PRODUCT INFORMATION FILE

＜TOPICLEAR DIAMOND COMPLEXION CREAM＞

September 2025, Republic of China (Taiwan)

Table of Contents

(1) Basic information of the product

Item	Description
Product Name	Topiclear Diamond Complexion Cream
Product Category	Lotions / Oils / Creams & Emulsions – Others
Dosage Form	Ointment
Purpose	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	Packager: TOP-WELL Cosmetics Industry Co., Ltd. Address: No. 11, Ln. 71, Fude Rd., Shuwang Vil., Dali Dist., Taichung City 412016 Country: Taiwan
Manufacturer Information	Manufacturer: TOP-WELL Cosmetics Industry Co., Ltd. Address: No. 11, Ln. 71, Fude Rd., Shuwang Vil., Dali Dist., Taichung City 412016 Company Representative: Lin, Feng-Yu Contact Phone: 04-24063459 Unified Business No.: 84080908

(2) Evidentiary documents of completing product notification

Registration No.: 84080908-0000-F008DCC001

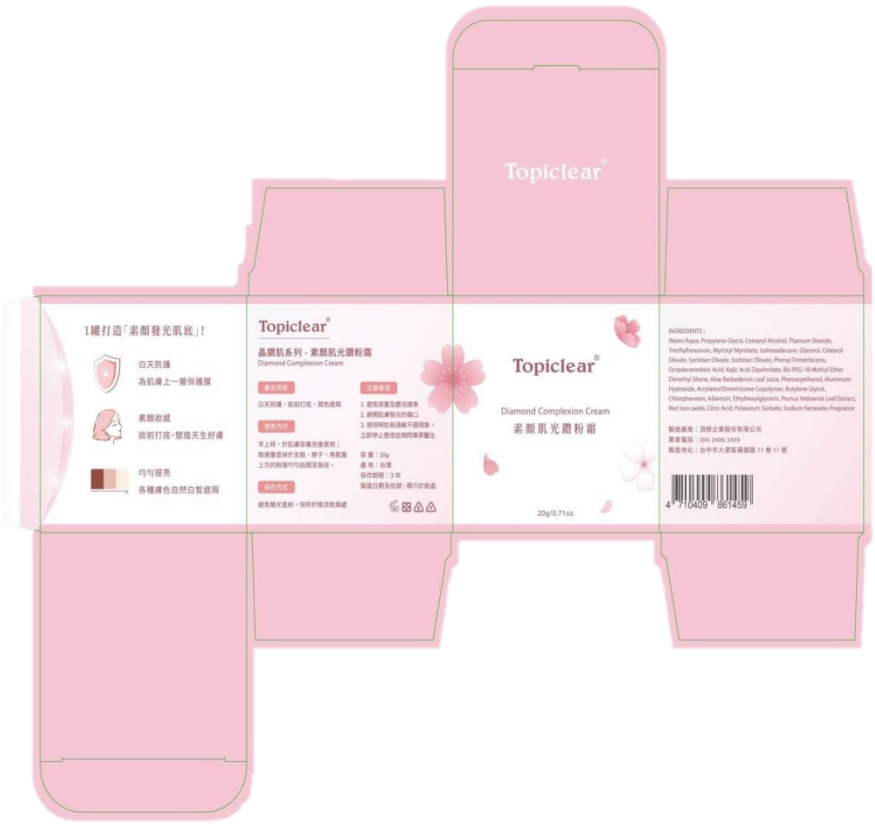
Appendix 3：Topiclear Diamond Complexion Cream

(3) Full ingredient names and the individual content.

	INCI Name	%	**Cas No**	Function
1	Water/Aqua	51.435	7732-18-5	Solvent
2	Propylene Glycol	10.00	57-55-6	Humectant
3	Cetearyl Alcohol	8.00	67762-27-0	Thickener
4	Titanium Dioxide	6.30	13463-67-7	Colorant
	Aluminum Hydroxide	0.35	21645-51-2	
	Acrylates/Dimethicone Copolymer	0.35	756819-45-1	
5	Triethylhexanoin	5.00	7360-38-5	Emollient
6	Myristyl Myristate	3.00	3234-85-3	Emollient
7	Isohexadecane	3.00	93685-80-4	Emollient
8	Glycerol	3.00	56-81-5	Humectant
9	Sorbitan Olivate	3.00	223706-40-9/ 92202-01-2/ 97358-61-7/ 97281-21-5	Thickener
10	Cetearyl Olivate	1.50	85116-80-9 / 91697-49-3 / 348616-34-2 / 2778-96-3 / 97404-33-6	Thickener
11	Phenyl Trimethicone	1.50	70131-69-0	Emollient
12	Octadecenedioic Acid	0.50	20701-68-2	Skin Conditioner
13	Kojic Acid Dipalmitate	0.50	79725-98-7	Skin Conditioner
14	Bis-PEG-18 Methyl Ether Dimethyl Silane	0.50	67846-47-3	Humectant
15	Aloe Barbadensis Leaf Juice	0.49865	94349-62-9	Skin Conditioner
	Potassium Sorbate	0.0005	24634-61-5	
	Sodium Benzoate	0.00025	532-32-1	

