

Personal Care
Product Dossier
SYN®-HYCAN



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Product Information Product Data Sheet

SYN®-HYCAN

Product code: 5038333

Description

SYN®-HYCAN is a patented synthetic tripeptide for cosmetic application, easy to formulate with. The unique structure is Tetradecylaminocarbonyl-Dab-Val-Dab. SYN®-HYCAN does not contain intentionally added substances regulated/listed as preservative.

Product identification

Product code: 50 3833 3

Composition

INCI name	Content	CAS No.	EINECS/ELINCS	Chemical name
Tetradecyl Aminobutyroylvalyl- aminobutyric Urea Trifluoroacetate	0.1-1 %	934368-60-2	none	Tetradecylamino- carbonyl-Dab-Val- Dab bistrifluoroacetate salt
Glycerin	> 50 %	56-81-5	200-289-5	Glycerin
Aqua	25-50 %	7732-18-5	231-791-2	Water
Magnesium Chloride	0.01-0.1 %	7786-30-3	232-094-6	Magnesium Chloride

Specifications

Appearance: opalescent to hazy, colorless to yellowish, viscous

liquid

 Relative density d20/20:
 1.150 - 1.220

 Refractive index n25:
 1.410 - 1.440

 Peptide content:
 900 - 1300 ppm

Total Viable Aerobic Count:

Total Aerobic Microbial Count (TAMC): ≤ 100 CFU / ml
Total Yeast/ Moulds Count (TYMC): ≤ 100 CFU / ml
Specified microorganisms: Absence in 1 ml

Replaces Version 01: 2016-02-22

Version 02: 2019-11-15



Product Information Product Data Sheet

SYN®-HYCAN

Product code: 5038333

Solubility

SYN®-HYCAN is miscible with water.

Stability and storage

SYN®-HYCAN may be stored for at least 36 months from the date of manufacture in the unopened original container protected from light in a clean place and at a temperature between 2 and 8°C. The 'Best use before' date is printed on the label. Keep package tightly closed. Once opened, use contents quickly. In order to avoid secondary microbial contamination, following opening, the content of the containers should be handled with special care.

Uses

SYN®-HYCAN is a synthetic peptide for skin care products. It can be processed either warm (for maximum 2 hours at 80°C) or cold and should be incorporated into the aqueous phase of a cosmetic formulation. For skin care preparations, the addition of 2.5 % SYN®-HYCAN is recommended. Basic Guide Formulations are available upon request.

Patent Information

DSM Nutritional Products Ltd. holds the patent rights for the production and topical application of SYN®-HYCAN.

Safety

This product is safe for the intended use. Avoid ingestion or direct contact by applying suitable protective measures and personal hygiene.

Replaces Version 01: 2016-02-22

Version 02: 2019-11-15



Product Information Product Data Sheet

SYN®-HYCAN

Product code: 5038333

DSM Nutritional Products Ltd

Product Management

Additional information

To find out more about our ingredients, please contact your nearest DSM Nutritional Products office.

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DSM Nutritional Products China No. 476, Li Bing Road Zhangjiang High-Tech Park Pudong Area, Shanghai 201203 P.R. of China	Tel.: +86 (0)21 6141 8188 Internet www.dsmnutritionalproducts.cn
DSM Produtos Nutricionais Brasil S. A. Avenida Engenheiro Billings, nº 1729 – Prédio 31 Sala A CEP:05321-010 São Paulo – SP	Tel.: + 55 (11) 3760-6300 Internet <u>www.dsmnutritionalproducts.com</u>

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Brasil



Product Code: 50 3833 3 Version 01: 2016-02-22

Replaces version: New

Ref:AnGr/FC

SYN®-HYCAN

Manufacturing Principle

The synthesized and purified peptide is dissolved in water. The resulting solution is homogenized and magnesium chloride (as hexahydrate) is added. Then the solution is pH adjusted. Glycerin is added to achieve a final composition of SYN®-HYCAN consisting of 900 - 1300 ppm of peptide in 69% glycerin. This solution is filtered and filled into containers.

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Product Information Specifications & Tests

SYN®-HYCAN

Product code: 5038333

1. Appearance: Opalescent to hazy, colourless to yellowish, viscous liquid

According to a visual inspection

2. Relative density d20/20: 1.150 -1.220

According to the EP 2.2.5

3. Refractive index n25: 1.410 -1.440

According to the EP 2.2.6

4. Peptide content: 900 -1300 ppm

By Reversed Phase HPLC-UV

Stationary phase:	Waters, Symmetry C18, 75 mm x 4.6 mm x 3.5 µm, Part No. WAT066224 or equivalent
Column temperature:	Nominal 25° C
Mobile phase A:	Trifluoracetic acid 0.07%in water
Mobile phase B:	Trifluoracetic acid 0.07%in acetonitrile
Flow rate:	1.0 ml/ min
Injection volume:	80 μl
Sample temperature:	10°C ± 5°C
Detection:	UV / 220 nm
Elution time:	SYN-HYCAN peptide elutes at approx. 5.6 minutes
Test solution:	500 mg/ ml in water
Reference solution:	c \approx 500 µg/ml in 1,1,1,3,3,3- Hexafluoro-2-propanol solution (20%in water) / water = 1/9

Replaces Version 01: 2016-02-22

Version 02: 2019-11-15



Product Information Specifications & Tests

SYN®-HYCAN

Product code: 5038333

Gradient					
Time [min]	%A	%В	Flow [ml/min]	Wavelength [nm]	
0	90	10	1.0	220	
8	1	99	1.0	220	
10	1	99	1.0	220	
11	90	10	1.0	220	
13	90	10	1.0	220	

5. Total Viable Aerobic Count

According to the EP 2.6.12, membrane filtration

Total Aerobic Microbial Count (TAMC): ≤ 100 CFU / ml
 Total Yeast/Moulds Count (TYMC): ≤ 100 CFU / ml

6. Specified microorganisms:

According to the EP 2.6.13 or equivalent validated method

Pseudomonas aeruginosa
Absence in 1 ml
Staphylcoccus aureus
Absence in 1 ml
Candida albicans
Absence in 1 ml
Escherichia coli
Absence in 1 ml

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Personal Care

Product: 5038333 SYN®-HYCAN
Origin: Village Neuf (France)

1. Source of ingredient(s)

Source of active ingredient(s)	Yes	No	Comments
Synthetic	Χ		Tetradecyl Aminobutyroylvalylaminobutyric Urea Trifluoracetate
Biotechnology		Χ	
Vegetable		Χ	
Animal		Χ	
Mineral		Χ	
Source of formulation ingredient(s)	Yes	No	Comments
Synthetic		Χ	
Biotechnology		Χ	
Vegetable	Χ		Glycerin (from rape seeds)
Animal		Χ	
Mineral	Χ		Aqua, Magnesium Chloride
Additional ingredient(s) source information	Yes	No	Comments
GMO statement available	Χ		
BSE/TSE statement available	Χ		
Palm oil or palm oil derived		Χ	
Petroleum derived	Χ		Tetradecyl Aminobutyroylvalylaminobutyric Urea
			Trifluoracetate
Landan Alam disting	V	NI.	Community
lonisation/Irradiation	Yes	No	Comments
Ionisation or irradiation applied to this product		Χ	



Personal Care

Product: 5038333 SYN®-HYCAN
Origin: Village Neuf (France)

2. Function of the ingredient(s)

Function	Yes	No	Comments
Active substance(s)	Χ		Tetradecyl Aminobutyroylvalylaminobutyric Urea Trifluoracetate (skin conditioning agent)
Solvent(s) / carrier(s)	Χ		Glycerin, Aqua
Antioxidant(s)		Χ	
Ingredient(s) listed in Annexes (II, III, IV, V, VI) of Cosmetic Regulation (EC) 1223/2009		Χ	
Others	Χ		Magnesium Chloride

3. Substance(s) potentially contained

Food allergens	Yes	No	Comments
Cereals containing gluten and products thereof			Not applicable
Milk and dairy products (incl. lactose)			Not applicable
Nuts and nut products (incl. peanuts)			Not applicable
Coconut and products thereof			Not applicable

Other various substances	Yes	No	Comments
Ethanol and denatured alcohol		Χ	Not expected and not determined
Formaldehyde and formaldehyde releasers		Χ	Not expected and not determined
Acetaldehyde		Χ	Not expected and not determined
Phthalates		Χ	Not expected and not determined
Glycol ethers		Χ	Not expected and not determined
1,4-Dioxane		Χ	Not expected and not determined
Free amines		Χ	Not expected and not determined
Nitrosamines		Χ	Not expected and not determined
Acrylamide		Χ	Not expected and not determined
Monomer residues		Χ	Not expected and not determined
Dioxin/PCB		Χ	Not expected and not determined



Personal Care

Product: 5038333 SYN®-HYCAN
Origin: Village Neuf (France)

Other various substances	Yes	No	Comments
PAH(s)		Χ	Not expected and not determined
Heavy metals statement available	Χ		
Residual solvents statement available	Χ		
Pesticide statement available	Χ		
4. Regulatory information			
EU cosmetic legislation (Reg (EC) 1223/2009)	Yes	No	Comments
Compliance statement available	Χ		
Fragrance allergen statement available	Χ		
CMR statement available	Χ		
Animal testing statement available	Χ		
Last animal testing date for cosmetic purpose		Х	Neither the product nor its ingredients have been tested on animals for cosmetic purposes, by or on behalf of DSM Nutritional Products Ltd.
Last animal testing date for non-cosmetic purpose		Х	Neither the product nor its ingredients have been tested on animals for non-cosmetic purposes, by or on behalf of DSM Nutritional Products Ltd.
EU chemical legislation (Reg (EC) 1907/2006)	Yes	No	Comments
REACh statement available	Χ		
PBT/vPvB information	Χ		For any available information see Safety Data Sheet, section 12.5
SVHC statement available	Χ		



Personal Care

Product: 5038333 SYN®-HYCAN
Origin: Village Neuf (France)

US legislation Yes No Comments

Californian Proposition 65 statement available X

China legislation Yes No Comments

China regulatory status statement available X

Global regulatory overview Yes No Comments

Global regulatory status statement available X

Nanomaterial information Yes No Comments

Nano statement (Reg (EC) 1223/2009) available

Not applicable: The product does not contain nano

material according to the definition of Regulation (EC)

No 1223/2009 (Article 2, (k)).

