

PRODUCT INFORMATION FILE

< TOPICLEAR SKIN-STRENGTHENING SERUM >

September 2025, Republic of China (Taiwan)

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(1) Basic information of the product

Item	Description
Product Name	Topiclear Skin-Strengthening Serum
Product Category	Lotions / Oils / Creams & Emulsions – Others
Product Form	Emulsion
Intended Use	Emollient
Manufacturing Site Information	Manufacturer: TOP-WELL Cosmetics Industry Co., Ltd. Address: No. 11, Ln. 71, Fude Rd., Shuwang Vil., Dali Dist., Taichung City 412016 Country: Taiwan
Packaging Site Information	Packaging Company: TOP-WELL Cosmetics Industry Co., Ltd. Address: No. 11, Ln. 71, Fude Rd., Shuwang Vil., Dali Dist., Taichung City 412016 Country: Taiwan
Manufacturer Information	Company: TOP-WELL Cosmetics Industry Co., Ltd. Address: No. 11, Ln. 71, Fude Rd., Shuwang Vil., Dali Dist., Taichung City 412016 Responsible Person: Mr. Lin, Feng-Yu Tel: +886-4-24063459 Unified Business Number (UBN): 84080908

(2) Evidentiary documents of completing product notification

Registration Number : 84080908-0000-F008E50002

Appendix 3 : Topiclear Skin-Strengthening Serum

(3) Full ingredient names and the individual content.

	INCI Name	%	Cas No	Function
1	Water/Aqua	70.68	7732-18-5	Solvent
2	Glycerin	5.00	56-81-5	Humectant
3	Cetyl Ethylhexanoate	5.00	59130-69-7	Emollient
4	Water/Aqua	3.2595115	7732-18-5	Skin Conditioner
	Glycerin	1.375	56-81-5	
	Pseudoalteromonas Ferment Extract	0.20	N/A	
	Xanthan Gum	0.06	11138-66-2	
	Alanine	0.005	56-41-7	
	Proline	0.005	147-85-3	
	Serine	0.005	56-45-1	
	Sodium Phosphate	0.0045	13472-35-0	
	Sodium Hydroxide	0.00095	1310-73-2	
	Tocopherol	0.0000385	10191-41-0	
	Caprylyl Glycol	0.05	1117-86-8	
	Ethylhexylglycerin	0.035	70445-33-9	
5	Phenyl Trimethicone	2.00	70131-69-0	Emollient
6	Squalane	2.00	111-01-3	Emollient
7	Isohexadecane	0.50	93685-80-4	Thickene
	Polysorbate 80	0.20	9005-65-6	
	Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer	0.80	77019-71-7	
	Water/Aqua	0.50	7732-18-5	
8	Cetyl PEG/PPG-10/1 Dimethicone	1.50	144243-53-8	Thickener
9	Pentylene Glycol	1.50	5343-92-0	Humectant
10	Dipropylene glycol	1.00	25265-71-8	Humectant
11	Cocamidopropyl Betaine	0.60	61789-40-0	Humectant
12	Sodium Lactate	0.50	867-56-1	Skin Conditioner

