohol)	0.109
Verstatil® SL (Aqua; Sodium Levulinate; Potassium Sorbate)	1.50%
Phase B	
Xanthan Gum (Keltrol CG-RD, CP Kelco)*	0.30%
Phase C	
dermofeel® GSC SG (Glyceryl Stearate Citrate)	3.50%
TEGO® Alkanol 1618 (Cetearyl Alcohol)	2.00%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	6.00%
Squalane*	6.00%
Helianthus Annuus (Sunflower) Seed Oil	5.009
dermosoft® GMCY MB (Glyceryl Caprylate)	0.309
dermofeel® Toco 70 non GMO (Tocopherol; Helianthus Annuus (Sunflower) Seed Oil)	0.159

Preparation

- 1. Prepare phase A and C separately and heat up to 78°C.
- 2. Add phase B to phase A under stirring and wait until everything is dissolved.
- 3. Add phase B to A while stirring.
- 4. Homogenize.
- 5. Cool down under medium stirring.
- 6. Adjust pH to 5.2 5.4.

Remarks

Viscosity (Brookfield (21°C): TF; Speed 10 rpm): ~15 Pas

Stability between 4°C and 40°C

Natural content c_n (incl. water, ISO 16128): 81.4%

Natural origin content c_{no} (incl. water, ISO 16128): 99.8%

*Not considered for calculation of cn and cno Microbiological safety: challenge test passed

Phase A	
AXOL® C 62 Pellets MB (Glyceryl Stearate Citrate)	1.509
TEGOSOFT® DEC (Diethylhexyl Carbonate)	6.009
TEGOSOFT® OP (Ethylhexyl Palmitate)	5.009
TEGOSOFT® P (Isopropyl Palmitate)	2.509
Phase B	
Water	74.80
SKINMIMICS® (Ceteareth-25; Glycerin, Cetyl Alcohol; Behenic Acid; Cholesterol; Ceramide EOP; Ceramide EOS, Ceramide NP, Ceraamide NS; Ceramide AP; Caprooyl Phytospingosine; Caprooyl Sphingosine)	5.009
Glycerin	3.009
Phanthenol	0.509
Phase C	
TEGO® Carbomer 141 (Carbomer)	0.20
TEGOSOFT® OP (Ethylhexyl Palmitate)	0.809
Phase D	
Sodium Hydroxide (10% sol. In water) (Sodium Hydroxide)	q.s
Phase E	
Phenoxyethanol; Ethylhexylglycerin (Euxyl PE 9010, Schülke&Mayr GmbH)	0.709
Phase Z	
Perfume	q.s

Preparation

- 1. Heat phase A and phase B separately to approx. 80 °C.
- 2. Add phase A to phase B with 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 and phase E below 40 °C.
- 1) Important: If phase A has to be charged into the vessel first, phase B must be added without stirring.

Remarks

Viscosity (Brookfield RV DV-I, sp. 4, 5 rpm): 8 Pas pH value: 5.5 - 6.0

A 04/19

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Product specification

Material DERMOFEEL GSC SG Spec.Code K00 STANDARD

Inspection Characteristics	Method	Limits	Units	Z
Appearance		OK		С
Acid Value		0.0-20.0	mg KOH/g	X
Saponification Value		215.0-265.0	mg KOH/g	Χ
Appearance	white to light yellow powder			

Report on inspection certificate: X = specific/actual value, C = unspecific value/conformity, T = not reported

This product is certified according to the rules set out by RSPO Supply

Chain Segregated (SG).

RSPO Certification Number: RSPO-V-14-13553.

This document is computer printed and therefore valid without signature.

All warranty claims in respect of the conformity of our product are subject to our General Terms and Conditions of Sale and

Delivery. The data listed above reflects the criteria for our internal quality tests. We do not hereby make any express or implied warranty, whether for specific properties or for fitness for any particular application or purpose. All values are valid for the product when despatched from the works.

The Standard Test Methods can be obtained from specialized publishers. Evonik's test methods are available on request.