Nano declaration informationNot applicableAdditional nano informationNot applicable

Other confirmations Yes No Comments

 ${\hbox{\it Compendia compliance}} \qquad \qquad {\hbox{\it X}} \qquad {\hbox{\it The ingredient glycerin is compliant to European}}$

Pharmacopeia

Cites listed X

In scope of Nagoya Protocol X Product launched before ratification of Nagoya

Protocol (October 2014)

5. Safety and environment

Toxicology Yes No Comments

Toxicological information statement available X

Ecotoxicological information available X For any available information see Safety Data Sheet,

section 12



Personal Care

Product: 5038333 SYN®-HYCAN
Origin: Village Neuf (France)

Volatile organic compound(s)

Yes No Comments

VOC substance(s) according to positive list of Swiss

VOC Regulation contained

Χ

6. Product suitability

Eco certification Yes No Comments

Ecocert certificate available
Natrue certificate available
Not applicable
Cosmos certificate available
Not applicable
Fair Trade certificate available
Not applicable

Kosher / Halal status Yes No Comments

Kosher certificate/statement available X

Halal certificate/statement available X

7. Packaging materials

Packaging compliance Yes No Comments

Traceability of packaging materials statement

available

Compliance of packaging materials statement

available

Treatment of pallets statement available X The pallets are heat-treated according to IPPC

Χ

Χ

Standard ISPM-15.

8. Quality information

Quality standards Yes No Comments

GMP standard applied for this product X EFfCI GMP (2012) compliant



Personal Care

Product: 5038333 SYN®-HYCAN
Origin: Village Neuf (France)

9. Supportive documentation

General statements Yes No Comments

Microbiology statement available X See Product Data Sheet

Sustainability document available X

Lot code explanation available X

10. Additional information

Technical Dossier Yes No Comments

Glossary Technical Dossier available X

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SYN®-HYCAN

GMO Statement

We hereby confirm that the product SYN®-HYCAN is manufactured by conventional processes** and therefore does not contain GMO-DNA.

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Product Code: 50 3833 3

Date: 2016-Mar-31

Reference:

^{**} The term "conventional process" refers to chemical synthesis, fermentation using non GMM, extraction from conventional plants.



Product Information BSE/TSE Statement

SYN®-HYCAN

Product code: 5038333

With regards to TSE/BSE potential risk transmission, the EU Cosmetic Products Regulation (EC) 1223/2009 prohibits the use of below materials in cosmetic products:

- Annex II, entry 416: Cells, tissues or products of human origin
- Annex II, entry 419: Category 1 and Category 2 materials as defined in Articles 8 and 9 of Regulation (EC) 1069/2009 (repealing Articles 4 and 5 respectively of Regulation (EC) No 1774/2002). Category 1 materials include all Specified Risk Materials as defined by Annex V of Regulation (EC) 999/2001.

We hereby confirm that this product is not derived from animal or human, furthermore no animal or human origin material is used during the manufacture of this product.

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Replaces Version 01: 2016-02-22

Version 02: 2019-02-04



Product Information Heavy Metals Statement

SYN®-HYCAN

Product code: 5038333

We hereby state that there are appropriate procedures in place to control heavy metals.

The following specifications are met 1:

Antimony	max.	2.0 ppm
Arsenic	max.	1.0 ppm
Cadmium	max.	0.5 ppm
Lead	max.	1.0 ppm
Mercury	max.	0.1 ppm
Nickel	max.	2.0 ppm

The procedures are based on relevant Quality and/ or Good Manufacturing Practice (GMP) standards.

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¹ According to ICP-MS or AAS methods (EP 2.2.58 or E.P 2.2.23 or USP 233)



Product Code: 50 3833 3 Version 01: 2016-02-22

Replaces version: New

Ref:AnGr/FC

SYN®-HYCAN

Residual Solvent Statement

We hereby confirm that we produce SYN®-HYCAN without using solvents, and therefore SYN®-HYCAN does not contain residual solvents from our manufacturing process.

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SYN®-HYCAN

Pesticide Statement

This confirmation refers to the definition and limits of pesticide residues as laid down in the international pharmaceutical or food regulations, such as the European Pharmacopoeia or Regulation (EC) No 396/2005¹, applying to ingredients derived from vegetable sources.

We hereby confirm that above mentioned product contains ingredient(s) of vegetable origin.

Based on the ingredient(s) or product information available, we confirm that compliance with the limits for pesticide residues as set in the European Pharmacopoeia (current version) and/or in Regulation (EC) No 396/2005¹ and/or equivalent regulation is warranted.

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¹ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC and subsequent amendments.



Product Code: 5038333

Ref: AGG/CFJ

Version Date: 03.06.2016

Replaces Version: 05.02.2016

SYN®-HYCAN

Compliance confirmation

We hereby confirm that the above mentioned product at the DSM recommended applications and the use levels, conforms to all the requirements laid down for cosmetic ingredients in the Regulation (EC) No 1223/2009¹ on cosmetic products.

This includes the compliance with:

- 1. Article 14.1. (a) of this Regulation which relates to the absence of prohibited substances as listed in Annex II
- 2. Article 14.1. (b) of this Regulation which relates to the absence of restricted substances if not used in accordance with the restrictions laid down in Annex III
- 3. Article 17 of this Regulation which relates to the allowance of traces of banned substances under the condition that they are technically unavoidable in good manufacturing practices and do not cause damage to human health when applied under normal or reasonably foreseeable conditions of use.

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¹ and subsequent amendments



SYN®-HYCAN

Fragrance Allergen Statement

Regulation (EU) 1223/2009 and subsequent amendments, lists a number of substances that may cause allergic reactions following dermal application in sensitized individuals. These substances have to be stated in the ingredients list if present at specified levels in the finished cosmetic product.

We hereby confirm that none of the potential fragrance allergens¹ is intentionally added and not expected to be present in this product.

1 see	annexed	list

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Product Code: 5038333



List of potential fragrance allergens as listed in Regulation (EC) 1223/2009 and subsequent amendments:

Ingredient name	CAS number(s)
Alpha-Isomethyl Ionone	127-51-5
Amyl Cinnamal	122-40-7
Amylcinnamyl Alcohol	101-85-9
Anise Alcohol	105-13-5
Benzyl Alcohol	100-51-6
Benzyl Benzoate	120-51-4
Benzyl Cinnamate	103-41-3
Benzyl Salicylate	118-58-1
Butylphenyl Methylpropional	80-54-6
Cinnamal	104-55-2
Cinnamyl Alcohol	104-54-1
Citral	5392-40-5
Citronellol	106-22-9
Coumarin	91-64-5
Eugenol	97-53-0
Evernia Prunastri (oakmoss) Extract	90028-68-5
Evernia Furfuracea (treemoss) Extract	90028-67-4
Farnesol	4602-84-0
Geraniol	106-24-1
Hexyl Cinnamal	101-86-0
Hydroxycitronellal	107-75-5
Isoeugenol	97-54-1
Limonene (sum of d, l and dl)	5989-27-5
Linalool	78-70-6
Methyl 2-Octynoate	111-12-6

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Product Code: 5038333



Product Information CMR Statement

SYN®-HYCAN

Product Code: 5038333

Article 15 of Regulation (EC) n°1223/2009¹ related to Cosmetic Products prohibits the use of substances which are classified and listed under Regulation (EC) n°1272/2008¹ in Part 3 of Annex VI as CMR (Carcinogenic, Mutagenic, Reprotoxic), categories 1A, 1B and 2.

In some cases, the use of CMR classified substances may be allowed if certain conditions are fulfilled, including the evaluation and approval by the European Scientific Committee for Consumer Safety (SCCS) and exemption granted by the Commission.

Furthermore, according to Regulation (EC) n°2019/831 of 22 May 2019, called the first annual "Omnibus Act", amending Regulation (EC) n°1223/2009¹, CMR classified substances are now and will also be in future included and listed either in the prohibited substances list (Annex II) or the restricted/authorized substances lists (Annexes III/IV to VI) to that Regulation.