	Citric Acid	0.0006	77-92-9	
16	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	
17	Phenoxyethanol	0.36	122-99-6	Preservative
	Ethylhexylglycerin	0.04	70445-33-9	
18	Fragrance	0.30	N/A	Fragrance
19	Chlorphenesin	0.20	104-29-0	Preservative
20	Allantoin	0.15	97-59-6	Skin Conditioner
21	Red iron oxide	0.0135	1309-37-1	Colorant
	Acrylates/Dimethicone Copolymer	0.0015	756819-45-1	
		100.00		

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

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

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

bsi.

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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(6) Manufacturing methods and procedures

	INCI Name	%	**Cas No**	Function
1	Water/Aqua	51.435	7732-18-5	Solvent
2	Propylene Glycol	10.00	57-55-6	Humectant
3	Cetearyl Alcohol	8.00	67762-27-0	Thickener
4	Titanium Dioxide	6.30	13463-67-7	Colorant
	Aluminum Hydroxide	0.35	21645-51-2	
	Acrylates/Dimethicone Copolymer	0.35	756819-45-1	
5	Triethylhexanoin	5.00	7360-38-5	Emollient
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11	Phenyl Trimethicone	1.50	70131-69-0	Emollient
12	Octadecenedioic Acid	0.50	20701-68-2	Skin Conditioner
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	Citric Acid	0.0006	77-92-9	
16	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	
17	Phenoxyethanol	0.36	122-99-6	Preservative
	Ethylhexylglycerin	0.04	70445-33-9	
18	Fragrance	0.30	N/A	Fragrance

19	Chlorphenesin	0.20	104-29-0	Preservative
20	Allantoin	0.15	97-59-6	Skin Conditioner
21	Red iron oxide	0.0135	1309-37-1	Colorant
	Acrylates/Dimethicone Copolymer	0.0015	756819-45-1	
		100.00		

Manufacturing Process:

A. Mix raw materials 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, and 21 evenly to obtain **Mixture A**.

B. Mix raw materials 1, 2, 8, 15, and 16 evenly to obtain **Mixture B**.

C. Add **Mixture B** into **Mixture A** and mix evenly.

D. Mix raw materials 17, 18, 19, and 20 evenly to obtain **Mixture C**.

E. Add **Mixture C** into the combined **Mixture A + B** and mix evenly.

F. Take samples for testing.

G. If the test results meet the specifications, proceed to filling.

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

Usage Methods, Body Parts, and Dosage: Face

Target Population: Teenagers and Adults

Usage Frequency: Twice daily

Daily exposure leves 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 applie(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 reaction events have been reported for this product. In the event of adverse or serious adverse reactions, the information will be promptly provided to the safety assessor for review and evaluation, and updated in this Product Information File.

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

See Appendix 1: SDS Data

(10) Toxicological data of the ingredients

See Appendix 2: Toxicological Data

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

2.Propylene Glycol

Acute Toxicity

typ. dose	mode	specie	amount	units	other
TDLo	orl	chd	79	gm/kg/56W-I	
LD50	orl	dog	22	gm/kg	
LD50	orl	gpg	19	gm/kg	
LD50	orl	mus	24	gm/kg	
LD50	orl	rat	20	gm/kg	
LDLo	orl	rbt	14300	mg/kg	
LD50	skn	rbt	20800	mg/kg	

Skin corrosion/irritation :Non-irritating to the skin.

Serious eye damage/eye: irritation Non-irritating to the eyes.

Respiratory or skin sensitization:Not sensitizing.

Germ cell mutagenicity :Negative for genotoxicity using both in vitro and in vivo tests.

Carcinogenicity:Long term toxicity studies conducted in rodents and dogs demonstrate that this substance is not a carcinogen.