Material: DERMOFEEL GSC SG		Spec-Code: K00 STANDARD	Page 1 from 1
Print date: 22.03.2019	Valid from:	Version:	



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dermofeel® GSC SG

Product Data Record (PDR)

1. General Information

1.1 Supplier

Evonik Operations GmbH
Division Nutrition & Care
Business Line Care Solutions
Rellinghauser Straße 1-11
45128 Essen | Germany
personal-care@evonik.com
https://www.evonik.com/personal-care

1.2 Product Description

dermofeel® GSC SG is in full compliance with current Cosmetic Regulation (EC) No 1223/2009.

1.2.1 Raw Material Category/Function

O/W Emulsifier

1.2.2 INCI Declaration

Glyceryl Stearate Citrate

1.2.3 Composition

Components (INCI EU/US)	Source	Percentage [%]
Glyceryl Stearate Citrate	Vegetable/microbial	100

This composition information serves for information of our customers only. It is neither relevant for the composition listing according to Cosmetic Regulation (EC) No 1223/2009, nor does it reflect the chemical composition according to the different chemical regulations in the world which is disclosed in the table "information on ingredients/hazardous components" in the relevant parts of the respective (Material) Safety Data Sheets.

1.2.4 Additives (e.g. Antioxidants, Preservatives)

INCI	CAS No. / REACH Reg. No.	EINECS / EC No.	Content	Function
no additives				

Unless mentioned in our PDR under section 2.2 (By-Products/ Impurities) or 2.3 (CMR Substances), no components which are listed in Annex II of the current Cosmetic Regulation (EC) No 1223/2009 are added to and are not to be expected in the above mentioned product, due to the raw materials and the production process.



2. Production Process

2.1 General Information on the Production Process

The product is obtained by esterification of glyceryl stearate with citric acid.

Description and Origin of plant based materials:

Palm (Elaeis guineensis), rape/canola (Brassica), sugar cane (Saccharum officinale), sugar beet (Beta vulgaris) and/or corn (Zea mays)

Irradiation: dermofeel® GSC SG was not irradiated with y-rays.

dermofeel® GSC SG is produced in the absence of any animal derived material of any type. Based on the information on the manufacturing process and production site no contamination with BSE/ TSE risk materials is to be expected.

CITES: dermofeel® GSC SG is not based on raw materials from species listed in CITES appendices.

GMO Status:

The item contains moieties from rape, sugar beet and/or corn (including oils and other refined ingredients). During the production no GMOs and derivatives from GMOs are used. Citric acid is produced by fermentation using a wildtype microbial strain. All reasonable measures have been taken to avoid cross-contamination with GMOs or derivatives from GMOs.

2.2 By-Product/Impurities

Potentially occurring by – products are not added intentionally. Impurities e.g. residual solvents are technically unavoidable.

Description	Expected Values
Residual organic solvents	not applicable
Free amines	not applicable
Nitrosamines	not applicable
Monochloroacetic Acid	not applicable
Dichloroacetic acid	not applicable
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides
Total heavy metals	max. 20 ppm
As, Cd, Co, Cr, Hg, Ni, Pb, Sb	each < 1 ppm
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
DEG	< 0.1 %



2.3 CMR Substances

According to Cosmetic Regulation (EC) No 1223/2009 the use of substances classified as CMR (**C**arcinogenic, **M**utagenic or **R**eprotoxic) substances of category 1A or 1B or 2, under Part 3 of Annex VI to CLP Regulation (EC) No 1272/2008 in cosmetic products shall be prohibited.

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

The presence of these substances has to be seen as non-intended and it is technically unavoidable in good manufacturing practice. Traces of CMR substances can derive from impurities of the starting materials or the manufacturing process.