13	Water/Aqua	0.245	7732-18-5	Skin Conditioner
	Butylene Glycol	0.245	107-88-0	
	Prunus Yedoensis Leaf Extract	0.01	928156-32-5	
14	Panthenol	0.50	81-13-0	Skin Conditioner
15	Rosa Centifolia Flower Water	0.4995	84604-12-6	Skin Conditioner
	Methylparaben	0.0005	99-76-3	
	Citric Acid	0.00025	77-92-9	
16	Isostearyl Alcohol	0.25	N/A	Thickener
	Butylene Glycol Cocoate	0.225	73138-39-3	
	Ethylcellulose	0.025	9004-57-3	
17	Phenoxyethanol	0.27	122-99-6	Preservative
	Ethylhexylglycerin	0.03	70445-33-9	
18	Fragrance	0.30	N/A	Fragrance
19	Acrylates/C10-30 Alkyl Acrylate Crosspolymer	0.20	N/A	Thickener
20	Aminomethyl Propanol	0.20	124-68-5	PH adjuster
21	Polyglyceryl-4 Isostearate	0.10	63705-03-3	Thickener
22	Hexylene Glycol	0.0416	107-41-5	Skin Conditioner
	Fructose	0.01	57-48-7	
	Glucose	0.01	50-99-7	
	Sucrose	0.001	57-50-1	
	Urea	0.001	57-13-6	
	Dextrin	0.001	9004-53-9	
	Alanine	0.0001	56-41-7	
	Glutamic Acid	0.0001	56-86-0	
	Aspartic Acid	0.0001	56-84-8	
	Hexyl Nicotinate	0.0001	23597-82-2	
	Water	0.035	7732-18-5	
23	Sodium Hyaluronate	0.01	9067-32-7	Humectant
24	Water	0.0099395	7732-18-5	Skin Conditioner
	Acetyl Hexapeptide-8	0.0000055	N/A	
	Caprylyl Glycol	0.000055	1117-86-8	
		100.00		

(4) The outer packaging of the products, containers, labels or leaflets

Item	Data
Container / Inner Packaging Label / Outer Packaging (Front and Back Panels)	
	

(5) GMP compliance certificates or self-declarations which the manufacturing facilities comply with cosmetic Good Manufacturing Practice Regulations



Certificate of Registration

GOOD MANUFACTURING PRACTICE - ISO 22716:2007

This is to certify that: Top-Well Cosmetics Industry Co., Ltd.
No. 11, Lane 71, Fu Der Road
Ta-Li District
Taichung City
412
Taiwan

頂郁企業股份有限公司
臺灣
台中市
大里區
福德路71巷11號
412

Holds Certificate No: **CGMP 659092**

And operates a system according to the guidelines of BS/EN ISO 22716:2007 Cosmetics - Good Manufacturing Practices (GMP) for the following scope:

Please see scope page.

For and on behalf of BSI:

Joe Hsieh, Managing Director Northeast Asia, APAC Assurance

Original Registration Date: 2016-09-08
Latest Revision Date: 2025-07-10

Effective Date: 2025-09-08
Expiry Date: 2028-09-07

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Taiwan Headquarters: 2nd Floor, No.37, Ji-Hu Rd., Nei-Hu Dist., Taipei 114, Taiwan, R.O.C.
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(6) Manufacturing methods and procedures

	INCI Name	%	Cas No	Function
1	Water/Aqua	70.68	7732-18-5	Solvent
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4	Water/Aqua	3.2595115	7732-18-5	Skin Conditioner
	Glycerin	1.375	56-81-5	
	Pseudoalteromonas Ferment Extract	0.20	N/A	
	Xanthan Gum	0.06	11138-66-2	
	Alanine	0.005	56-41-7	
	Proline	0.005	147-85-3	
	Serine	0.005	56-45-1	
	Sodium Phosphate	0.0045	13472-35-0	
	Sodium Hydroxide	0.00095	1310-73-2	
	Tocopherol	0.0000385	10191-41-0	
	Caprylyl Glycol	0.05	1117-86-8	
	Ethylhexylglycerin	0.035	70445-33-9	
5	Phenyl Trimethicone	2.00	70131-69-0	Emollient
6	Squalane	2.00	111-01-3	Emollient
7	Isohexadecane	0.50	93685-80-4	Thickene
	Polysorbate 80	0.20	9005-65-6	
	Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer	0.80	77019-71-7	
	Water/Aqua	0.50	7732-18-5	
8	Cetyl PEG/PPG-10/1 Dimethicone	1.50	144243-53-8	Thickener
9	Pentylene Glycol	1.50	57-55-6	Humectant
10	Dipropylene glycol	1.00	25265-71-8	Humectant
11	Cocamidopropyl Betaine	0.60	61789-40-0	Humectant
12	Sodium Lactate	0.50	867-56-1	Skin Conditioner
13	Water/Aqua	0.245	7732-18-5	Skin Conditioner
	Butylene Glycol	0.245	107-88-0	
	Prunus Yedoensis Leaf Extract	0.01	928156-32-5	
14	Panthenol	0.50	81-13-0	Skin Conditioner
15	Rosa Centifolia Flower Water	0.4995	84604-12-6	Skin Conditioner