We hereby confirm that this product does not contain intentionally added substances classified and listed as CMR either in Annexes II to VI under Regulation (EC) n°1223/2009¹ or in Annex VI under Regulation (EC) 1272/2008¹.

We finally confirm the compliance with Article 17 of Regulation (EC) n°1223/2009¹ which relates to the allowance of traces of banned substances under the condition that they are technically unavoidable in good manufacturing practices and do not cause damage to human health when applied under normal or reasonably foreseeable conditions of use.

1	and	subsec	uent	amend	ments

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Product Code: 5038333

Ref: DM/CFJ

Version Date: 05.02.2016

Replaces Version: New Document

SYN®-HYCAN

Animal Testing Statement

Article 11 (2) (e) of Regulation (EC) No 1223/2009¹ on cosmetic products requires that cosmetic companies shall keep information on animal tests readily available, including information on animal tests carried out on the finished cosmetic product as well as its ingredients.

We hereby confirm that, this product and its components were not tested on animals by or on behalf of our company after 11 September 2004, and are in compliance with Regulation (EC) No 1223/2009¹ (Article 18).

An update of this statement will be made in the exceptional case that animal tests should be necessary.

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¹ and subsequent amendments



Product Information EU REACh Statement

SYN®-HYCAN

Product code: 5038333

DSM Nutritional Products is fully aware of the REACh requirements and timetable.

Hereby, we confirm that all products commercialized by DSM Nutritional Products are compliant with the EU REACh Regulation (EC 1907/2006)¹.

All relevant substances have been registered under REACh either by DSM Nutritional Products or by the relative supplier, or are exempt from REACh registration. For all relevant substances in DSM Nutritional Products, an Only Representative (OR) in accordance with Article 8 of EU REACh Regulation (EC 1907/2006)¹ has been appointed.

DSM Nutritional Products also tracks all necessary details of the supply chains to ensure continuity of supply to the Personal Care Industry in Europe. The REACh status of the individual substances is listed in the table below:

Substance	CAS No.	EINECS/ ELINCS No.	REACH Registration No.	Status
Tetradecyl Aminobutyroylvalylaminobutyr ic Urea Trifluoroacetate	934368-60-2	none	Not available	Exempt, below 1 ton
Glycerin	56-81-5	200-289-5	Not applicable	Exempt, Annex V - Paragraph 9 (**)
Aqua	7732-18-5	231-791-2	Not applicable	Exempt, Annex IV (§)
Magnesium Chloride	7786-30-3	232-094-6	Not available	Exempt, below 1 ton

^(§) Annex IV of EU REACh Regulation (EC 1907/2006)¹ sets out substances that are exempted from the registration, evaluation and downstream user provisions of REACh as sufficient information is known about them. Those substances are considered to cause minimum risk due to their intrinsic properties.

Substances included in Annex IV are exempted from REACh registration (as well as downstream user requirements and evaluation) for all their possible uses irrespective of the tonnage in which they are manufactured or imported (currently or in the future).

In particular, paragraph 9 of Annex V sets out the following substances as exempted from the registration, evaluation and downstream user provisions of REACh if they are obtained from natural sources and if they are not chemically modified: vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C 6 to C 24 and their potassium, sodium, calcium and magnesium salts; glycerol. Glycerol is also commonly called glycerin(e) or propane-1,2,3-triol and forms the backbone of triglycerides bound to a number of fatty acids.

However, the exemption is not applicable to substances which meet the criteria for classification as dangerous according to Directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant

^(**) Annex V of the EU REACH Regulation sets out substances that are exempted from the registration, evaluation and downstream user provisions of REACh because registration is deemed inappropriate or unnecessary and their exemption does not prejudice the objectives of REACh. Substances included in Annex V are exempted from registration (as well as downstream user requirements and evaluation) for all their possible uses irrespective of the tonnage at which they are manufactured or imported (currently or in the future).



Product Information EU REACh Statement

SYN®-HYCAN

Product code: 5038333

[R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).

For classified substances imported or manufactured in quantity above 10 tons/ year exposure scenarios are needed (Regulation (EC) 1278/2008). DSM Nutritional Products covers Cosmetics Europe (COLIPA) uses (PC39) and corresponding risk management summarized in the extended SDS.

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¹ and subsequent amendments



SYN®-HYCAN

SVHC Statement

The information related to the presence of Substances of Very High Concern (SVHC) is contained in section 3 of the Safety Data Sheet of above mentioned product.

Based on product composition and manufacturing process we confirm that the above mentioned product does not contain any substance(s) listed on the ECHA web site¹ at more than 0.1%.

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⁻ Candidate list of Substances of Very High Concern (SVHC) for authorization as defined in the REACh Regulation (EC) No 1907/2006, Articles 57 and 59(1). For the current version of the list, please consult: http://echa.europa.eu/web/guest/candidate-list-table

⁻ Authorization list (Annex XIV) as defined in the REACh Regulation (EC) No 1907/2006, Article 58. For the current version of the list, please consult: https://echa.europa.eu/de/authorisation-list



Product Code: 5038333

Date: 2016-03-16

Ref: ES

SYN®-HYCAN

Proposition 65 Statement

DSM Nutritional Products as a global company is fully committed to ensure the safety of all our raw materials and products to be in compliance with global legislations.

Based on knowledge of the production process, trace amounts of impurities listed under California law Proposition 65 Safe Drinking Water and Toxic Enforcement Act of 1986 (<u>Proposition 65 list dated from December 4, 2015</u>) may be present in chemicals used in the manufacturing process and we can certify that our final product will be below the established maximum limits set below.

Ethylene glycol ≤ 690 ppm Lead ≤ 1 ppm Cadmium ≤ 0.5 ppm Mercury ≤ 0.1 ppm Arsenic ≤ 1 ppm Nickel ≤ 2 ppm

Inclusion rates may vary in finished consumer products due to impact from other ingredients in the final formula. Please consider the above reference values when calculating consumer exposure in the commercially available product.

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Product Code: 5038333

Replaces version: new

Ref: EW/JJ/AW

Version date: 03.02.2016

SYN®-HYCAN

Regulatory Status - China

Usability of raw materials for Personal Care Products in China is depending on the listing of raw materials on IECSC and IECIC inventories or on the notification/registration status of the raw material. Below table provides the above mentioned status:

Composition	Chemical IECSC listing ¹ or New	Cosmetic IECIC listing ² or New Cosmetic	Notes banned/restricted In finished	
CFDA INCI name	Chinese INCI name	Chinese Chemical	Ingredient registration done (Y/N)	cosmetic product ³
Tetradecyl Aminobutyroylvalylaminobutyric Urea Trifluoroacetate	十四烷基氨基丁酰 缬氨酰胺基丁酸脲 三氟乙酸盐	Y	Y	-
Glycerin	甘油	Y	Y	-
Aqua	水	Y	Y	-
Magnesium Chloride	氯化镁	Y	Y	-

Y = Yes N = NoE = Exempted

Please note that there is no positive cosmetic ingredient list existing in China except for colorants, UV filters, preservative, hair dyes and restricted ingredients. This information does not exclude that Chinese cosmetic authorities may ask for additional information related to the above mentioned product during the finished cosmetic product registration or notification process.

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¹ IECSC = Inventory of Existing Chemical Substances in China.

² IECIC = Inventory of Existing Cosmetic Ingredients in China, June 30, 2014, also called CFDA inventory of cosmetic ingredients which have been used in China.

Refers to Chinese Hygienic Standard for Cosmetics Version 2007



SYN®-HYCAN

Regulatory Status

Country/region ¹	Chemical Inventory	Chemical Registration status based on the listing of individual ingredients in inventory and volume exemption applying (Y/N/R/E)	Cosmetic ¹ (Y/N) Note: Claims on finished cosmetic products must comply with national cosmetic legislation
Andean	No inventory	No inventory	Υ
ASEAN	No inventory	No inventory	Y
Australia	AICS	R (≤ 10 kg/y referring to CAS 934368-60-2)	Y (see chemical)
Canada	DSL NDSL ICL	R (≤ 100 kg/y referring to CAS 934368-60-2)	Y (see chemical)
China	IECSC	Υ	See separate statement
Europe	EINECS/ELINCS REACH	R (≤ 1 t/y referring to CAS 934368-60-2 and 7786-30-3)	Y
Japan	ENCS (CSCL)	E	Υ
Korea	KECI (TCCA)	E	Υ
Mercosur	No inventory	No inventory	Υ
Mexico	INSQ	Inventory is not supported by legal framework	Y
New Zealand	NZIoC	Υ	Y
Philippines	PICCS	E	Υ
Switzerland	EINECS/ELINCS	R (≤ 1 t/y referring to CAS 934368-60-2)	Y
Taiwan	NECI	Υ	Y
USA	TSCA	E	Υ

¹ above product can be freely imported and sold as cosmetic ingredient also into further countries as e.g. Algeria, Bahrain, Brunei Darussalam, Egypt, Morocco, the Russian Federation, Tunisia, Turkey, the United Arab Emirates, as long as the safe use is warranted and the products do comply with the legal requirements as laid down in the Regulation on Cosmetic Products (EC) No. 1223/2009

Chemical Legislation

Yes (Y): The DSM product contains only substances which are either listed in the respective chemical inventory, have been notified as new chemical substance by DSM or exempted from the chemical notification (e.g. natural)

No (N): The DSM product contains at least a substance not listed or not notified by DSM or not exempted (not compliant with respective chemical inventory)

Restricted (R): The DSM product contains at least a substance not listed or not notified by DSM or not exempted from the respective chemical notification but can be imported in the respective country under volume exemption (e.g. Australia, Canada, Europe, Switzerland)

Exempted (E): under specific exemption applying to cosmetic ingredients (e.g. US, Japan)



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Replaces version: new

Ref: DM/RS

Version date: 03.02.2016

<u>Cosmetic Regulation</u>

Yes (Y): product free for sales as cosmetic ingredient for the application and use level recommended by DSM (see marketing documentation). If any condition of use exists for the active substance, this must be mentioned.

