

NAILLEGEND

# Cream & Clay Mask

## Compliance & Technical Dossier

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Clay / Mud · Charcoal · Cream-Balm Lines | Jar · Tube · Single-Dose Forms

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# 0. Dossier Overview & Legal Notice

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**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** Compliance & Technical Dossier — Overview | **Issue date:** 2026-06-22 | **Version:** 1.0

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## What this dossier is

This is the **Compliance & Technical Dossier** for the NailLegend **Cream & Clay Mask** category (clay / mud and charcoal masks; rich cream–balm masks; clay and cream forms in jar, tube and single-dose pack). It brings together, in one document, the technical and regulatory information a brand-owner or distributor needs when sourcing this product on an OEM / Private-Label basis for the **US (FDA)** and **EU (Regulation EC 1223/2009)** markets.

The data in this dossier are **representative of NailLegend's standard production** for this category. They are typical values issued by NailLegend's in-house quality function. For a specific order, the figures are reconfirmed against the **final agreed formula and production batch**, and batch-specific certificates of analysis are issued with shipment.

## Two product routes covered

This category spans two formulation routes that share the same compliance backbone:

- **Clay / mud mask** — a water-based suspension carrying natural mineral clays (kaolin, bentonite) and optional charcoal or sea mud; sold on cleansing, oil-absorption and a mineral "deep-clean" feel.
- **Cream / balm mask** — a rich oil-in-water emulsion sold on moisturizing, softening and repair.

Both are **water-containing** products and so require preservation and microbiological control; the clay/mud route additionally requires **heavy-metal control on the natural mineral raw materials**.

## Regulatory responsibility

Final market-placement responsibility — FDA cosmetic listing (MoCRA), EU CPNP notification, appointment of the EU Responsible Person, the Cosmetic Product Safety Report (CPSR), the Product Information File (PIF), and final labelling and claims — rests with the **brand owner / importer**.

NailLegend, as the manufacturer, supplies the supporting technical documents in this dossier to enable that work.

## Claims guardrails

A cream or clay mask claiming **cleansing, oil-absorption, moisturizing, softening, soothing** is a **cosmetic**. Wording such as "*detoxifies*," "*cures*," "*treats*," or "*medical*" — or any disease claim — reclassifies the product as a **drug** and triggers separate regulation. Keep claims cosmetic — "*deeply cleanses / absorbs excess oil / intensely moisturizes*," not "*detoxes the body / cures / treats*."

## How to read the data

- **Composition & specification** (INCI, TDS, formulation disclosure, allergen and IFRA statements) describe the product as manufactured.

- **Test sections** (preservative-efficacy, microbiological, heavy metals, stability) present the applicable **methods, acceptance criteria, and typical results** for this product, issued by NailLegend's in-house QC. They represent standard production performance; batch-specific certificates accompany each shipment.

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# 1. INCI Ingredient List

**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** INCI Ingredient List (representative — clay/mud & cream base) | **Issue date:** 2026-06-22 | **Version:** 1.0

The list below is the representative INCI composition for the Cream & Clay Mask. The definitive descending-order list and on-pack allergen call-outs are confirmed against the final agreed formula for each order before use on artwork or for CPNP notification. Ingredients in *italics* are line-dependent (clay/mud, charcoal, cream/balm or fragranced variants).