	Methylparaben	0.0005	99-76-3	
	Citric Acid	0.00025	77-92-9	
16	Isostearyl Alcohol	0.25	N/A	Thickener
	Butylene Glycol Cocoate	0.225	73138-39-3	
	Ethylcellulose	0.025	9004-57-3	
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20	Aminomethyl Propanol	0.20	124-68-5	PH adjuster
21	Polyglyceryl-4 Isostearate	0.10	63705-03-3	Thickener
22	Hexylene Glycol	0.0416	107-41-5	Skin Conditioner
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	Glucose	0.01	50-99-7	
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	Aspartic Acid	0.0001	56-84-8	
	Hexyl Nicotinate	0.0001	23597-82-2	
	Water	0.035	7732-18-5	
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24	Water	0.0099395	7732-18-5	Skin Conditioner
	Acetyl Hexapeptide-8	0.0000055	N/A	
	Caprylyl Glycol	0.000055	1117-86-8	
		100.00		

- A. Mix raw materials **3, 5, 6, 7, 8, 16, and 21** uniformly to form **Phase A**.
- B. Mix raw materials **1, 2, 9, 10, 11, 19, and 20** uniformly to form **Phase B**.
- C. Add **Phase B** into **Phase A** and mix uniformly.
- D. Mix raw materials **4, 12, 13, 14, 15, 16, 17, 18, 22, 23, and 24** uniformly to form **Phase C**.
- E. Add **Phase C** into **Phase A+B** and mix uniformly.
- F. Take samples for testing.
- G. Upon passing inspection, proceed to filling.

(7) Usage methods, body parts, dosage, frequencies, and the targeted population

Method of Use, Application Area, and Dosage: Face

Target Users: Adolescents and Adults

Frequency of Use: Twice daily

Daily exposure levels for different cosmetics product categories in Europe, calculated by multiplying daily amounts (SCCNFP/0321/00; Hall et al., 2007, 2011)

Product type	Estimated daily amount applied(g/day)	Relative daily amount applied(mg/kg/bw /day)	Retention factor	Calculated daily exposure(g/day)	Calculated relative daily exposure (mg/kg/bw /day)
Face cream	1.54	24.14	1.0	1.54	24.14

(8) Adverse effects of the product application

Currently, no adverse events related to this product have been reported. In the event that any adverse or serious adverse reactions occur, the information will be promptly provided to the safety assessor for verification and evaluation, and will be updated in the Product Information File.

(9) Physical and chemical characteristics of the products and individual ingredients.

As shown in Appendix 1: Safety Data Sheet (SDS)

(10) Toxicological data of the ingredients

As shown in Appendix 2: Toxicological Data

1. Water :Not considered hazardous. Essential for life. Non-toxic under normal use conditions. °

2. Glycerin

Acute toxicity Acute toxicity (Oral) : Rat LD50 > 24,000 mg/kg.

Irritant properties Skin corrosion/irritation: Not irritating to skin in animal and human tests (up to 100% neat)

Skin sensitization: No sensitization.

NOAEL : 10,000 mg/kg/day (2-year dietary study)

Reference: Safety Assessment of Glycerin as Used in Cosmetics

3.Cetyl Ethylhexanoate

Acute toxicity Acute toxicity (Oral) : Rat LD50 > 2000 mg/kg.

Irritant properties Skin corrosion/irritation: Not irritating

Skin sensitization: No sensitization.