No (N): product not for sales in the respective country (contain at least a substance not allowed in cosmetic in the respective

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This document and the DSM safety studies referred to therein are proprietary information of DSM relating to the above-named product. The summary information for the DSM studies are specific for this DSM product according to the method of manufacture, and should not be used to support the safety of other non-DSM products.

Conclusion of the Safety Evaluation

The above mentioned product can be used safely in finished cosmetic products as given in the annex of this assessment.

This conclusion is based on the available information and conservative assumptions.

This conclusion does not take into consideration any potential ingredient incompatibility within the final cosmetic product and/or other exposure scenarios. Such aspects need to be assessed at a formula level by those responsible for the finished cosmetic goods.

Product Description and Use

The composition and physical-chemical characteristics for the above mentioned product are included in the Product Data Sheet.

This product is recommended for use in finished cosmetic products as given in the annex.

Toxicology

The safety of the product for use in finished cosmetic products has been evaluated based on toxicological data owned by DSM, toxicological data and publically available information in the literature, as well as published expert opinions, that are specifically relevant to the product and its components. Data from related structural analog (surrogate) substances are also considered when appropriate. All used data is included in the following summarized information.

The sales product SYN®-HYCAN is a formulated product of SYN®-HYCAN peptide, content as specified in the product data sheet, in a glycerin water solution.

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Absorption, Distribution, Metabolism, Excretion, Dermal/Percutaneous Absorption

In silico analysis of dermal absorption taking into account the physico-chemical characteristics of SYN®-HYCAN peptide resulted in a default worst case dermal penetration value of 10% calculated with the NIOSH Finite Dose Skin Permeation Calculator.

The metabolic fate of SYN®-HYCAN peptide was also assessed in silico using the program METEOR (Lhasa Limited). At the probable level, phase I reactions including various hydroxylation reactions, oxidative deamination and beta-oxidation of carboxylic acids are predicted. Predictions of phase II reactions are glucuronidation. At the probable level, hydrolysis of the peptide to release the individual amino acids is not predicted. However, besides various other oxidation and conjugation reactions, hydrolysis and release of the palmitoyl-chain is predicted.

Acute toxicity

Acute toxicity studies were not performed due to low inclusion level of SYN®-HYCAN peptide in the formulated sales product which is further diluted in the finished cosmetic product.

Reaction of Skin and Eye

Skin irritation

See human data

Eye irritation

Reference	DSM 2007a. Bovine Corneal Opacity and Permeability (BCOP-test), study		
	conducted at EVIC France, Bio Department, 33290, Blanquefort; EVIC Study		
	No. Bn 0673/ 07-1323.		
Study type	in vitro eye irritation test		
Guideline and deviations	Gautheron et al., 1992.		
GLP	QAU audited report		
Test substance/batch	801202 (=SYN®-HYCAN), Lot 586-7		
Test system	Bovine cornea		

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Reference	DSM 2007a. Bovine Corneal Opacity and Permeability (BCOP-test), study conducted at EVIC France, Bio Department, 33290, Blanquefort; EVIC Study No. Bn 0673/07-1323.
Dosage/ concentration	200 ppm SYN®-HYCAN peptide
Remark	-
Report date	25-May-2007
Result	weakly irritant response

Skin sensitization

See human data

Repeated Dose Toxicity

SYN®-HYCAN peptide is not genotoxic and is classified as a Cramer Class III compounds. Studies on repeated dose toxicity with SYN®-HYCAN peptide was not considered necessary due to the low calculated exposure of 48 μ g/ day (60 kg person and dermal absorption rate of 10%) for body lotion use at a maximum concentration of 5% This is below the Threshold of Toxicological Concern (TTC) level for Cramer Class III compounds of 90 μ g/ day for systemic toxicity (Kroes et al., 2007).

Reproduction Toxicity

Studies on reproductive and developmental toxicity with SYN®-HYCAN peptide was not considered necessary due to the low calculated exposure which is well below the TTC level for Cramer Class III compounds (see above).

Mutagenicity / Genotoxicity

Reference	DSM 2007c. Reverse Mutation Assay using Bacteria, study conducted at BSL	
	Bioservice, 82152 Planegg, Germany; Project No. 071233.	
Study type	Reverse Mutation Assay using Bacteria	
Guideline and deviations	OECD guideline No. 471	
GLP	Yes	
Test substance/batch	801202 (= SYN®-HYCAN), Lot 586-7	
Test system	in vitro test - bacteria	

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Reference	DSM 2007c. Reverse Mutation Assay using Bacteria, study conducted at BSL
	Bioservice, 82152 Planegg, Germany; Project No. 071233.
Dosage/ concentration	31.6, 100, 316, 1000, 2500, and 5000 µg/ plate per plate
	With and without S9-mix obtained from male Wistar rats treated with
	Phenobarbital and B-naphthoflavone.
Remark	Batch 586-7 was a specific formulation with a peptide content of 200 ppm
Report date	19-July-2009
Result	Not mutagenic in Salmonella typhimurium and Eschericia coli strain WP2
	uvrA

Reference	DSM 2010. Reverse Mutation Assay microsuspension test, study conducted		
	at DSM Nutritional Products, Kaiseraugst, Switzerland.		
Study type	Reverse Mutation Assay using Bacteria		
Guideline and deviations	OECD guideline No. 471		
GLP	No		
Test substance/batch	SYN®-HYCAN peptide, Lot 41387501		
Test system	in vitro test - bacteria		
Dosage/ concentration	up to 500 μg/ plate per plate		
	With and without S9-mix obtained from male Wistar rats treated with		
	Phenobarbital and B-naphthoflavone.		
Remark	The maximum concentration of 500 µg per plate in this assay is comparable		
	to the maximum concentration of 5000 µg per plate in the standard assay		
	as recommended in the OECD 471 guideline.		
Report date	9-March-2010		
Result	Not mutagenic in Salmonella typhimurium		

Reference	DSM 2009b. In vitro Mammalian Micronucleus assay, study conducted at BSL		
	Bioservice, 82152 Planegg, Germany; Project No. 090567.		
Study type	In vitro Mammalian Micronucleus assay for clastogenicity and/ or		
	aneugenicity		
Guideline and deviations	Draft OECD 487 (3rd version)		
GLP	Yes		
Test substance/batch	801202 (= SYN®-HYCAN), Lot 41301901		
Test system	in vitro test - Chinese Hamster CHO Cells		
Dosage/ concentration	with metabolic activation: 5, 4, 3, 2.5 and 1µL/ mL (4 h)		
	without metabolic activation: 5, 2.5 and 1µL/ mL (4 and 24 h)		
Remark	Lot 41301901 has stated peptide content of 990 ppm		

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Reference	DSM 2009b. In vitro Mammalian Micronucleus assay, study conducted at BSL
	Bioservice, 82152 Planegg, Germany; Project No. 090567.
Report date	05-Oct ober-2009
Result	Non-genotoxic with respect to clastogenicity and/or aneugenicity

Reference	DSM 2011. In vitro Mammalian Micronucleus assay, study conducted at DSM		
	Nutritional Products, Kaiseraugst, Switzerland.		
Study type	In vitro Mammalian Micronucleus assay for clastogenicity and/or		
	aneugenicity		
Guideline and deviations	OECD 487(22 July 2010)		
GLP	No		
Test substance/batch	SYN®-HYCAN peptide, Lot 41387501		
Test system	in vitro test - Chinese Hamster CHO Cells		
Dosage/ concentration	Up to 25 μg/ mL		
	With and without S9-mix obtained from rats treated with Phenobarbital		
	and B-naphthoflavone		
Remark	-		
Report date	29-July-2011		
Result	Non-genotoxic with respect to clastogenicity and/or aneugenicity		

Carcinogenicity

Studies on carcinogenicity with SYN®-HYCAN peptide were not considered necessary due to the absence of genotoxicity potential and the low calculated exposure which is well below the TTC level for Cramer Class III compounds (see above).

Photo-induced toxicity

Phototoxicity

With regard to photosafety, including phototoxicity, photosensitization and photomutagenicity, it was not considered necessary to conduct a test because SYN®-HYCAN peptide does not absorb UV-Visible light in the spectrum of 200-750 nm.