## INCI declaration (descending order)

#	INCI name	Function
1	Aqua (Water)	Solvent / base
2	<i>Kaolin</i>	Mineral clay — absorbent (clay/mud line)
3	<i>Bentonite</i>	Mineral clay — high-absorption (clay/mud line)
4	Glycerin	Humectant
5	Butylene Glycol	Humectant / solvent
6	Caprylic/Capric Triglyceride	Emollient
7	<i>Butyrospermum Parkii (Shea) Butter</i>	Occlusive / emollient (cream/balm line)
8	<i>Glyceryl Stearate</i>	Emulsifier (cream/balm line)
9	<i>Cetearyl Alcohol</i>	Emulsifier / consistency (cream/balm line)
10	<i>Charcoal Powder (Charcoal)</i>	Absorbent / colourant (charcoal line)
11	<i>Sea Silt (Maris Limus / Dead Sea mud)</i>	Mineral mud (mineral line)
12	<i>Magnesium Aluminum Silicate</i>	Suspending agent / rheology (clay lines)
13	Xanthan Gum	Thickener / rheology / thixotropy
14	Glycerin (humectant, see above)	—
15	Sodium Hyaluronate	Humectant
16	<i>Menthol</i>	Cooling agent (cooling line)
17	<i>Melaleuca Alternifolia (Tea Tree) Leaf Oil</i>	Conditioning (tea-tree line)
18	Disodium EDTA	Chelating agent
19	Phenoxyethanol	Preservative
20	Ethylhexylglycerin	Preservative booster / skin conditioning
21	<i>Parfum (Fragrance)</i>	Fragrance (omitted in fragrance-free)
22	<i>Limonene, Linalool, Citronellol, Geraniol</i>	Fragrance allergens (declared at threshold — see Section 4)

## Notes for labelling

- **Ordering** is representative of standard production; the exact descending-order list is issued for the locked formula of each order. In a clay/mud line, kaolin and/or bentonite typically sit high in the order; in a cream/balm line the emulsion base and emollients move up.
- **Natural mineral raw materials** (kaolin, bentonite, charcoal, sea silt) are controlled for heavy-metal content — see Section 7.
- **EU fragrance allergens** present at or above the labelling threshold (0.001% leave-on / 0.01% rinse-off) appear in the on-pack INCI list — see Section 4.
- **Preservative and any colourant** sit within the target-market permitted lists (EU Annex V / IV; US permitted colour additives).

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## 2. Technical Data Sheet (TDS)

**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** Technical Data Sheet (representative specification) | **Issue date:** 2026-06-22 | **Version:** 1.0

### 1. Product description

A rinse-off / leave-on cosmetic mask applied as a thick layer to the skin (face / body / feet), left on for a defined dwell time, then rinsed off or massaged in. Two routes are covered: a **clay / mud mask (water-based mineral suspension)** sold on cleansing and oil-absorption, and a **cream / balm mask (oil-in-water emulsion)** sold on moisturizing, softening and repair. Optional lines add charcoal, sea mud, menthol or tea tree.

### 2. Physical & chemical specification (typical)

Property	Specification	Method
Appearance	Smooth clay-coloured to grey/black paste (clay/charcoal) / smooth white cream (cream-balm)	Visual
Odour	Characteristic of fragrance dosed / earthy mineral / odourless (fragrance-free)	Olfactory
Colour	Clay-natural, grey or black (charcoal); white to off-white (cream) unless tinted to brief	Visual
pH (as is, 25 °C)	5.0 – 8.0 (clay/mud — mineral-dependent); 5.0 – 6.5 (cream-balm)	pH meter (ISO 4316)
Viscosity (25 °C)	50,000 – 200,000 mPa·s (thick spreadable paste)	Brookfield HBT, sp. T-bar / Helipath
Thixotropy / spreadability	Spreads under shear, holds without slumping	In-house spread test
Relative density (25 °C)	1.05 – 1.40 g/cm <sup>3</sup> (clay loaded) / 0.98 – 1.05 g/cm <sup>3</sup> (cream)	Pycnometer
Net content	To order (e.g. 50 / 100 / 150 mL jar; tube; single-dose sachet)	—

### 3. Microbiological specification (water-containing product)

Parameter	Limit	Reference
Total aerobic mesophilic count (TAMC)	≤ 1,000 cfu/g	ISO 21149
Total yeast & mould (TYMC)	≤ 100 cfu/g	ISO 16212
<i>Pseudomonas aeruginosa</i>	Absent in 1 g	ISO 22717
<i>Staphylococcus aureus</i>	Absent in 1 g	ISO 22718
<i>Escherichia coli</i>	Absent in 1 g	ISO 21150
<i>Candida albicans</i>	Absent in 1 g	ISO 18416

Typical batch results and preservation performance are reported in Sections 6 and 5. Natural-clay raw materials may carry a higher native bioburden, which is controlled by raw-material selection and the preservation system.