NOAEL : 10,00 mg/kg/day

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/11691/7/6/2>

4.1.Pseudoalteromonas Ferment Extract

Skin cell cytotoxicity test: No cytotoxicity

Fibroblast cytotoxicity test: No cytotoxicity

Ocular irritation (HET-CAM test): Non-irritant

Mutagenicity/Carcinogenicity (Ames test): Non-carcinogenic

Erythrocyte toxicity (hemolysis test): No hemolytic effect

Primary skin irritation test: Non-irritant

Acute toxicity test: Non-toxic

Skin sensitization (hypoallergenic): Non-sensitizing

Reference: XPERTMOIST molecular film Safety Assessment Summary

4.2Xanthan Gum

Acute toxicity Acute toxicity (Oral) : Rat LD50 > 5000 mg/kg.

Irritant properties Skin corrosion/irritation: Not irritating

Skin sensitization: No sensitization.

NOAEL : 500 mg/kg/day

Reference: RHODICARE T SDS

4.3Alanine

Acute toxicity Acute toxicity (Oral) : Rat LD50 > 16000 mg/kg.

Irritant properties Skin corrosion/irritation: Not irritating

Skin sensitization: No sensitization.

NOAEL : 6800mg/kg/day

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/24843/7/6/2>

4.4Proline

Acute toxicity Acute toxicity (Oral) : Rat LD50 > 5110 mg/kg.

Irritant properties Skin corrosion/irritation: Not irritating

Skin sensitization: No sensitization.

NOAEL : 2772.9mg/kg/day

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/13104/7/6/2>

4.5Serine

Irritant properties Skin corrosion/irritation: Not irritating

Skin sensitization: No sensitization.

NOAEL : 2765mg/kg/day

Reference:

Tolerable amounts of amino acids for human supplementation summary and lessons from published peer reviewed studies

4.6Sodium Phosphate

Acute toxicity Acute toxicity (Oral) : Rat LD50 > 8290 mg/kg.

LOAEL : 290 mg/kg/day

Reference: REVIEW OF POTENTIALLY RELEVANT DATA (NONCANCER AND CANCER)

4.7Sodium Hydroxide.

Acute toxicity Acute toxicity (Oral) : Rat LD50 > 325 mg/kg.

Irritant properties Skin corrosion/irritation: Category 1 (corrosive) based on GHS criteria

Skin sensitization: No sensitization.

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/15566/7/3/2>

4.8Tocopherol

Acute effects

Acute oral toxicity

Parameter : LD50

Exposure route : Oral

Species : Rat

Effective dose : > 5 mL/kg

Test result : not toxic

Irritant and corrosive effects

Primary irritation to the skin

Parameter : Primary irritation to the skin

Species : Rabbit

Result : Not irritant

Method : Draize test (5 %, water)

Irritation to eyes Parameter : Irritation to eyes Species : Rabbit Result : No objections to the use in the vicinity of the eye. Method : DRAIZE-TEST

Reference: Tocopherol Oil CLR SDS

4.9Caprylyl Glycol

Acute toxicity Acute toxicity (Oral) : Rat LD50 > 2000 mg/kg.

Irritant properties Skin corrosion/irritation: Not irritating

Skin sensitization: No sensitization.

NOAEL : 150mg/kg/day

Reference: ECHA

<https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/14120/7/6/2>

5.Phenyl Trimethicone

Acute toxicity Acute toxicity (Oral) : Rat LD50 > 2000 mg/kg.

Irritant properties Skin corrosion/irritation: Not irritating

Skin sensitization: No sensitization.

NOAEL : 1000mg/kg/day

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/19337/7/6/2>

6.Squalane

Acute toxicity Acute toxicity (Oral) : Rat LD50 > 50 mL/kg.

Irritant properties Skin corrosion/irritation: Not irritating

Skin sensitization: No sensitization.

NOAEL : 1000mg/kg/day

Reference:

1.Final Report on the Safety Assessment of Squalane and Squalene

2.Supporting Information for Low-Priority Substance Tetracosane, 2,6,10,15,19,23-Hexamethyl (CASRN 111-01-3) (Squalane) Final Designation

7.1Isohexadecane

Acute toxicity Acute toxicity (Oral) : rat LD50 > 36600 mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

Mutagenicity :In vitro negative.