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Human Data

Reference	DSM 2009a. Human Patch Test with 801202, study conducted at Derm		
	Consult GmbH, 53347 Alfter, Germany.		
Study type	Human patch test		
Guideline and deviations	COLIPA guidelines (Walker et al., 1996)		
GLP	No		
Test substance/ batch	801202 (= SYN®-HYCAN), Lot 41301901		
Test system	Human volunteers		
Species/strain/sex	50 participants, both sexes		
Dosage/ concentration	200 ppm in water		
Remark	-		
Report date	06-March-2009		
Result	Not irritant to human skin		

Reference	DSM 2007b. Human Repeat Insult Patch Test with Peptide Solution 801202,		
	(Study conducted at EVIC Romania, Bucharest, Romania; Study EF Pn		
	094/ 07-1323/ ER 07/ 099-9/ 07-0652.		
Study type	Human Repeated Insult Patch Test for skin sensitization		
Guideline and deviations	Marzulli and Maibach, 1976		
GLP	No		
Test substance/batch	801202 (= SYN®-HYCAN), Lot 586-7		
Test system	Human volunteers		
Species/strain/sex	50 participants, both sexes		
Dosage/ concentration	200 ppm in water		
Remark	-		
Report date	4-July-2009		
Result	Not sensitizing to human skin		

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Toxicological data on formulation ingredients

Glycerin (CAS No. 56-81-5)

Based on current reported uses, the CIR Expert Panel concluded that Glycerin was safe when used in cosmetic formulations up to 79.2% in leave-on, 99.4% in rinse-off and 47.9% in dilutions for bath products (CIR, 2015).

Magnesium chloride (CAS No. 7786-30-3)

Only pharmaceutical grade magnesium chloride is used.

MgCl₂ is affirmed as generally recognized as safe (GRAS) and has no hazardous properties as defined by CLP (EC) No 1272/2008). The ingredient is used in food with no limitation other than current good manufacturing practice (FDA, 21CFR184.1426).

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Exposure and Safety Assessment

The calculation of the Systemic Exposure Dosage (SED) was performed according to the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 9th revision (2016) and are shown in the Table below for the different single uses. Safe exposure levels (below the Threshold of Toxicological Concern (TTC) for Cramer Class III compounds (0.09 mg/ day)) for relevant cosmetic product types are shown in following tables.

Product type (SCCS, 2016)	Body lotion	Face cream	Hand cream	Liquid foundation	Mascara	Lipstick
Calculated relative daily exposure [A] (mg/kg bw/day)	123.20	24.14	32.70	7.90	0.42	0.90
SYN-HYCAN in cosmetic product (%)	5	5	5	5	5	5
SYN-HYCAN peptide in cosmetic product [C] (%)	0.0065	0.0065	0.0065	0.0065	0.0065	0.0065
Dermal Absorption [DA _p] (%)	10	10	10	10	10	10
Systemic Exposure Dose (mg/kg bw/day)	0.00080	0.00016	0.00021	0.00005	0.00000	0.00001
SED calculated for a 60 kg person (mg/day)	0.048	0.009	0.013	0.003	0.000	0.000

Safety Assessment Conclusions

Based on the toxicological profile (absence of mutagenicity, skin irritation, eye irritation, skin sensitization), and acceptable estimated human systemic exposures (below the threshold of toxicological concern), it is concluded that SYN®-HYCAN is safe for use at the recommended use levels in the intended cosmetic products as given in the annex.

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Glossary

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ADME: Absorption, Distribution, Metabolism, Excretion

CIR: Cosmetic Ingredient Review

CLP: Classification, Labelling and Packaging (of substances and mixtures)

SCCS: Scientific Committee on Consumer Safety

SED: Systemic Exposure Dosage

TTC: Threshold of Toxicological Concern

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Product code: 5038333

References:

Cosmetic Ingredient Review (2015) Safety Assessment of Glycerin as Used in Cosmetics. https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR679.pdf

DSM 2007a. Bovine Corneal Opacity and Permeability (BCOP-test), study conducted at EVIC France, Bio Department, 33290, Blanquefort; EVIC Study No. Bn 0673/07-1323.

DSM 2007b. Human Repeat Insult Patch Test with Peptide Solution 801202, (Study conducted at EVIC Romania, Bucharest, Romania; Study EF Pn 094/07-1323/ ER 07/099-9/07-0652.

DSM 2007c. Reverse Mutation Assay using Bacteria, study conducted at BSL Bioservice, 82152 Planegg, Germany; Project No. 071233.

DSM 2009a. Human Patch Test with 801202, study conducted at Derm Consult GmbH, 53347 Alfter, Germany.

DSM 2009b. In vitro Mammalian Micronucleus assay, study conducted at BSL Bioservice, 82152 Planegg, Germany; Project No. 090567.

DSM 2010. Reverse Mutation Assay microsuspension test, study conducted at DSM Nutritional Products, Kaiseraugst, Switzerland.

DSM 2011. In vitro Mammalian Micronucleus assay, study conducted at DSM Nutritional Products, Kaiseraugst, Switzerland.

Gautheron P, Dukic M, Alix D and Sina JF (1992) Bovine Corneal Opacity and Permeability Test: an in Vitro Assay of Ocular Irritancy, Fundam Appl Toxicol. 18: 442-449.

Kroes R, Renwick AG, Feron V, Galli CL, Gibney M, Greim H, Guy RH, Lhuguenot JC, van de Sandt JJM (2007) Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients, Food Chem Tox 45:2533-2562.

Marzulli FN and Maibach HI (1976) Contact allergy: predictive testing in man, Contact dermatitis, 1976, 2, pp1-17.

NIOSH Finite Dose Skin Permeation Calculator:

https://www.cdc.gov/niosh/topics/skin/finiteskinpermcalc.html

SCCS (Scientific Committee on Consumer Safety), SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 9th revision, 29 September 2015, SCCS/1564/15, revision of 25 April 2016.

Replaces Version 01: 2016-06-15

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Walker AP, Basketter DA, Baverel M, Diembeck W, Matthies W, Mougin D, Paye M, Röthlisberger R, Dupuis J (1996) Test guidelines for assessment of skin compatibility of cosmetic finished products in man, Food Chem Toxicol. 34(7):651-60.

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SYN®-HYCAN

Product code: 5038333

Annex: General recommended use levels per application

These recommendations are based on a conservative safety evaluation made on the above mentioned product. This conclusion is based on the available information and conservative assumptions. This conclusion does not take into consideration any potential ingredient incompatibility within the final cosmetic product and/ or other exposure scenarios. Such aspects need to be assessed at a formula level by those responsible for the finished cosmetic goods.

Product type	Recommended use level (%)
Rinse-Off	
Shower gel	-
Hand wash soap	-
Shampoo	-
Make-up remover	-
Feminine hygiene	-
Leave-On	
Hair styling products	-
Semi-permanent hair dyes (and lotions)	-
Oxidative/ permanent	-
hair dyes	
Body lotion	5%
Face cream	5%
Hand cream	5%
Liquid foundation	5%
Eye shadow	-
Mascara	5%
Eyeliner	•
Deodorant non-spray	-
Deodorant aerosol spray	-
Deodorant spray	-
Suncare	
Suncare Lotion - Oils	-
Suncare Sprays	-
Oral	
Lipstick, lip salve	5%
Toothpaste (adult)	-
Mouthwash	-
Baby - Infants	
Baby products	-
Products for infants	-

Version 02: 2019-02-19 Replaces Version 01: 2016-06-15



Halal Certification Services Halalzertifizierungsdienste Services certification Halal

Certificate (Document) #	786217 21 - 006.414
Revision date	15 / 01 / 20
Pa	age 1 of 2
Date	21 / 06 / 2021



شهادة حلال HALAL CERTIFICATE

Pos	Code	Product
Food	Products	
001	0408859	APOCAROTENAL Crist. 33
002	0421413	RIBOFLAVINE 5'-PHOSPHATE SODIUM
003	0426954	CANTHAXANTHINE CRIST
004	5016261	RIBOFLAVIN 5'-PHOSPHATE Ph
005	0411876	ZEAXANTHINE (ZTN06)
006	0419117	VITAMINE D3 BUTYRATE
007	0431397	Redivivo (LYCOPENE 05)
008	0437824	MONOBENZOATE (VKP12)
009	0470236	C5 WITTIG ALDHEYDE (APA 32)
010	0482935	ACETATE DE LYCOPYL (LPN4)
011	5009278	VITAMINE D3 PURE CRIST.
012	5011655	d-BIOTINE PURE
013	5016264	d-BIOTIN PURE PH
014	5016263	VITAMINE D3 CRISTALLINE PH
015	5012554	DRY VITAMIN A PALMITATE 250S/N
016	5012740	DRY VITAMINE E 50% CWS/S
017	5015142	Ferrous Sulfate SD 3.05% FE
018	5015710	Ferrous Sulfate SD 3% FE
019	5015149	FloraGLO Lutein 1% SD/S
020	5015567	COPPER SULFATE SD 1,5% CU
021	5015568	ZINC SULFATE SD 3% ZN
022	5015569	POTASSIUM IODIDE SD 0,25% I
023	5015570	MANGANESE SULFATE SD 0,1% MN
024	5015721	DRY MIXED TOCOPHEROL 30% IP
025	5015776	B-Carotene 15% LCS
026	5016088	Dry Natural Vitamin E SF
027	0427233	B-CAROTENE 30% FS