NOAEL：1,000 mg/kg/day（90-day repeated oral dose study in rats）

Reference:PG USP SDS

3.Cetearyl Alcohol

Skin corrosion/irritation Rabbit – No skin irritation

Serious eye damage/eye irritation Rabbit – No eye irritation

NOAEL：750 mg/kg/day（90-day repeated oral dose study in rats）

Reference:ECHA

https://echa.europa.eu/registration-dossier/-/registered-dossier/16007/7/6/2

4.1.Titanium Dioxide

Acute toxicity Acute toxicity (Oral) : rat LD50 > 20000 mg/kg.
Irritant properties Skin corrosion/irritation: No irritation.
Skin sensitization: No sensitization.
NOAEL：2500 mg/kg/day（90-day repeated oral dose study in rats）
Reference: Safety assessment of titanium dioxide (E171)

4.2.Aluminum Hydroxide
Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000 mg/kg.
Irritant properties Skin corrosion/irritation: No irritation.
Skin sensitization: No sensitization.
NOAEL：2400 mg/kg/day（60-day repeated oral dose study in rats）
Reference: Safety Assessment of Alumina and Aluminum Hydroxide as Used in Cosmetics

4.3. Acrylates/Dimethicone Copolymer
Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000 mg/kg.
Irritant properties Skin corrosion/irritation: Mild/slight irritation in rabbit tests
Skin sensitization: No sensitization.
NOAEL：No specific repeat-dose oral study/NOAEL identified for this copolymer class; NICNAS notes no repeat-dose oral data for the analog and, given low bioavailability, oral risk is not expected under intended uses
Reference:NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

5. Triethylhexanoin
Acute toxicity Acute toxicity (Oral) : mouse LD50 > 4840 mg/kg.
Irritant properties Skin corrosion/irritation: No irritation.
Skin sensitization: No sensitization.
NOAEL：4770 mg/kg/day（90-day repeated oral dose study in rats）
Reference: DUB TOCG SDS

6. Myristyl Myristate
Acute toxicity Acute toxicity (Oral) : rat LD50 > 10000 mg/kg.
Skin corrosion/irritation: No irritation.
Serious eye damage/eye irritation: slight irritation.
NOAEL：
Not identified for Myristyl Myristate (no 90-day oral study available in MM-specific dossier).
High-MW fatty acid ester; low systemic toxicity expected; safe as used in cosmetics when formulated to be non-irritating
Reference: Final Report on the Safety Assessment of Myristyl Myristate and Isopropyl Myristate

7. Isohexadecane
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

8. Glycerol
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

9.Sorbitan Olivate
10. Cetearyl Olivate
Human Patch Test – skin irritation: Not irritating
RBC Test – ocular irritation :No ocular irritation potential
Reference: HALLSTAR COSMETIC INGREDIENT INFORMATION SHEET

11. Phenyl Trimethicone
Acute toxicity Acute toxicity (Oral) : rat LD50 > 2000mg/kg.
Irritant properties Skin corrosion/irritation: No irritation.
Skin sensitization: No sensitization.
NOAEL：1000 mg/kg/day（90-day repeated oral dose）
Reference: ECHA
https://echa.europa.eu/registration-dossier/-/registered-dossier/19337/7/6/2

12. Octadecenedioic Acid
Acute toxicity Acute toxicity (Oral) : rat LD50 > 2000mg/kg.
Irritant properties Skin corrosion/irritation: No irritation.
Skin sensitization: No sensitization.
NOAEL：741 and 855 mg/kg bw/day for males and females（90-day repeated oral dose）
Reference: ECHA
https://echa.europa.eu/registration-dossier/-/registered-dossier/11427/7/6/2

13. Kojic Acid Dipalmitate
Acute toxicity Acute toxicity (Oral) : No oral LD50 reported.
Irritant properties Skin corrosion/irritation: No irritation.
Skin sensitization: No sensitization.
NOAEL：Not available for KAD
This products is not an extremely hazardous substance.
Reference: SpecWhiteTM KAD SDS

14. Bis-PEG-18 Methyl Ether Dimethyl Silane
Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000mg/kg.
Irritant properties Skin corrosion/irritation: No irritation.
Skin sensitization: No sensitization.
NOAEL：Not available
This products is not an extremely hazardous substance.
Reference: DOWSIL™ 2501 SDS