NOAEL : 1000 mg/kg/day (90-day repeated oral dose study in rats)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/2089/7/6/2/?documentUUID=c877a591-3108-4d57-92da-082deab4c7d1>

7.2 Polysorbate 80

Acute toxicity Acute toxicity (Oral) : rat LD50 > 20000 mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

Mutagenicity :In vitro negative.

NOAEL : 5000 mg/kg/day (90-day repeated oral dose study in rats)

Reference: Safety Assessment of Polysorbates as Used in Cosmetics

7.3 Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

Reference: Safety Assessment of Acryloyldimethyltaurate Polymers as Used in Cosmetics

8. Cetyl PEG/PPG-10/1 Dimethicone

Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000 mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

Mutagenicity :In vitro negative.

NOAEL : 5000 mg/kg/day (90-day repeated oral dose study in rats)

Reference: Safety Assessment of Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients as Used in Cosmetics

9. Pentylene Glycol

Acute toxicity Acute toxicity (Oral) : rat LD50 > 12700 mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

Mutagenicity :In vitro negative.

NOAEL : 2450 mg/kg/day (28-day repeated oral dose study in rats)

Reference: Safety Assessment of 1,2-Glycols as Used in Cosmetics

10. Dipropylene glycol

Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000 mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 530 mg/kg/day (90-day repeated oral dose study in rats)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/16016/7/6/2>

11.Cocamidopropyl Betaine

Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000 mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOEL : 250mg/kg/day (90-day repeated oral dose study in rats)

Reference: Cocamidopropyl Betaine- CIR

12.Sodium Lactate

Acute toxicity Acute toxicity (Oral) : rat LD50 3750 ± 430 mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 1330mg/kg/bw/d) (90-day repeated oral dose)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/13841/7/6/2>

13.1Butylene Glycol

Acute toxicity Acute toxicity (Oral) : rat LD50 > 29590mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 5600 mg/kg/bw/d) (90-day repeated oral dose)

Reference: Butylene Glycol SDS

13.2Prunus Yedoensis Leaf Extract

Acute Oral Toxicity Oral Mice ALD : Not less than 10g/kg

Primary Skin Irritation: No Irritation (Undiluted)

Cumulative Skin Irritation: No Irritation (Undiluted)

Skin Sensitization (+ Adjuvant) : No Sensitization (Undiluted)

Photo Toxicity: No Irritation (Undiluted)

Photosensitization (— Adjuvant) :No Sensitization (Undiluted)

Ocular Irritation Almost :no Irritation (Undiluted) :

Mutagenicity(Reverse mutation) : Reverse mutation was negative

Reference: SAKURA Extract B SDS

14.Panthenol

Acute toxicity Acute toxicity (Oral) : rat LD50 > 2000 mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 1000mg/kg/bw/d) (90-day repeated oral dose)

Reference: ECHA

15.1 Rosa Centifolia Flower Water

Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

Reference: Safety Assessment of Rosa centifolia-Derived Ingredients as Used in Cosmetics

15.2 Methylparaben

Acute toxicity Acute toxicity (Oral) : rat LD50 > 2100mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 2000 mg/kg/bw/d)

Reference: Safety Assessment of Parabens as Used in Cosmetics

15.3 Citric Acid

Acute toxicity Acute toxicity (Oral) : rat LD50 > 3000mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 1200 mg/kg/bw/d) (24-month repeated oral dose)

Reference: SIDS Initial Assessment Report-CITRIC ACID

16.1 Isostearyl Alcohol

16.2 Butylene Glycol Cocoate

16.3 Ethylcellulose

Acute toxicity Acute toxicity (Oral) : rat LD50 > 2001mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

Reference: EMULFREE CBG MB SDS

17.1 Phenoxyethanol

Acute toxicity Acute toxicity (Oral) : rat LD50 > 1840mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 369 mg/kg/bw/d) (90-day repeated oral dose)

17.2 Ethylhexylglycerin

Acute toxicity Acute toxicity (Oral) : rat LD50 > 2000mg/kg.