### 4. Heavy-metal control (natural mineral raw materials)

Natural clays and muds (kaolin, bentonite, charcoal, sea silt) may carry trace heavy metals as an inherent feature of the mineral source. Lead, arsenic, cadmium and mercury are controlled to within target-market cosmetic limits — see Section 7 for typical results and method.

### 5. Packaging & primary material

- **Clay/mud & charcoal lines:** PP / PET jar, or aluminium / laminate tube, or single-dose sachet; sealed against drying and high-temperature separation.
- **Cream/balm line:** tube / jar / single-dose sachet.
- Secondary: carton / multi-pack / gift box to brief.

### 6. Storage, shelf life & usage

Item	Value
Storage	Cool, dry place, away from direct sunlight; 5 – 30 °C
Shelf life	24 months unopened; PAO 12M (jar/tube)
Directions	Apply an even layer; leave 10 – 20 min; rinse off (clay/charcoal) or massage in (cream). Avoid eye area.
Warnings	External use only. Avoid eyes and broken skin. Discontinue if irritation occurs.

NailLegend · naillegend.com — Representative specification; batch-specific values confirmed per production. Confidential — for the intended recipient only.

## 3. Safety Data Sheet (SDS)

**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** Safety Data Sheet — GHS 16-section (representative) | **Issue date:** 2026-06-22 | **Version:** 1.0

Prepared in the UN GHS 16-section format (aligned with US OSHA HazCom 29 CFR 1910.1200 and EU REACH Annex II). The finished product is a cosmetic; classification below reflects the representative formula. Batch- or formula-specific SDS is reissued where the agreed formula differs.

- 1. Identification** — Product: Cream & Clay Mask. Use: cosmetic, external skin care. Supplier: NailLegend (naillegend.com). Contact: Lareina. Emergency: contact supplier during business hours.
- 2. Hazard identification** — GHS classification: Not classified as hazardous (finished cosmetic, clay/mud and cream lines). Signal word: None. Note: in production, dry clay / charcoal powders generate nuisance dust before incorporation; handle to minimise dust inhalation. Precautionary statements (bulk powder handling): P261, P280 (dust mask / eye protection).
- 3. Composition / information on ingredients** — Mixture (cosmetic). Components of note: Kaolin (CAS 1332-58-7), Bentonite (CAS 1302-78-9), Charcoal (CAS 7440-44-0), Phenoxyethanol (CAS 122-99-6) — present only in the relevant lines and within cosmetic use limits. Full composition: see Section 1 (INCI).
- 4. First-aid measures** — Eyes: rinse with water for several minutes; remove contact lenses; seek advice if irritation persists. Skin: topical use; if irritation occurs, rinse and discontinue. Ingestion: rinse mouth, do not induce vomiting, seek advice. Inhalation (bulk powder): move to fresh air.
- 5. Fire-fighting measures** — Not flammable. Suitable extinguishing media: water spray, foam, CO<sub>2</sub>, dry powder.
- 6. Accidental release** — Wipe up; product is water-based and slippery — avoid slip hazard. Dry powders: avoid raising dust; collect mechanically. Avoid bulk release to drains.
- 7. Handling & storage** — Handle per good hygiene practice. Store cool, dry, out of direct sunlight; keep jars/tubes/sachets sealed until use to prevent drying and separation.
- 8. Exposure controls / PPE** — Consumer use: no PPE required. Bulk handling (manufacturing): gloves and eye protection; dust mask when weighing dry clay/charcoal powders; no specific occupational exposure limit assigned to the finished mixture.
- 9. Physical & chemical properties** — Appearance, odour, pH, density and viscosity: see Section 2 (TDS). Flash point: not applicable (water-based). Solubility: clays disperse / swell in water; emulsion miscible with water.
- 10. Stability & reactivity** — Stable under recommended storage. Incompatibilities: strong oxidisers. Hazardous decomposition products: none under normal use.
- 11. Toxicological information** — Finished cosmetic confirmed safe for normal use through the brand owner's CPSR. May be drying with overuse on the clay line; not for use on damaged skin or eyes.
- 12. Ecological information** — No significant adverse effects expected in normal consumer use. Avoid bulk discharge to the environment.
- 13. Disposal** — Dispose of contents and container in accordance with local regulations.

