Technical Information

LACTIL®

NMF mimicking blend

INTENDED USE

Active for skin care

BENEFITS AT A GLANCE

- Blend of humectants in aqueous solution as a substitute for the “Natural Moisturizing Factor” (NMF) of human skin
- Especially suitable for use in hydro-regulative cosmetics and anti-aging products

INCI (PCPC NAME)

Sodium Lactate; Sodium PCA; Glycine; Fructose; Urea; Niacinamide; Inositol; Sodium Benzoate; Lactic Acid

Chemical and physical properties (not part of specifications)	
Form	liquid

PROPERTIES

Besides lipids the skin needs an optimal proportion of water to retain its softness and suppleness. The ability of the horny layer of the skin to absorb moisture depends on the moisturizing factors contained in the epidermis – the "Natural Moisturizing Factors“ (NMF). The NMF are easily washed out by using soaps or other surfactants. This results in the premature desquamation of the epithelial cells and loss of suppleness.
Hydro-regulative cosmetics can help to counteract this effect by substituting the natural substances that have been washed out. In form of emulsions these cosmetics are excellent preparations supplying the skin with lipids and moisture. The skin’s inherent NMF consist mainly of lactate and pyroglutamate components. In **LACTIL®**, sodium lactate and sodium PCA (2-pyrrolidone-5-carbonic acid) are the major functional components. In addition, **LACTIL®** contains glycine, urea and niacinamide, which further enhance moisturization.

EFFICACY STUDIES

Moisturizing properties of LACTIL®
General study setup
To evaluate the skin moisturization benefits of **LACTIL®** studies were performed with 16 volunteers. The moisturization of the skin was determined by means of the Corneometer CM 825 (Courage & Khazaka, Cologne, D). Measurements were carried out under standardized conditions in a climatic room at ambient temperature and 55% relative humidity. The panellists acclimatized for 15 minutes before each measurement. At the beginning of the tests the baseline moisture content (t = 0) was determined for every test area. Further measurements followed after application of the test formulations at 2 hours or 2 and 6 hours, respectively. The differences between the initial baseline corneometer units (CU) and the CU after application were calculated for each panellist and are presented as ΔCU (delta CU) for the test formulations. The test formulations were randomized over both inner forearms of the volunteers with 4 test fields of 5 cm² per arm. The studies included a control and a vehicle test field.

- ***Dose response short term moisturization***

An O/W test emulsion was used and 0% (vehicle), 1%, 2%, and 3% of **LACTIL®** were incorporated. 4 µg/cm² of each O/W emulsion were applied on the test fields on the forearms. The skin moisture was determined before and 2 hours after application.
The results verify that **LACTIL®** rebalances the hydration status of the skin and provides excellent short term skin hydration efficacy (Fig. 1)

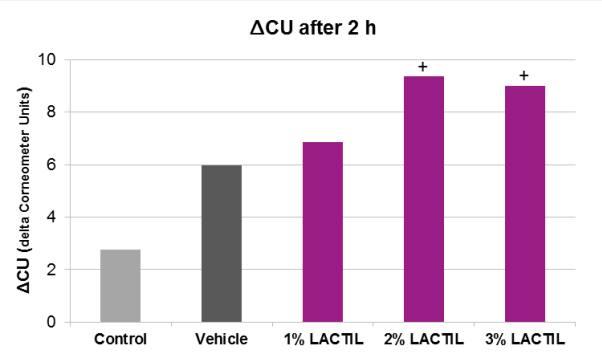

Figure 1: Short term moisturization (+p<0.05 compared to vehicle)

- *Combination of LACTIL® and glycerin*

In a third study the properties of glycerin in concentrations of 2.5% and 5% were compared to the combinations of 2.5% **LACTIL®** and 2.5% glycerin as well as 5% **LACTIL®** and 5% glycerin (formulations and procedure as described before). After 6 hours the moisturization properties of glycerin are prolonged significantly by **LACTIL®** due to its NMF mimicking composition (Fig. 2).

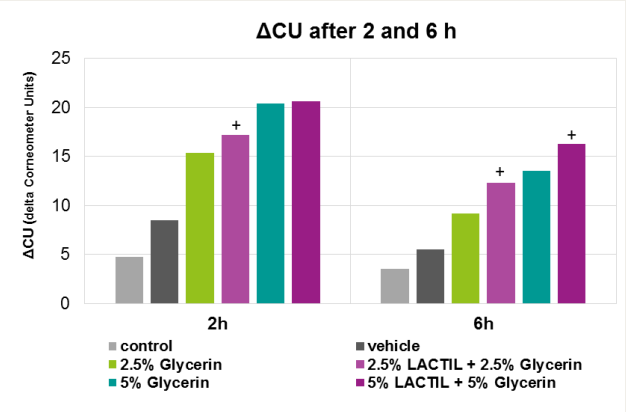

Figure 2: Prolonged moisturization properties of glycerin in combination with LACTIL® (+p<0.05 compared to 2.5% and 5% glycerin)