Irritant properties Skin corrosion/irritation: Slight, transient irritation.

Skin sensitization: No sensitization.

NOAEL : 100 mg/kg/bw/d) (28-day repeated oral dose)

Reference: EUXYL PE 9010 SDS

18.Fragrance

Reference: IFRA

19.Acrylates/C10-30 Alkyl Acrylate Crosspolymer

Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

Reference: Amended Safety Assessment of Acrylates Copolymers as Used in Cosmetics

20.Aminomethyl Propanol

Acute toxicity Acute toxicity (Oral) : rat LD50 > 2900mg/kg.

Irritant properties Skin corrosion/irritation: No Skin corrosion.

Skin sensitization: No sensitization.

NOAEL : 0.73 mg/kg/bw/d)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/11767/7/6/2>

21.Polyglyceryl-4 Isostearate

Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 1000 mg/kg/bw/d)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/11209/7/6/2>

22.1Hexylene Glycol

Acute toxicity Acute toxicity (Oral) : rat LD50 > 2000mg/kg.

Irritant properties Skin corrosion/irritation: Slightly irritation.

Skin sensitization: No sensitization.

NOAEL : 450 mg/kg/bw/d)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/14212/7/6/2>

22.2Fructose

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 4500 mg/kg/bw/d)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/7620/7/6/2>

22.3 Glucose

Acute toxicity Acute toxicity (Oral) : rat LD50 > 2000mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 1000 mg/kg/bw/d) (90-day repeated oral dose)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/11721/7/6/2>

22.4 Sucrose

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 4500 mg/kg/bw/d)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/7620/7/6/2>

22.5 Urea

Acute toxicity Acute toxicity (Oral) : rat LD50 > 16000mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 6750 mg/kg/bw/d) (90-day repeated oral dose)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/16152/7/6/2>

22.6 Dextrin

Acute toxicity Acute toxicity (Oral) : rat LD50 > 10000mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 5000 mg/kg/bw/d) (90-day repeated oral dose)

Reference: Assessment of the safety of hydrogenated resistant maltodextrin: reverse mutation assay, acute and 90-day subchronic repeated oral toxicity in rats, and acute no-effect level for diarrhea in humans

22.7 Glutamic Acid

Acute toxicity Acute toxicity (Oral) : rat LD50 > 5110mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 1500 mg/kg/bw/d) (90-day repeated oral dose)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/12560/7/6/2>

22.8 Aspartic Acid

Acute toxicity Acute toxicity (Oral) : rat LD50 > 2000mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 697 mg/kg/bw/d) (90-day repeated oral dose)

Reference: ECHA

<https://echa.europa.eu/registration-dossier/-/registered-dossier/14876/7/6/2>

22.9 Hexyl Nicotinate

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

Reference: Hexyl nicotinate SDS

23. Sodium Hyaluronate

Acute toxicity Acute toxicity (Oral) : rat LD50 > 1200mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

NOAEL : 1333 mg/kg/bw/d)

Reference: Safety Assessment of Hyaluronates as Used in Cosmetics

24.1 Acetyl Hexapeptide-8

Acute toxicity Acute toxicity (Oral) : rat LD50 > 2500mg/kg.

Irritant properties Skin corrosion/irritation: No irritation.

Skin sensitization: No sensitization.

Reference: Safety Assessment of Acetyl Hexapeptide-8 and Acetyl Hexapeptide-8 Amide as Used in Cosmetics