000				
028	0442534	RONOXAN A		
029	0480932	APOCAROTENAL 20 % S		
030	5000203	REDIVIVO (LYCOPEN) 10% FS		
031	5000238	B-CAROTENE 30 % FS/SF		
032	5002001	ORTISHARP (ZEA.) 20% FS		
033	5008352	B-CAROTENE 7% MILLED		
034	5011256	B-CAROTENE 5% EM K		
035	5011876	FLORAGLO® LUTEIN 20% SAF		
036	5012085	FLORA GLO LUTEIN 20% SAF-Z		
037	5012538	B-CAROTENE 10% EMULSION RED		
038	5014387	B-CAROTENE 30% FS PH		
039	5015896	Floraglo optisharp 5/1 24%		
040	5016039	B-CAROTENE 30% FS/SF-T		
041	5016281	FLORAGLO® LUTEIN 20 % SAF-T		
Perso	nal Care Prod	lucts		
042	5038330	Syn-Coll		
043	5038331	Syn-Ake		
044	5038332	Syn-Tacks		
045	5038333	Syn-Hycan		
046	5038334	Syn-TC		
047	5038336	Lipogard		
048	5038344	Syn-Star (TM)		
049	5016282	BEL-EVEN		
050	5000858	STAY-C 50		
051	5000947	STAY C-50 SOLUTION		
052	5000858	STAY-C 50		

نشهد ان المنتج المذكور اعلاه, و المنتج بواسطة It is certified that the above-mentioned product marketed by

DSM Village Neuf

1 Boulevard d'Alsace, 68128 Village-Neuf, France.

is Halal according to the Islamic Jurisdiction and fit for consumption by humans حلال طبقا لأحكام الإسلام و مصالح للإستهلاك الأدمى.

The verified and audited system is complying with و مراجعته متوافق مع HS 09 – 001 and is constantly supervised by و يتم مراقبته بإستمرار بواسطة Halal Certification Services.

This Certificate, in combination with هذه الشهادة, مأخوذة مع شهادة HCS' Certificate for Production Site (786217 21 - 005.413), is valid effective from صالحة بداية من June 21st 2021 until و حتى June 30th 2022.

It remains the property of the الشهادة ملكية حصرية لـ Halal Certification Services and can be revoked, at any time, in an event of breach of the Islamic code or HCS' "Halal Guidelines" or the Agreement. و يمكن ويمكن المنافق عند المنافق ا

Halal Certification Services GmbH

التوثيق د محمد طفيل Dr. Mohammad Tufail, Certification Manager

لخاتم الرسمي fficial Seal)

Rheinfelden, 21st June 2021 / 11th Dhul Qadah 1442

Halal Certification Services GmbH, Tel: +41 61 813 30 64

P.O. Box 247, Fax: +41 61 813 30 65 4310 Rheinfelden, Switzerland Email: info@halalcs.org



Halal Certification Services Halalzertifizierungsdienste Services certification Halal

Certificate (Document) #	786217 21 - 006.414	
Revision date	15 / 01 / 20	
Pa	ige 2 of 2	
Date	21 / 06 / 2021	



This product is free from any haram animal ingredients and alcohol. The equipment used for production process does not come in contact with haram products. The storage facilities are indiscriminately separate, having no contact, what so ever, to any other haram products. The producer is comprehensively advised about "Halal, Haram and Mushbooh" (suspected), is committed to the halal guidelines as prescribed by Islamic law and is dedicated in his endeavour to comply with Islamic Halal requirements.

The ingredients used in the production of the mentioned products are clear. They are free from any haram, suspect and genetically modified components.

The certificate is based on personal inspection of the production site and thorough study of the ingredients, the hygienic conditions, the packing, the packing material requirements, the storage facilities and its effects on the products during the maximum storage time as well as guaranteed continuous quality control of the process during and after production by the producer. It includes detailed consultations with the internal board, an evaluation of the prescribed formulas and scrutinization of the concerning data provided by the company. We have studied the details of the contents and have satisfied ourselves that the mentioned product(s) do not contain any "haram ingredients" or "haram by-products".

هذا المنتج خالى من اى مكونات حرام و من الكحول. المعدات المستخدمة فى عملية الإنتاج لا تتلامس مع اى منتجات حرام اخرى. المخازن مفصولة بعناية و لا يوجد بها خلط من اى نوع مع اى منتج آخر حرام. تم توعية المُنتِج بإستفاضة عن الحلال, الحرام و المشبوه. والمُنتِج ملتزم بمعايير الحلال كما نُصَ عليها فى الشريعة الإسلامية و جاد فى مسعاه للإمتثال لمعايير الحلال

المكونات المستخدمة في انتاج المُنتَج المذكور اعلاه واضحة و خالية من اى مكون حرام مشبوه او معدل وراثياً

الشهادة مبنية على زيارة موقع الإنتاج و على الدراسة المستفيضة للمكونات, المعايير الصحية, التغليف, مواد التغليف, المخازن و تأثيرها على المنتجات خلال مدة التخزين القصوى و كذلك ضمان مراقبة الجودة المستمر خلال و بعد عملية الإنتاج

و تتضمن الشهادة ايضا استشارات مع المجلس الإستشارى, تقييم للمعادلات و تمحيص البيانات المقدمة من الشركة المنتجة. لقد إطلعنا على كل التفاصيل و اطمأنت لدى انفسنا ان المنتج المذكور لا يحتوى على "مكونات حرام" او "مكونات مشتقة من حرام

Halal Certification Services GmbH

Dr. Mohammad Tufail, Certification Manager



HFCE

المجلس الأوروبي للأغذية الحلال Halal Food Council of Europe

4 Rue de la Presse, 1000 Brussels, Belgium | Tel: +32-2227-1114, +32-2227-2728 | Fax: +32-2218-3141 | www.HFCE.eu

Registration No: 827964482

شهادة حلال HALAL CERTIFICATE

المجلس الأوروبي للأغذية الحلال يشهد بأن المنتجات المذكورة أدناه قد إستوفت شروط الحلال وفقاً للشريعة الإسلامية

The Halal Food Council of Europe hereby certifies that the products listed below have met the Halal requirements in accordance with Islamic laws.

Date: **November 18, 2020**

Document #: 5256.5296.IH200628

Company Name & Address: DSM Nutritional Products, Ltd. PO Box 2676 Postfach, Basel-City CH - 4002 Switzerland

Plant Name & Address: DSM Nutritional Products 1 Boulevard d'Alsace Village-Neuf, Alsace 68128 France

ProductNameProduct CodeHalal-IDProduct Certificate #1. Syn-Hycan5038333B72620HC-20DS9X52

Mujahid Masood, Ph.D.
Vice President

This Certificate is valid until **November 30, 2021** and subject to renewal at that time.





Page 1 of 1

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LEMBAGA PENGKAJIAN PANGAN, OBAT-OBATAN DAN KOSMETIKA THE ASSESSMENT INSTITUTE FOR FOODS, DRUGS AND COSMETICS



MAJELIS ULAMA INDONESIA INDONESIA COUNCIL OF ULAMA LAMPIRAN KETETAPAN HALAL

THE ATTACHMENT OF HALAL CERTIFICATE
NO : LPPOM-00150127660921

Nama Perusahaan : DSM NUTRITIONAL PRODUCTS LTD

Alamat Perusahaan
Company Address: BOULEVARD D'ALSACE BP 170

Nama Fasilitas : DSM NUTRITIONAL PRODUCTS SITE VILLAGE-NEUF Facility Name :

Alamat Fasilitas : 1 BOULEVARD D'ALSACE Facility Address

 $\begin{array}{lll} \hbox{Kelompok Produk} \\ \hbox{\it Product Group} \end{array} & : & \hbox{COSMETIC (KOSMETIK)} \end{array}$

Berlaku sampai dengan : SEPTEMBER 28th, 2025

Dikeluarkan di Jakarta pada : SEPTEMBER 29th, 2021

Daftar Produk List of Product

No	Nama Product Product Name	Tipe Produk <i>Product Type</i>	Kode QR <i>QR Code</i>
1	5016282 BEL-EVEN	Others (Lain-lain)	
2	5038331 Syn-Ake	Others (Lain-lain)	
3	5038330 Syn-COLL	Others (Lain-lain)	
4	5038332 Syn-TACKS	Others (Lain-lain)	
5	5038333 Syn-HYCAN	Others (Lain-lain)	
6	5038334 Syn-TC	Others (Lain-lain)	
7	5038336 LIPOGUARD	Others (Lain-lain)	
8	5038344 Syn-Star	Others (Lain-lain)	



Product Information Pallet Treatment

Hereby, DSM Nutritional Products confirms that all manufactured goods are delivered on heat treated pallets.

The regulations and specifications that we apply are as follows:

- IPPC-ISPM 15
- Cleanliness:
- Free of impurities, particles, insects, mold, bark or lubricant residues
- Heavy metals:
- Cumulative trace content of lead, mercury and chromium (VI) less than 100 ppm
- Residual moisture:
- Less than 18% in compliance with the IPPC standard

In addition, the pallets show the following identification marks:

- Supplier sign
- IPPC-Standard (HT) registration number

We trust these assurances address your concerns. Should you have further questions please contact our local agent.