FORMULATION HINTS

LACTIL® is water soluble and cold processable, if the formulation type itself allows this.
In O/W emulsions it is recommended to add **LACTIL®** during the cooling process at temperatures below 40 °C. At usage levels of >3% it is recommended to increase the concentration of fatty alcohols, fatty acids or glyceryl stearate to ensure sufficient stability of the formulation. Due to its anionic character, **LACTIL®** cannot be applied in cationic emulsions. The combination with hydrocolloids like carbomer is only recommended for hot processed formulations.
In W/O emulsions **LACTIL®** is added to the water phase and the emulsion is prepared as usual.

APPLICATIONS

LACTIL® is suitable as an additive for hydro-regulative cosmetics of all kinds:

- Moisturizing creams and lotions
- Body creams and lotions
- Anti-aging creams

RECOMMENDED USAGE CONCENTRATION

1.0% – 5.0%

GUIDELINE FORMULATIONS

If you are interested in guideline formulations please visit our homepage
https://personal-care.evonik.com.

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.

M 09/19

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EVONIK
POWER TO CREATE

Product specification

Material LACTIL
Spec.Code K00 STANDARD

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Inspection Characteristics	Method	Limits	Units	Z
Refractive index / 20°C	GM_0120_01	1.4180-1.4250		X
Density / 20°C	GM_0110_01	1.268-1.276	g/ml	X
Solid content	GM_0090_43	50.0-55.0	%	X
pH-Value as is	GM_0130_01	6.7-7.6		X
Nitrogen content	no Method	2.00-2.50	%	X

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

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.

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LACTIL®

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

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

1.2.1 Raw Material Category/Function

Cosmetic Active Ingredient blend based on Amino Acids Derivatives

1.2.2 INCI Declaration

Aqua; Sodium Lactate; Sodium PCA; Glycine; Fructose; Urea; Niacinamide; Inositol; Sodium Benzoate; Lactic Acid

1.2.3 Composition

Components (INCI EU/US)	Source	Percentage [%]
Sodium Lactate	Vegetable/microbial	approx. 25
Sodium PCA	Vegetable/microbial	approx. 25
Glycine	Synthetic	NMT 1.0
Fructose	Vegetable	NMT 1.0
Urea	Synthetic	NMT 1.0
Niacinamide	Synthetic	NMT 1.0
Inositol	Synthetic	NMT 1.0
Lactic Acid	Vegetable/microbial	NMT 1.0
Aqua		approx. 48

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
Sodium Benzoate	CAS 532-32-1 / 01-2119460683-35	208-534-8	0.4 %	Preservative

Known restrictions:
Sodium Benzoate
Europe:
Benzoic acid and its salts are listed in Annex V (No.1) of the Cosmetic Regulation (EC) No 1223/2009: Max concentration in ready for use preparation depending on application from 0.5 up to 2.5 % of the acid.

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 mixing the compounds.

Description and Origin of plant based materials:
Sugar beet (Beta vulgaris), sugar cane (Saccharum)

Irradiation: LACTIL® was not irradiated with γ-rays.

LACTIL® 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: LACTIL® is not based on raw materials from species listed in CITES appendices.

GMO Status:
The item contains moieties from sugar beet (including oils and other refined ingredients). During the production no GMOs and derivatives from GMOs are used. All reasonable measures have been taken to avoid cross-contamination with GMOs or derivatives from GMOs.

2.2 By-Product/Impurities

Below listed compound are technically unavoidable by-products or traces of unremovable impurities (e.g. residual solvents). They are not added intentionally.
Information on potentially occuring by - products, impurities and selected substances of general interest known to be CMR are summarized in section "2.3 CMR Substances".

Known by-products and product specific impurities*

Description	Expected values
none	

Additional standard parameters**

Description	Expected values
Sum of heavy metals (as Pb)	NMT 20 ppm
As, Cd, Co, Cr, Cu, Hg, Ni, Pb, Sb	each NMT 1 ppm
Residual organic solvents	not applicable
VOC	NMT 3 % according to SR (Swiss Right) 814.018
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides
Latex	not to be expected in the product due to the raw materials used and the production process

* monitored by dedicated product analysis or statistical testing
** monitored by statistical testing and/or spot checks

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 (EO)	75-21-8	no	
Propylene oxide (PO)	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 sulfate	77-78-1	no	
Dioxane (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, shall be indicated in the list of ingredients in addition to the terms perfume or aroma.
The cosmetic raw materials and the cosmetic actives supplied by Evonik Care Solutions 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 perfume 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.