(11) The product stability test reports

頂郁企業股份有限公司

安定性試驗報告

產品編號	F-008-E50-002					檢驗數量						
產品品名	TOPICEAR 柔光美肌修護晶露					2PCS						
檢驗規格與項目												
檢測項目：				檢驗規格								
1. 室溫、45℃外觀				乳狀								
2. 室溫、45℃氣味				比對標準品								
3. 室溫、45℃顏色				微淡粉色								
4. pH 值				6.0-7.0								
5. 粘度				S05/10rpm:18000-36000cps								
6. 離心												
7. 硬度												
8. 熔點												
9. 總菌落數												
				<100 cfu/1 ml(g)								
檢測結果												
抽樣日期		2024.6.18		抽樣數量		2PCS		抽樣人員		葉子文		
抽樣批次		F2-0002-8		抽樣批數		1		檢驗人員		葉子文		
檢驗項目		室溫			45℃			pH	離心	粘度	熔點	總菌落數
檢驗間隔		外觀	顏色	味道	外觀	顏色	味道					
DAY 1		OK	OK	OK	OK	OK	OK	6.16		26320 cps		pass
DAY 7		OK	OK	OK	OK	OK	OK					
DAY 14		OK	OK	OK	OK	OK	OK					
1(M)		OK	OK	OK	OK	OK	OK					
3(M)		OK	OK	OK	OK	OK	OK					
6(M)		OK	OK	OK	OK	OK	OK	6.11		25360 cps		pass
12(M)		OK	OK	OK	OK	OK	OK	6.13		25680 cps		pass
24(M)												
36(M)												

※外觀、顏色、味道之檢測結果若符合規格可以 OK 標示

EP01S18R01

(12) The microbiological test reports

頂郁企業股份有限公司
成品檢驗報告單

產品編號	A-008-E50-200		產品名稱	TOPICLEAR 50G 柔光 美肌修護晶露		檢驗單號	QR-AN0166
批號	A2-N0028		生產日期	2024/6/26		批量	300PCS
申請單位	製造課		抽樣人員	蔡青秀		抽樣數量	2 PCS
抽樣日期	2024/6/26	檢驗日期	2024/6/26	檢驗完成日期	2024/6/28		
檢驗項目		檢驗規格		檢驗結果		備註	
顏色		比對標準品 A-008-E50-200		Pass			
氣味		比對標準品 A-008-E50-200		Pass			
性狀		比對標準品 A-008-E50-200		Pass			
總生菌數 依據 EP01S31 作業標準		<100 cfu/ml(g)		Pass			
以下空白							
判定		允收					
檢驗人員		蔡青秀 2024.6.28		檢驗主管		陳子文 2024.6.28	

EP01S45R02

(13) Information about the packaging materials which have contact with the products.

Net Content :

Packaging Material	Packaging Components
Bottle	PE/PP
Cap	PP

(14) Product safety information:

(1) Safety evaluation conclusion and suggestion

The following table includes the relevant available NOAEL and MoS calculated for each ingredient of the formula.

$$SED = E_{\text{product}} \times C / 100 \times D_{\text{ap}} / 100$$

$$MoS = POD_{\text{sys}} / SED$$

****SED (mg /kg bw/day) ; Eproduct (mg /kg bw/day) ; C(%) ; DAp(%) ; PODsys**

	INCI name	C(%)	DAp(%)	NOAEL (mg/kg bw/day)	SED (mg/kg bw/day)	MoS
1	Water/Aqua	76.379201	-	-	-	>100
2	Glycerin	5.00	50	10000	0.6035	16570.00829
3	Cetyl Ethylhexanoate	5.00	50	1000	0.6035	1657.000829
4	Pseudoalteromonas Ferment Extract	0.20	-	-	-	-
5	Xanthan Gum	0.06	50	500	0.007242	69041.70119
6	Alanine	0.0051	100	6800	0.00123114	5523336.095
7	Proline	0.005	100	2772.9	0.001207	2297348.799
8	Serine	0.005	100	2765	0.001207	2290803.645
9	Sodium Phosphate	0.0045	50	290	0.00054315	533922.4892
10	Sodium Hydroxide	0.00095	-	-	-	-
11	Tocopherol	0.0000385	-	-	-	-
12	Caprylyl Glycol	0.050055	100	150	0.012083277	12413.85098
13	Ethylhexylglycerin	0.035	-	-	-	-
14	Phenyl Trimethicone	2.00	50	1000	0.2414	4142.502071
15	Squalane	2.00	50	1000	0.2414	4142.502071
16	Isohexadecane	0.50	50	1000	0.06035	16570.00829
17	Polysorbate 80	0.20	50	5000	0.02414	207125.1036