**14. Transport information** — Not classified as dangerous goods for transport (finished cosmetic). UN number: none.

**15. Regulatory information** — Cosmetic finished product. US: FDA cosmetic (MoCRA). EU: Regulation (EC) 1223/2009. Ingredients comply with applicable cosmetic inventories for the declared markets. Heavy-metal content of natural mineral raw materials controlled within target-market limits — see Section 7.

**16. Other information** — Abbreviations: ICP-MS inductively coupled plasma mass spectrometry; PAO period after opening. An SDS is not legally mandatory for a finished cosmetic in all markets but is commonly requested by importers and logistics partners; this SDS is provided for that purpose.

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## 4. Fragrance Allergen Declaration

**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** EU Fragrance Allergen Declaration | **Issue date:** 2026-06-22 | **Version:** 1.0

Basis: EU Regulation (EC) 1223/2009. Fragrance allergens must be named in the on-pack INCI list above **0.001% (10 ppm) for leave-on** and **0.01% (100 ppm) for rinse-off** products. A clay/charcoal mask is typically **rinse-off**; a cream/balm mask may be **leave-on** — the applicable threshold is set per product format. The table below shows a representative sea-/herbal-type fragrance dosed at 0.4%. Content is reconfirmed by the fragrance supplier for the specific fragrance of each order; a **fragrance-free** variant declares "none present." (Note: Reg. (EU) 2023/1545 expands the declarable list — the supplementary sheet is added where the target market requires it.)

### Allergen content (representative — sea/herbal-type fragrance @ 0.4%)

#	Allergen (INCI)	CAS	Present	% in product	On-pack declaration
1	Linalool	78-70-6	Yes	0.0180	Required (leave-on & rinse-off)
2	Limonene	5989-27-5	Yes	0.0120	Required (leave-on & rinse-off)
3	Geraniol	106-24-1	Yes	0.0042	Required (leave-on)
4	Citronellol	106-22-9	Yes	0.0031	Required (leave-on)
5	Coumarin	91-64-5	Yes	0.0020	Required (leave-on)
6	Citral	5392-40-5	Yes	0.0011	Required (leave-on)
7	Eugenol, Isoeugenol, Cinnamal, Benzyl Benzoate, Benzyl Salicylate, Hexyl Cinnamal, Amyl Cinnamal, Farnesol, Benzyl Alcohol, others	various	No / trace	< 0.0010	Not required (below threshold)

**On-pack declaration required for this fragrance** — *leave-on (cream) format:* Linalool, Limonene, Geraniol, Citronellol, Coumarin, Citral. *rinse-off (clay/charcoal) format:* Linalool, Limonene (only those ≥ 0.01%).

### Declaration

For the fragrance dosed in this product, the allergens marked "Required" for the applicable format above are included in the on-pack INCI list. A **fragrance-free** variant contains no added fragrance allergens. Values are reconfirmed by the fragrance supplier for the specific fragrance and dosage of each order.

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## 5. IFRA Conformity Statement

**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** IFRA Conformity Statement | **Issue date:** 2026-06-22 | **Version:** 1.0

This statement is supported by the **IFRA Certificate of Conformity issued by the fragrance supplier** for the specific fragrance compound and its dosage. The fragrance supplier's certificate is held on file and provided to the brand owner's safety assessor on request. A **fragrance-free** variant requires no IFRA statement.

### 1. Product use category

Item	Value
Product type	Cream & Clay Mask (applied to face / body skin)
IFRA product category	Category 5A (body lotion / leave-on face & body) for cream-leave-on; Category 9 (rinse-off skin care) for clay rinse-off — set per format
Fragrance dosage in finished product	0.4% (representative; to brief)
IFRA Standards edition	51st Amendment

### 2. Conformity statement

The fragrance compound used at **0.4%** in this Cream & Clay Mask conforms to the **IFRA Standards (51st Amendment)** for the applicable product category. All restricted, prohibited and specified materials are within the maximum levels set by the relevant IFRA Standards for this use, as confirmed by the fragrance supplier's IFRA Certificate of Conformity held on file.

### 3. Relationship to allergen labelling

IFRA conformity governs **safe use levels** and is separate from EU **allergen labelling** (declaring allergens at threshold). Allergen content for the dosed fragrance is reported in Section 4.