CMR Substance	CAS No.	Starting material	Max. concentration/ Remark
Ethylene Oxide	75-21-8	no	
Propylene Oxide	75-56-9	no	
Octamethylcyclotetrasiloxane (D4)	556-67-2	no	
2-Ethylhexanoic Acid	149-57-5	no	
n-Hexane	110-54-3	no	
Methyl Chloride	74-87-3	no	
Dimethyl Sulphate	77-78-1	no	
1,4-Dioxane	123-91-1	no	
Formaldehyde	50-00-0	no	For more information on formaldehyde please refer to our factsheet available via our intoBeauty website. https://intobeauty.evonik.com/

2.4 "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 of Cosmetic Regulation (EC) No 1223/2009, shall be indicated in the list of ingredients in addition to the terms "Perfume" or "Aroma".

None of those substances have been intentionally added to our cosmetic ingredients or are formed during the manufacturing process according to our knowledge of the chemistry. An analytical proof for the absence of traces of those substances is not performed in our cosmetic ingredients.

2.5 Food Ingredients listed in Annex II of Regulation (EU) No 1169/2011

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.

2.6 Nanomaterial

The product is not a nanomaterial according to the definition given by Cosmetic Regulation (EC) No 1223/2009, the Commission Recommendation 2011/696/EU and the French Decree No. 2012-232. For details, a separate statement is available on request.

2.7 Substances of Very High Concern (SVHC)

The candidate list of substances of very high concern is regularly updated and published by ECHA. If applicable, the information on the substance/s from the candidate list, contained in our product in reportable amounts, is included in section 3 of the product related Safety Data Sheet (SDS).

2.8 Country of Origin

dermofeel® GSC SG is manufactured in: Denmark



3. Animal Testing

We hereby confirm that we have never conducted any animal tests with our product dermofeel® GSC SG nor that we have ordered such tests at third parties or third parties have conducted such tests with our knowledge and acceptance to fulfil the requirements of Cosmetic Regulation (EC) No 1223/2009.

Therefore dermofeel® GSC SG is in full compliance with Cosmetic Regulation (EC) No 1223/2009.

4. Microbiological Status

Total Viable Count: max. 100 cfu/g

Pathogens*: absent/g

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

5. Shelf Life / Storage Conditions

1080 days after production (unopened original packaging)

6. Regulatory Status

6.1 HS-Code: 382499

EU-CN-Code: 38249993

6.2 Regulatory Status (Chemical Regulations)

Europe

Components Chemical Name/INCI	REACH Status*	CAS No.	EINECS / EC No.
	Reg. No. 01- 2119971751- 32	91744-39-7	294-601-7

^{*)} Any REACH registration no. referred to in this document covers the substance manufactured and/or imported into the European Community by Evonik Operations GmbH (or by our affiliates or by our EU suppliers). In case that a customer purchases material produced outside the EU which was not imported into the EU before supply and subsequently imports that material into the EU, this is not covered by any of our existing REACH registrations.



Non EU - Countries / Regions:

Component	Country	Inventory	yes / no	Remark
Glyceryl Stearate Citrate	Australia	AIIC (former AICS)	no	Self assessment: Exempted (Very Low Risk)*
	China	IECSC	yes	
	Canada	DSL	no	listed on ICL by CAS No. 39175-72-9
	Canada	NDSL	no	
	Taiwan	TCSI	yes	

^{*} Glyceryl Stearate Citrate was assessed based on available data for this substance and interpretation was done according the assessment criteria as published in AICIS' Industrial Chemicals (General) Rules, 2019. We emphasize that our self-assessment does not relieve the importer from any requirements (e.g. reporting obligations) stipulated by AICIS. In case that the Australian authority requests full tox reports, we can share them under CDA in case Evonik has ownership rights.

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

Brazil, Japan, South Korea, Philippines, USA

6.2.1 Regulatory Status (Non EU - Cosmetic Regulations)

Other countries:

Component	Country	Inventory	yes / no	Remark
Glyceryl Stearate Citrate	China	CFDA	yes	IECIC No. 02493
	Japan	JSQI	no	JSQI specification exists (JSQI No. 004409), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 555994

7. Toxicology and Ecotoxicology

Refer to our document: "Summary of Toxicological and Ecotoxicological Data"

8. Packaging

360 kg (18 x 20 kg)

This information and all further technical advice are based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.