18	Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer	0.80	-	-	-	-
19	Cetyl PEG/PPG-10/1 Dimethicone	1.50	50	5000	0.18105	27616.68048
20	Pentylene Glycol	1.50	50	2450	0.18105	13532
21	Dipropylene glycol	1.00	50	530	0.1207	4391.052196
22	Cocamidopropyl Betaine	0.60	50	250	0.07242	3452.085059
23	Sodium Lactate	0.50	100	1330	0.1207	11019.05551
24	Prunus Yedoensis Leaf Extract	0.01	-	-	-	-
25	Panthenol	0.50	50	1000	0.06035	16570.00829
26	Rosa Centifolia Flower Water	0.4995	-	-	-	-
27	Methylparaben	0.0005	100	2000	0.0001207	16570008.29
28	Citric Acid	0.00025	100	1200	0.00006035	19884009.94
29	Isostearyl Alcohol	0.25	-	-	-	-
30	Butylene Glycol Cocoate	0.225	50	5600	0.0271575	206204.5475
31	Ethylcellulose	0.025	-	-	-	-
32	Phenoxyethanol	0.27	100	369	0.065178	5661.419497
33	Fragrance	0.30	-	-	-	-
34	Acrylates/C10-30 Alkyl Acrylate Crosspolymer	0.20	-	-	-	-
35	Aminomethyl Propanol	0.20	10	0.73	0.004828	151.2013256
36	Polyglyceryl-4	0.10	50	1000	0.01207	82850.04143
37	Isostearate					
38	Hexylene Glycol	0.0416	100	450	0.01004224	44810.71952
39	Fructose	0.01	100	4500	0.002414	1864125.932
40	Glucose	0.01	100	1000	0.002414	414250.2071
41	Sucrose	0.001	100	4500	0.0002414	18641259.32
42	Urea	0.001	100	6750	0.0002414	27961888.98
43	Dextrin	0.001	50	5000	0.0001207	41425020.71
44	Glutamic Acid	0.0001	100	1500	0.00002414	62137531.07
45	Aspartic Acid	0.0001	100	697	0.00002414	28873239.44
46	Hexyl Nicotinate	0.0001	-	-	-	-
47	Sodium Hyaluronate	0.01	50	1333	0.001207	1104391.052

48	Acetyl Hexapeptide-8	0.0000055	-	-	-	-
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Summary

In accordance with the EU Cosmetics Regulation (Regulation (EC) No. 1223/2009) and the SCCS Notes of Guidance (SCCS/1564/15, 9th Revision), a comprehensive toxicological assessment has been conducted for the cosmetic product TOPICLEAR Skin-Strengthening Serum.

Each ingredient was evaluated for acute toxicity (LD50), skin irritation, sensitization, and repeated-dose toxicity (NOAEL). Systemic Exposure Dose (SED) and Margin of Safety (MoS) were calculated where applicable. The results are as follows:

- All calculated MoS values are greater than 100, meeting the minimum safety threshold established by SCCS, indicating no systemic health risk.
- Key solvents, humectants, and emollients (e.g., Glycerin, Propylene Glycol, Squalane) show no irritation or sensitization at the concentrations used.
- The preservative system (e.g., Phenoxyethanol, Ethylhexylglycerin) and other functional ingredients are within regulatory limits and pose no safety concerns.
- The intended user population is adolescents and adults, with application to the face twice daily, which is consistent with safe use conditions.
- No adverse effects or serious adverse events have been reported to date.

Final Conclusion:

Based on the toxicological data, SED and MoS calculations, it is concluded that this cosmetic formulation is safe for daily consumer use under the intended conditions of application, provided it is manufactured in compliance with ISO 22716 Good Manufacturing Practice (GMP). The product presents no risks of acute toxicity, skin irritation, or sensitization, and provides sufficient systemic safety margins.