15.1. Aloe Barbadensis Leaf Juice
Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000mg/kg.
Irritant properties Skin corrosion/irritation: No irritation.
Skin sensitization: No sensitization.
NOAEL：No 90-day oral NOAEL specifically for Aloe leaf juice identified; however, a 14-day dietary NOEL for acemannan = 50,000 ppm (~4.1–4.6 g/kg/day) in rats is reported by CIR
Reference: Final Report on the Safety Assessment of Aloe AndongensisExtract, Aloe Andongensis Leaf Juice, Aloe Arborescens LeafExtract, Aloe Arborescens Leaf Juice, Aloe Arborescens LeafProtoplasts, Aloe Barbadensis Flower Extract, AloeBarbadensis Leaf, Aloe Barbadensis Leaf Extract, AloeBarbadensis Leaf Juice, Aloe Barbadensis LeafPolysaccharides, Aloe Barbadensis Leaf Water, Aloe FeroxLeaf Extract, Aloe Ferox Leaf Juice, and Aloe Ferox LeafJuice Extract

15.2.Potassium Sorbate
Acute toxicity Acute toxicity (Oral) : rat LD50 > 10500mg/kg.
Irritant properties Skin corrosion/irritation: No irritation.
Skin sensitization: No sensitization.
NOAEL：Male: 6800 mg/kg/bw/d and female: 7200 mg/kg/bw/d)（90-day repeated oral dose）
Reference: ECHA
https://echa.europa.eu/registration-dossier/-/registered-dossier/11008/7/6/2

15.3.Sodium Benzoate
Acute toxicity Acute toxicity (Oral) : rat LD50 > 3140mg/kg.
Irritant properties Skin corrosion/irritation: No irritation.
Skin sensitization: No sensitization.

NOAEL： 1000 mg/kg/bw/d)（24-month repeated oral dose）
Reference: ECHA
https://echa.europa.eu/registration-dossier/-/registered-dossier/14966/7/6/2

15.4.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

16.1Butylene 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

16.2Prunus 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 Irritaiton (Undiluted)：
Mutagenicity(Reverse mutation) : Reverse mutation was negative
Reference: SAKURA Extract B SDS

17.1Phenoxyethanol
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）
17.2Ethylhexylglycerin
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:JO-MALONE TYPE　628015 IFRA

19. Chlorphenesin
Acute toxicity Acute toxicity (Oral) : rat LD50 > 3000mg/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: ECHA
https://echa.europa.eu/registration-dossier/-/registered-dossier/22482/7/6/2

20. Allantoin
Acute toxicity Acute toxicity (Oral) : rat LD50 > 5000mg/kg.
Irritant properties Skin corrosion/irritation: Slight, transient 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/13641/7/6/2

21. Red iron oxide
MUTAGENICITY : Ames test: Negative
NOAEL：　1000 mg/kg/bw/d)（90-day repeated oral dose）
Reference: EFSA
https://www.noaelproject.it/content/re-evaluation-iron-oxides-and-hydroxides-e-172-food-additives

(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-DCC-001	檢驗數量
產品品名	TOPICLEAR 20G 素顏肌光鎖粉霜	2pcs

檢驗規格與項目	
檢測項目：	檢驗規格
1. 室溫、45℃外觀	乳劑
2. 室溫、45℃氣味	香水
3. 室溫、45℃顏色	粉色
4. pH 值	5.0-6.0
5. 粘度	s07/100rpm: 15000-25000cps
6. 離心	
7. 硬度	
8. 熔點	
9. 總菌落數	<100 cfu/ml(g)

檢測結果												
抽樣日期	2024.7.2		抽樣數量		2pcs		抽樣人員	黃子芝				
抽樣批次	F2-N0039		抽樣批數		1		檢驗人員	黃子芝				
檢驗項目 / 檢驗間隔	室溫			45℃			pH	離心	粘度	熔點	總菌落數	
	外觀	顏色	味道	外觀	顏色	味道						
DAY 1	ok	ok	ok	ok	ok	ok	5.24		22120 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	5.22		21120 cps			
12(M)	ok	ok	ok	ok	ok	ok	5.24		21280 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-DCC-100		產品名稱	TOPICLEAR 20G 素顏肌光鑽粉霜	檢驗單號	QR-AN0175
批號	A2-N0039		生產日期	2024/7/12	批量	PCS
申請單位	製 造 課		抽樣人員	蔡青秀	抽樣數量	2 PCS
抽樣日期	2024/7/12	檢驗日期	2024/7/12	檢驗完成日期	2024/7/15	

檢 驗 項 目	檢 驗 規 格	檢 驗 結 果	備 註
顏色	比對標準品 A-008-DCC-100	Pass	
氣味	比對標準品 A-008-DCC-100	Pass	
性狀	比對標準品 A-008-DCC-100	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 2024.7.15	檢驗主管	沈千芝 2024.7.15

EP01S45R02

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

Product Capacity :

Packaging Materials	Material Composition
Bottle Body	Acrylic + PP
Bottle Cap	ABS + PP
Bottle Head	ABS + PU