This document is valid without signature.



Product Information Packaging Materials

Confirmation

We hereby confirm that all of the primary packaging materials used for the products marketed by DSM Nutritional Products Ltd comply with the current legislation on materials and articles intended to come into contact with food, namely:

- European Parliament and Council Directive 94/62/EC of 20 December 1994¹
- European Parliament and Council Regulation (EC) 1935/2004¹,
- Commission Regulation (EC) 2023/2006¹ and
- Commission Regulation (EU) 10/2011¹ for the EU,

and the Federal Food, Drug and Cosmetic Act of the United States of America (among others articles; 21 CFR 174 – 178 and 186).

The primary packaging material chosen assures compliance with the products' specifications during the specified maximum shelf life when stored under the conditions recommended.

The secondary and further packaging is suitable for mechanical protection, store, transportation, customer and handling requirements.

We trust these assurances address your concerns. Should you have any further questions, please contact our local agent.

This document is valid without signature.



Product Information Traceability of Packaging Materials

Compliance with Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food

This legislations extends the traceability for ingredients used in the food chain (EU Food Framework Regulation (EC) 178/2002, article 18) to all materials and articles coming into contact with them at all stages of the production and transport in the chain. This requirement included packaging materials.

In the context of the above mentioned legislation and specifically of article 17 on the traceability of the packaging traceability means "the identification of the business from which and to which materials or articles are supplied". The traceability must be facilitated by an appropriate system of documentation or information.

DSM Nutritional Products Ltd has a system and procedures in place to allow full traceability of materials and articles coming in contact with the food or food ingredient and therefore is in compliance with the EU Regulation (EC) 1935/2004, specifically with article 17 on the traceability of packaging.

We trust these assurances address your concerns. Should you have any further questions, please contact our local agent.

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Introduction

DSM is a global supplier of life science products and performance materials. DSM defines sustainability as follows:

'Meeting the needs of the present generation without compromising the ability of future generations to meet their own needs.'

Sustainability is currently one of the DSM's fundamental business drivers in all our markets. In addition, it is the fundament of our 3 core principles for DSM behavior with regards to valuable partnership, respect for people and good corporate citizenship. Sustainability is driving our Triple-P concept, around:

- People+: Improving people's life through DSM activities and innovation;
- ECO+: Improving environmental impact of DSM activities and products;
- Profit+: creating profitable businesses, whilst meeting DSM People + and ECO+ objectives to provide solutions on global society needs.

Our belief in sustainability as our core value, key responsibility and important business driver is reflected in the recognition we receive in Environmental, Social, Governance (ESG) ratings and benchmarks:

- In June 2019, the investment research firm MSCI has upgraded DSM from an AA position to AAA. This improved ranking is due to a strong overall ESG performance across DSM's businesses as well a lowered risk profile based on DSM's business portfolio.
- In May 2018 DSM was assessed as an ESG leader within the chemicals industry by Sustainalytics, ranking number 1 out of 135 companies.
- In November 2018 DSM was again awarded a Gold CSR Rating by Ecovadis. Our score of 75 points puts us in the top 1% of companies assessed on the platform in our industry.
- In 2018 the Carbon Disclosure Project (CDP) assessed our climate strategy and water governance and strategy as A- for Climate Change and B- for Water Security.
- In July 2019, DSM was again confirmed as constituent of the FTSE4Good index. We have held a position on this list since 2004.

DSM is a constituent of the Vigeo Eiris Benelux 20, Europe 120, Eurozone 120 and World 120

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indices, based on the review performed in October 2017.

People+

The People+ concept in our production means that DSM strives for a safe working environment for its employees, with a very ambitious target of zero accidents on sites. This is to be achieved by 1) a fundamental culture change management leading to better understanding of our processes and their risks, 2) a better implementation of risk reducing measures at individual level, and 3) increased people training and awareness building in the work environment.

In addition, one of DSM's objectives is to improve people's life through innovation. To do so, DSM is developing metrics to evaluate progress in people's life and participate to global activities to reduce malnutrition (one of the key Millennium objectives).

ECO+

The objective of the ECO+ activities within DSM is to reduce the environmental footprint of the company's production systems. In addition, we aim to reduce the environmental footprint of our customers when using our products. We therefore compare our products and solutions with competitive solutions in the same market and place priorities on solutions and products, which provide our customers with the lowest environmental footprint.

To achieve these objectives, DSM has developed internal structure and process to:

- Improve its manufacturing processes through innovation by e.g.:
 - Developing the use of renewable resources, when possible, to produce our products (e.g. through white biotechnology¹)
 - Reducing the use of energy and water in our processes

¹ White Biotechnology is the use of living microorganisms to develop or make useful products. White Biotechnology tends to consume less in resources than traditional processes used to produce industrial goods (www.europabio.org)



- Innovate in new products linked to:
 - The reduction of emission from livestock production on farm²
 - The reduction of energy consumption for producing food
 - The reduction of food waste
- Source our raw materials from sustainable food chain:
 - Produce omega-3 and Omega-6 fatty acids from natural sustainable sources³ 0
 - Utilizing optimally the natural sources produced in a sustainable way⁴

Sustainable supply of Omega-3 and Omega-6 fatty acids

Omega-3 and Omega-6 fatty acids are essential nutrients for people Omega-3 and Omega-6 fatty acids are well spread in nature and they are mainly present in fatty fish, plants, and fungi.

DSM Nutritional Products is committed to provide sustainable source of Omega-3 and Omega-6 fatty acids from the different natural sources available on our planet.

When producing Omega-3 fatty acids (our MEG-3® product range) from aquatic sources (fish), DSM Nutritional Products is committed to the responsible and sustainable use of natural marine sources that promote marine biodiversity and will help to safeguard our marine environments and fish stocks for future generations. Therefore, DSM Nutritional Products sources fish-derived omega-3 fatty acids from qualified fisheries. DSM MEG-3 fish oil products has achieved Friend of the Sea certification. With a view to further promoting sustainable fishing practices, DSM Nutritional Products has built strong relationship with government agencies and major Peruvian producers⁵.

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² For more details, see our document: Innovation for sustainable animal production

³ For more details, see our document: Sustainable Omega-3 and Omega-6 production

⁴ For more details, see our document: Sustainable Palm Oil

 $^{^{5}}$ The Peruvian government is recognized worldwide for its control and regulation of the fishing Industry. Peruvian water is



DSM Nutritional Products has innovated in biotechnology during the last decades and has acquired knowledge and production facilities to develop the production of Omega-3 and Omega-6 fatty acids from algae and fungi (our *life's™* product range). Algae and fungi production enables the use of renewable materials, used for growing the algae and the fungi in fermenters. In addition, DSM Nutritional Products has developed natural concentration processes to provide ready to use Omega-3 and Omega-6 fatty acids.

Sustainable use of palm oil and derivatives

DSM Nutritional Products provides product forms and preparations enabling the proper and efficient use of the active substances in customers' products. This creates, for example, an increased stability of the active substances during storage and processing or an improved bioavailability for the end consumer.

Based on its experience and expertise, DSM Nutritional Products develops the best in class forms for the specific local markets. The use of palm oil in certain formulations provides benefits for the proper handling and use of our products by our customers. Furthermore, the application of our products only adds very low amounts of palm oil in our consumer's products, such as food as consumed.

Nevertheless, in line with DSM's sustainable approach of food products, DSM Nutritional Products limits the use of palm oil to product forms, in which it provides significant benefits in the application. We secure the sourcing of palm oil from sustainable sources, considering the environmental and social impact of palm oil production, particularly:

- DSM Nutritional Products sources only palm oil from companies proving adherence to the RSPO⁶ mission, i.e.:
 - o To advance the production, procurement, finance and use of

continually monitored by the Marine Institute of Peru (IMARPE) to ensure sustainability.

Version 03: 2021-03-12

Replaces Version 02: 2017-03-29

⁶ RSPO = Roundtable on sustainable palm oil(<u>www.rspo.org</u>)



sustainable palm oil products;

- To develop, implement, verify, assure, and periodically review credible global standards for the entire supply chain of sustainable palm oil;
- To monitor and evaluate the economic, environmental, and social impacts of the uptake of sustainable palm oil in the market;
- To engage and commit all stakeholders throughout the supply chain, including governments and consumers.
- DSM Nutritional Products manufacturing sites have been certified as compliant with the RSPO Supply Chain Certification Standard, implementing the «Segregation» and «Mass Balance» approaches. This certification covers all sites producing formulations containing palm oil and derivatives.

DSM Nutritional Products is committed to further secure the sustainable sourcing of palm oil. The above- mentioned certificate is valid until 3 June 2025.

Innovation in animal nutrition

Livestock production is one of the main contributors of emissions, which may have a detrimental effect on the environment within the food chain. Depending on the production systems and farm management, including feeding and nutrition management, the impact on the environment varies (different level and type of impacts).

DSM Nutritional Products is active in the field of animal nutrition since more than a century and has developed products that provide:

- Micronutrients for better livestock production and welfare and
- Feed ingredients supporting animal performance through proper feed digestion and/or better animal metabolism.

