

Regulatory Product Information

Only Valid for Use in Cosmetics (Version 2.1)

GlucoTain® Plus

1. General Information		
1.1	Trade name	GlucoTain® Plus
1.2	Manufacturer / Supplier <i>(address, phone no., fax no., contact person)</i>	Clariant Produkte (Deutschland) GmbH, 65926 Frankfurt Application Development Personal Care Phone: +49 (0)69 305 18172 Fax: +49 (0)69 305 38467 Corporate Product Stewardship Phone: +49 (0)6196 757 6228 Fax: +49 (0)6196 757 6244
1.3	Raw material category	Surfactant for the cosmetic industry
1.4	Chemical name	N-C8/10-acyl-N-methyl-glucamin and N-C12/14-acyl-N-methyl-glucamin
1.5	INCI (CTFA) name Composition	Capryloyl/Caproyl Methyl Glucamide (and) Lauroyl/Myristoyl Methyl Glucamide
1.6	EC (EINECS/ELINCS) no.	940-284-1 and 407-290-1
1.7	CAS no.	1591782-62-5 and 287735-50-6
1.8	Registration status <i>(e.g. EU, US, Japan)</i>	Listed on the chemical inventories of Australia, Canada, the European Union, Japan and Switzerland.
1.9	Regulations for cosmetic use	In conformity with the requirements relevant to cosmetic ingredients of the Cosmetics Regulation (EC) 1223/2009. USA: This product is not listed on the TSCA Inventory. It is to be used as a cosmetic ingredient only.
1.10	Country of origin	Germany

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2. Information on Production		
2.1	Origin of starting material (plant, animal, synthetic)	plant Product is based on materials which do not originate from animal sources and which are not produced from genetically modified material.
2.2	Does the material contain genetically modified organisms?	Product does not contain genetically modified organisms (GMOs).
2.3	Information on production process (general description)	Blend of N-C8/10-acyl-N-methyl-glucamin and N-C12/14-acyl-N-methyl-glucamin
3. Additives		
3.1	Preservatives	not added by recipe
3.2	Antioxidants	not added by recipe
3.3	Solvents	approx. 45 % water
3.4	Bleaching agents	not added by recipe
3.5	Fragrances (Allergens) according to the European Cosmetics Regulation (EC) 1223/2009, Annex III	not added by recipe
3.6	CMR classified ingredients	not added by recipe
3.7	Dangerous ingredients according to Annex I of Directive 67/548/EEC resp. Annex VI of Regulation (EC)1272/2008 or ingredients self-classified as dangerous	See EU safety data sheet, chapter 2 or 3 (regulatory information, hazardous components).
3.8	Others	Food allergens as of Directive 2000/13/EC (as amended), Annex IIIa and Regulation (EU) 1169/2011, Annex II are not added by recipe.

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4. Microbiological Specification		
4.1	Total viable count (colony-forming units/g)	< 100
5. By-products <i>The presence of traces of the substances listed in Annex II of Regulation (EC)1223/2009 (incl. cmr category. I-III substances marked with *) shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 3 of Regulation (EC)1223/2009.</i>		
5.1	1,4-Dioxane *	not expected from the process
5.2	Ethylene oxide *	not expected from the process
5.3	Residual solvents	approx. 4.5 - 6.0% propylene glycol max. 0.3 % Methanol
5.4	Residual monomers	not expected from the process
5.5	Amines	N-Methyl-glucamine < 2%
5.6	Nitrosamines	< 50 ppb (Apparent Total Nitrosamines Content)
5.7	Heavy metals	max. 20 ppm typical values: Cr,Co,Cd,Hg,Pb,As,Sb, each < 1 ppm Ni max. 2 ppm
5.8	Monochloroacetic acid	not expected from the process
5.9	Dichloroacetic acid	not expected from the process
5.10	Phthalates	not expected from the process
5.11	Pesticides	Based on information concerning raw materials, production process and equipment used, pesticides are not likely to be present.