(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= Eproduct×C/100)×Dap/100

MoS = PODsys/*S*ED

**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	51.68	-	-	-	>100
2	Propylene Glycol	10.00	50	1000	1.207	828.50041
3	Cetearyl Alcohol	8.00	50	750	0.9656	776.71914
4	Titanium Dioxide	6.30	50	2500	0.76041	3287.7001
5	Aluminum Hydroxide	0.35	50	2400	0.042245	56811.457
6	Acrylates/Dimethicone Copolymer	0.3515	-	-	-	-
7	Triethylhexanoin	5.00	50	4770	0.6035	7903.894
8	Myristyl Myristate	3.00	-	-	-	-
9	Isohexadecane	3.00	50	1000	0.3621	2761.668
10	Cetearyl Olivate	3.00	-	-	-	-
11	Sorbitan Olivate	1.50	-	-	-	-
12	Glycerol	3.00	50	10000	0.3621	27616.68
13	Phenyl Trimethicone	1.50	50	1000	0.18105	5523.3361
14	Octadecenedioic Acid	0.50	50	855	0.06035	14167.357
15	Kojic Acid Dipalmitate	0.50	-	-	-	-
16	Bis-PEG-18 Methyl Ether Dimethyl Silane	0.50	-	-	-	-

17	Aloe Barbadensis Leaf Juice	0.49865	100	4600	0.1203741	38214.197
18	Potassium Sorbate	0.10	100	7200	0.02414	298260.15
19	Sodium Benzoate	0.05	100	1000	0.01207	82850.041
20	Citric Acid	0.12	100	1200	0.028968	41425.021
21	Butylene Glycol	0.145	50	5600	0.0175015	319972.57
22	Prunus Yedoensis Leaf Extract	0.01	-	-	-	-
23	Phenoxyethanol	0.36	50	369	0.043452	8492.1292
24	Ethylhexylglycerin	0.04	50	100	0.004828	20712.51
25	Fragrance	0.30	-	-	-	IFRA
26	Chlorphenesin	0.20	50	100	0.02414	4142.5021
27	Allantoin	0.15	50	1000	0.018105	55233.361
28	Red iron oxide	0.0135	50	1000	0.0016295	613704.01

Summary

Product Safety Conclusion

According to the requirements of the EU Cosmetics Regulation (Regulation (EC) No. 1223/2009) and the methodology outlined in the **SCCS Notes of Guidance (SCCS/1564/15, 9th Revision)**, each ingredient of the present formulation has been assessed for its toxicological profile. Systemic Exposure Dose (SED) and Margin of Safety (MoS) values were calculated wherever possible.

1. **Acute Toxicity and NOAELs**
    - Relevant data on acute toxicity (LD50), skin irritation, skin sensitization, and repeated-dose toxicity (NOAEL) were considered for each ingredient.
    - All ingredients show **MoS values greater than 100**, which is the minimum safety threshold defined by SCCS.
2. **Local Tolerance**
    - Main excipients such as Cetearyl Alcohol, Propylene Glycol, Glycerol, Aloe Barbadensis Leaf Juice are not irritating or sensitizing at the concentrations used.
    - Specific ingredients such as Titanium Dioxide, Aluminum Hydroxide, Kojic Acid Dipalmitate are used within safe concentration limits, with no evidence of phototoxicity or sensitization in the finished formulation.
3. **Systemic Exposure (SED) and MoS**

- The highest-exposure ingredients (e.g., Propylene Glycol, Cetearyl Alcohol, Glycerol) still present MoS values far above 100 (ranging approximately 776 – 27,616).
- Other ingredients such as Octadecenedioic Acid, Potassium Sorbate, Citric Acid demonstrate extremely high safety margins (>10,000).
- Overall, the formula exhibits adequate safety margins for systemic exposure.

4. **Special Considerations**
   - Aloe Barbadensis Leaf Juice: Anthraquinone content must be controlled to ≤50 ppm to avoid potential irritation, phototoxicity, or carcinogenicity.
   - Preservative system (Potassium Sorbate, Sodium Benzoate): Used within the limits of Annex V of the EU Cosmetics Regulation and considered safe at the stated concentrations.

Final Conclusion

Based on the toxicological data, NOAEL values, SED and MoS calculations, it can be concluded that the present cosmetic formulation is safe for use under the intended conditions of application. Provided that the product is manufactured according to Good Manufacturing Practice (GMP, ISO 22716), it is considered safe for daily consumer use, with no acute toxicity, skin irritation, or sensitization risks, and with sufficient safety margins for systemic exposure.