2.5 Food Allergens listed on Annex II of Regulation (EU) No 1169/2011

None of these substances have been intentionally added to our cosmetic raw materials.

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

LACTIL® is manufactured in: France

3. Animal Testing

We hereby confirm that we have never conducted any animal tests with our product LACTIL® 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 LACTIL® 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

720 days after production (unopened original packaging)

6. Regulatory Status

6.1 HS-Code: 382499

EU-CN-Code: 38249992

6.2 Regulatory Status (Chemical Regulations)

Europe

Components Chemical Name/INCI	REACH Status*	CAS No.	EINECS / EC No.
Sodium 2-hydroxypropanoate/Sodium Lactate	Reg. No. 01-2119969948-09	72-17-3	200-772-0
Sodium (2S)-5-oxopyrrolidine-2-carboxylate/Sodium PCA	Reg. No. 01-2119986878-07	28874-51-3	249-277-1
2-aminoacetic acid/Glycine	Reg. No. 01-2119864796-18	56-40-6	200-272-2
Fructose	Exempt; Annex IV	57-48-7	200-333-3
Urea	Reg. No. 01-2119463277-33	57-13-6	200-315-5
Pyridine-3-carboxamide/Niacinamide	Reg. No. 01-2119968268-22	98-92-0	202-713-4
Inositol	Exempt; < 1t/Y	87-89-8	201-781-2
Benzoic acid, sodium salt/Sodium Benzoate	Reg. No. 01-2119460683-35	532-32-1	208-534-8
2-hydroxypropanoic acid/Lactic Acid	Exempt; < 1t/Y	50-21-5	200-018-0

*) 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
Sodium Lactate	Australia	AIIC	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Sodium PCA	Australia	AIIC	yes	
	China	IECSC	yes	
	Canada	DSL	no	but listed on Revised In Commerce List (R-ICL) by CAS No. 28874-51-3
	Canada	NDSL	no	
	Taiwan	TCSI	yes	
Glycine	Australia	AIIC	yes	
	China	IECSC	yes	
	Canada	DSL	yes	

Component	Country	Inventory	yes / no	Remark
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Fructose	Australia	AIIC	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Urea	Australia	AIIC	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Niacinamide	Australia	AIIC	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Inositol	Australia	AIIC	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Sodium Benzoate	Australia	AIIC	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Lactic Acid	Australia	AIIC	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	

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

Brazil, Japan, South Korea, USA

6.2.1 Regulatory Status (Non EU - Cosmetic Regulations)

Other countries:

Component	Country	Inventory	yes / no	Remark
Sodium Lactate	China	CFDA	yes	IECIC No. 05686
	Japan	JSQI	no	JSQI specification exists (JSQI No. 106682), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 553107
Sodium PCA	China	CFDA	yes	IECIC No. 00427
	Japan	JSQI	no	JSQI specification exists (JSQI No. 540007), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 550148
Glycine	China	CFDA	yes	IECIC No. 02387
	Japan	JSQI	no	JSQI specification exists (JSQI No. 102546), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 551101
Fructose	China	CFDA	yes	IECIC No. 02699
	Japan	JSQI	no	JSQI specification exists (JSQI No. 002078), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 552161
Urea	China	CFDA	yes	IECIC No. 04827
	Japan	JSQI	no	JSQI specification exists (JSQI No. 002286), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 553117
Niacinamide	China	CFDA	yes	IECIC No. 07359
	Japan	JSQI	no	JSQI specification exists (JSQI No. 0014630 (Nicotinamide)), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 551930
Inositol	China	CFDA	yes	IECIC No. 03145
	Japan	JSQI	no	JSQI specification exists (JSQI No. 500035), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 550711
Sodium Benzoate	China	CFDA	yes	IECIC No. 01289
	Japan	JSQI	no	JSQI specification exists (JSQI No. 002024), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 552785
Lactic Acid	China	CFDA	yes	IECIC No. 05649
	Japan	JSQI	no	JSQI specification exists (JSQI No. 001468), but compliance is not controlled

Component	Country	Inventory	yes / no	Remark
	Japan	JCIA	yes	JCIA No. 553104

Known restrictions:
Sodium Benzoate
Japan:
Benzoic acid is restricted according to Annex III of the Japanese Standard for Cosmetics (2000/2001) in all kinds of cosmetic applications by max. 0.2 % (as total).
Benzoates are restricted according to Annex III of the Japanese Standard for Cosmetics (2000) in all kinds of cosmetic applications by max. 1.0 % (as total).

7. Toxicology and Ecotoxicology

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

8. Packaging

25 kg