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5.12	Glycol ethers	Based on information concerning raw materials, production process and equipment used, Butyldiglycol, Ethyldiglycol and 2-Butoxyethanol are not likely to be present.
5.13	Others	< 0,5% Sorbitol, max. 0.5% Methylester C8-10-12-14 approx. 0.3 % Citric Acid is added as pH adjusting agent.
6. Toxicology		
6.1	Information on acute toxicity	Method: OECD 423 (rat) LD50 5.000 mg/kg Data referring to the main component
6.2	Information on skin irritation	Method: OECD 439 non-irritating Data referring to the main component
6.3	Information on irritation of the mucous membrane	Method: OCED 437 strongly irritant Data referring to the main component
6.4	Information on sensitisation potential	Method: OECD 406 non-sensitizing Data referring to the main component
6.5	Information on gene toxicity	Method: OCED 471 Not mutagenic in Ames-Test Data referring to the main component
6.6	Information on percutaneous permeation	no data available
6.7	Others	Repeated Dose toxicity: Method: OECD 407 (rat) NOAEL: 250 mg/kg Data referring to the main component

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	<p>Acute dermal toxicity: Method: OECD 402 (rat) LD50 > 2000 mg/kg Data referring to the main component</p> <p>Acute inhalation toxicity: Method: OECD 436 (rat) LC50 > 1-5 mg/L Data referring to the main component</p>
7. Ecology	
7.1 Degradability/Elimination	<p>Method: OECD 301B > 80 % (28d) Data referring to the main component</p>
7.2 Acute aquatic toxicity	<p>Fish Toxicity: Method: OECD 203 LC50 > 100 mg/l (96 h, zebra fish) Data referring to the main component</p> <p>Method: OECD 212 LC50 > 200 mg/l (9d, zebra fish) Data referring to the main component</p> <p>Daphnia Toxicity: Method: OECD 202 EC50 > 100 mg/l (48 h, Daphnia magna) Data referring to the main component</p> <p>Method: OECD 211 NOEC 50 mg/l (21d, Daphnia magna) Data referring to the main component</p> <p>Algae Toxicity: Method : OECD 201 EC50 >100 mg/l (72 h, Selenastrum capricornutum) Data referring to the main component</p>

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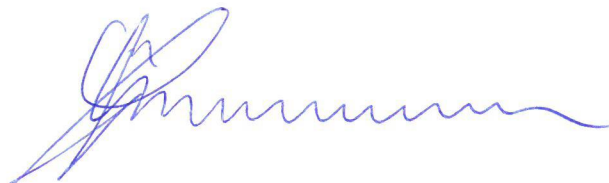
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	Method: OECD 201 NOEC 100 mg/l Data referring to the main component
7.3 Others	Bacteria Toxicity Method: OECD 209 EC50 > 1.000 mg/l (3h activated sludge) Data referring to the main component
8. Additional Information <i>(For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)</i>	
8.1 Nanomaterial	Product is not considered as a nanomaterial according (EC) No.1223/2009 definition art.2 (1k).

Date

04.01.2018

Regulatory Affairs Manager
(Dr. Lämmermann)



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NO EXPRESS OR IMPLIED WARRANTY IS MADE OF THE MERCHANTABILITY, SUITABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE OF ANY PRODUCT OR SERVICE.

CERTIFICATE OF COMPOSITION

Trade Name or Proposed Name:	GlucoTain Plus
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INCI Name	Concentration	CAS number	EINECS number	Function
Capryloyl/Caproyl Methyl Glucamide	Approx. 33 %	1591782-62-5	940-284-1	Active
Lauroyl/Myristoyl Methyl Glucamide	Approx. 22 %	287735-50-6	407-290-1	Active
Aqua	Approx. 45 %	7732-18-5	231-791-2	Solvent

Company representative : Dr. Dieter Lämmermann

Date:

04.01.2018

Function : Manager of Product Stewardship

Signature :

Geschäftsführer:
Oliver Kinkel (Vorsitz)
Lars Jansson

Handelsregister:
Frankfurt am Main
HRB 103782

**Sitz der
Gesellschaft:**
Frankfurt am Main

Bankverbindung:
Deutsche Bank AG
IBAN: DE41500700100092415900 EUR
IBAN: DE84500700100092415902 USD
SWIFT: DEUTDEFFXXX

Aufsichtsratsvorsitzender:
Patrick Jany