Scientists and policy makers has now recognized the benefit of performance improvement as one of the key elements to reduce the environmental footprint of



livestock product, within a given production system. Indeed, the improvement of animal performance leads to:

- Improved feed efficiency (i.e. less raw materials used for the same production of meat, milk, or eggs);
- Decreased numbers of animals needed for achieving the same farm production (e.g., by reducing the mortality or morbidity, linked to improved animal welfare; improved fertility and animal's longevity)
- Increased animal metabolism, though micronutrition (i.e., increase the performance of the natural metabolic use of the nutrients from the diet)

Over the last decade, DSM Nutritional Products has developed the use of solutions that cover the three above mentioned elements, with a view to improve the sustainability of livestock production, reducing the environmental footprint and providing economic benefits to the food chain. Ourenzymes (RONOZYME® HiPhos and ProAct), benzoic acid (VevoVitall®) and probiotics (CYLACTIN®) are the most prominent examples of DSM Nutritional Products contribution to sustainable livestock production.

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Product Information Lot Code Explanation (General)

Lot numbers for the products of DSM Nutritional Products do not translate directly into a date of production. The date (month and year) is printed on each carton label and mentioned on the "Certificate for Customer" which accompanies each shipment of material.

Lot numbers are assigned at each manufacturing facility in accordance with current site Standard Operating Procedures. The first two digits designate the site of manufacture and the rest relate to batch number identification. These lot codes can be tracked internally to specific batch records for the sake of traceability.

Thank you for your continued business with DSM Nutritional Products. We trust these assurances address your concerns. Should you have further questions please contact our local agent.

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Glossary

Abbreviations

BSE/TSE: Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy **CITES**: the Convention on International Trade in Endangered Species of Wild Fauna and Flora **COSING**: the database of the European Commission on cosmetic substances and ingredients

CMR: Carcinogenic, Mutagenic, or Toxic for Reproduction

GHS: Globally Harmonized System (of classification and labelling)

GMO: Genetically Modified Organism **GMP**: Good Manufacturing Practice

Nano: Nanomaterial

PAHs: Polycyclic Aromatic Hydrocarbons

PBT/vPvB: Persistent, Bioaccumulative and Toxic/very Persistent and very Bioaccumulative

(according to Regulation (EC) No 1907/2006)

PCB: PolyChlorinated Biphenyl

REACh: Registration, Evaluation, Authorisation and Restriction of Chemicals (according to

Regulation (EC) No 1907/2006)

SCCNFP: Scientific Committee on Cosmetic Products and Non-Food Products intended for

Consumers

SCCS: Scientific Committee on Consumer Safety

SVHC: Substance of Very High Concern (according to Regulation (EC) No 1907/2006)

VOC: Volatile Organic Compound

Definition of terms

Ingredient: substance intentionally added to the DSM sales product and having a function in

the sales product **Substance**: means a chemical entity

Not expected and not determined: based on our current knowledge of the production process, raw material(s) and/or equipment used for the manufacture of the product, the substance(s) is/are not expected to be present and consequently no measurement was performed.



Not applicable: the item is not relevant and therefore does not apply to the product (e.g. a CITES certificate for a synthetic product is not relevant).

Definition of criteria

1. Source of ingredient(s)

The information on the source of ingredients is based on DSM's internal knowledge or information provided by suppliers. One or more sources may apply to an ingredient (listed by its INCI name). In this case the last sourcing step is indicated (e.g. "fermentation of a sugar from plant" - the source is "Biotechnology").

Synthetic: ingredients which contain hydrocarbons or which are derived from coal or crude oil (see also petroleum derived) and/or ingredients which are made by a chemical reaction of one or several educts to form a new chemical entity.

Biotechnology: ingredients made from or with microorganisms (e.g. fermentation, hydrolysis by enzymes isolated from bacteria).

Vegetable: ingredients derived from plants in the sense of "botanical ingredients" (for comparison: ingredients derived from sugar(s) from plants and used for fermentation are <u>not</u> "botanical ingredients"). Fungi derived ingredients are included here despite fungi represent an own taxonomic group.

Animal: ingredients produced by animals (e.g. milk lipids, silk) or derived from animal tissues (e.g. collagen).

Mineral: ingredient(s) from an inorganic source (substances without hydrocarbons) **Petroleum derived:** ingredients derived from coal, unprocessed or refined crude oil.

Significant petrochemicals are olefins (including ethylene and propylene) and aromatics (including benzene, toluene and xylene isomers) and their derivatives, e.g. phenoxyethanol, propylene glycol, methylparaben, benzoic acid.



2. Function of Ingredient(s)

The functions of the ingredients are indicated as reported in cosmetic ingredient databases, such as CosIng.

Ingredients listed in Annexes (II, III, IV, V, VI) of Cosmetic Regulation (EC) 1223/2009: the given concentration represents the concentration in the product (<u>not</u> the max. allowed concentration).

3. Substance(s) potentially contained

Food allergens

Cereals containing gluten and products thereof: refers to materials such as wheat, rye, barley, oats, spelt, kamut or their hybridized strains and/or products thereof (according to Regulation (EU) No 1169/2011).

Nuts and nut products (incl. peanuts): refers to almonds (*Amygdalus communis L.*), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoiesis* (Wangenh.) K. Koch), brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia nuts or Queensland nuts (*Macadamia ternifolia*), peanut, beech nut, butter nut, chestnut, chinquapin, hickory nut, lichee nut, pine nut, pili nut, sheanut and products thereof (referring to EU and US Food Regulation).

Other various substances

Formaldehyde and formaldehyde releasers: refers to formaldehyde and formaldehyde releasers as mentioned in the SCCNFP Opinion on the Determination of Certain Formaldehyde Releasers in Cosmetic Products, 17 December 2002: Quaternium-15, Urea derivatives (e.g. Imidazolidinyl Urea, Diazolidinyl Urea), DMDM Hydantoin, 2-Bromo-2nitropropane-1,3-diol, Sodium Hydroxymethyl Glycinate, Benzylhemiformal, 5-Bromo-5-nitro-1,3-dioxane, Methenamine.

Replaces Version 02: 2017-01-19



Phthalates: refers to esters of phthalic acid (e.g. Dimethyl phthalate (DMP), Diethyl phthalate (DEP), Dibutyl phthalate (DBP), Butyl Benzyl phthalate (BBP), Di(2-ethylhexyl)phthalate (DEHP), Dimethoxyethyl phthalate (DMEP), Diisopentylphtalate (DIPP), Di-n-pentyl phthalate (DNPP), Di-n-octyl phthalate (DNOP), n-pentyl-isopentylphtalate (PIPP). The main source of phthalates are plasticizers used in packaging.

Glycol ethers: refers to ethers of Ethylene Glycol or Diethylene Glycol

Free Amines: refers to primary (monoalkylamines, monoalkanolamines), secondary (dialkylamines, dialkanolamines) and tertiary (trialkylamines, trialkanolamines) amines (see SCCS Opinion on Nitrosamines and Secondary Amines in Cosmetic Products, 27 March 2012):

$$\begin{matrix} R_1 \\ N \end{matrix} \begin{matrix} R_2 \\ R_3 \end{matrix}$$

R1, R2, R3 = H or organic group like alkyl, alkanol, alkylamine, aryl, aryl-alkyl

Nitrosamines: refers to the potential presence of nitrosamines based on the production

process and the used substances Monomer residues: refers to synthetic monomers

Dioxin and PCBs: refers to dioxins (PolyChlorinated Dibenzo-p-Dioxins [PCDDs] and Dibenzofurans [PCDFs]) and PCBs (PolyChlorinated Biphenyls) (according to Regulation (EC) No 1881/2006)

PAHs: refers to Polycyclic Aromatic Hydrocarbons, such as Benzo- (α) -pyrene, Benzo- (α) -anthracene, Benzo- (β) fluoranthene and chrysene (according to Regulation (EC) No 1881/2006)



4. Regulatory Information

Last animal testing date: toxicological tests done on animals <u>after March 2009</u> testing dates are indicated in the Animal Testing Statement according to (EC) No 1223/2009. For animal tests done <u>before March 2009</u> the last testing date is given in the Technical Dossier.

Nano declaration information: refers to e.g. the French annual declaration of substances at nanoscale (Decree no. 2012-232 of 17 February 2012 in application of article R. 523-4 of the French environment code) or similar.

Additional Nano information: refers to e.g. particle size distribution information of nanomaterials.

5. Safety and environment

VOC substance(s) according to positive list of Swiss VOC Regulation contained: means the substance(s) is/are present according to the definition in Swiss VOC Regulation (Ordinance 814.018 on the Incentive Tax on Volatile Organic Compounds) and more precisely in the corresponding positive list (Annex I of the Regulation). Ingredients part of our product composition are only considered (neither impurities nor residual solvents).

6. Product suitability

Kosher/Halal status: The product can be either Kosher and/or Halal compliant - based on DSM self-assessment (DSM statement) - or certified by a certifying body (Kosher/Halal certificate).



8. Quality information

GMP standard states the Good Manufacturing Practice which is **applied for this product.** The highest GMP standard applied to the product is given. The product is either certified by a certifying body or compliant based on DSM selfassessment (audit).

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