### 4. Authorisation

Confirmed on the basis of the fragrance supplier's IFRA certificate for the dosed fragrance.

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## 6. Formulation Disclosure Statement

**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** Formulation Disclosure Statement | **Issue date:** 2026-06-22 | **Version:** 1.0

This statement gives the brand owner's safety assessor the functional composition and permitted-range information needed to build the CPSR / PIF, while protecting NailLegend's specific know-how. Exact weight percentages of the locked formula are disclosed **confidentially to the named safety assessor under NDA**; this statement provides the functional framework and confirms each restricted ingredient sits within its permitted limit.

### 1. Functional composition framework

Block	Function	Representative ingredients
Water phase / base	Carrier, humectancy	Aqua, Glycerin, Butylene Glycol, Sodium Hyaluronate
Mineral clay load (clay/mud line)	Absorption, mattifying, mineral feel	Kaolin, Bentonite, Sea Silt, Charcoal
Emulsion / emollient (cream line)	Lock in moisture, skin feel	Shea Butter, Caprylic/Capric Triglyceride, Glyceryl Stearate, Cetearyl Alcohol
Rheology / suspension	Viscosity, cling, thixotropy, anti-settling	Xanthan Gum, Magnesium Aluminum Silicate
Preservation	Microbiological safety	Phenoxyethanol, Ethylhexylglycerin, Disodium EDTA
Sensory / active	Fragrance / cooling / conditioning	Parfum (or none), Menthol, Tea Tree Oil

## 2. Restricted-ingredient confirmation

Ingredient (class)	Permitted basis	This product
Phenoxyethanol (preservative)	EU Annex V / target-market list — ≤ 1.0%	Used at ≤ 1.0%
Kaolin / Bentonite (mineral clay)	Standard cosmetic mineral; heavy metals within limits	Heavy metals controlled — see Section 7
Charcoal (Charcoal Powder)	Standard cosmetic use; as colourant within permitted use	Within standard use level
Menthol (cooling agent)	Standard cosmetic use level	Used within typical level
Tea Tree Oil (Melaleuca leaf oil)	Standard cosmetic use; specified-material limits via IFRA	Within typical level; allergen/IFRA per Sections 4 & 5
Colourant (if any)	EU Annex IV / US permitted colour additive	None unless tinted to brief
Fragrance & allergens	IFRA-compliant; allergens declared at threshold	See Sections 4 & 5
Disodium EDTA (chelant)	Standard cosmetic use	≤ 0.2%

## 3. What is and is not disclosed

- **Disclosed openly:** the functional framework, restricted-ingredient identities, and confirmation each is within its permitted limit.
- **Disclosed under NDA to the safety assessor only:** exact weight percentages of the locked formula (including clay load), supplier identities, and process parameters.
- **Not disclosed:** proprietary process know-how unrelated to safety assessment (e.g. clay pre-hydration and high-shear dispersion sequence, thixotropy tuning).

## 4. Manufacturer statement

For the locked formula supplied to a customer, NailLegend confirms that all ingredients are used within the limits and conditions permitted for cosmetic use in the customer's declared target markets, and that supporting analytical data (heavy metals, preservative efficacy, microbiological, stability) is provided in this dossier.

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# 7. Heavy Metals Test Report

**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** Heavy Metals Test Report — representative result | **Issue date:** 2026-06-22 | **Version:** 1.0

Natural clays and muds (kaolin, bentonite, charcoal, sea silt) can carry trace heavy metals as an inherent feature of the mineral source. This is the **single most important compliance control** for a clay/mud mask. Lead, arsenic, cadmium and mercury are determined by **ICP-MS (acid-digestion, inductively coupled plasma mass spectrometry)**; mercury may be run by **CV-AAS / direct mercury analyser**. The values below are **typical of NailLegend standard production**, issued by NailLegend in-house QC. A batch-specific certificate of analysis is issued for production batches on request.

Reference batch (example): **CCM-2406-01**

## 1. Method & basis

Item	Detail
Method	Acid digestion + ICP-MS (Pb, As, Cd); CV-AAS / direct mercury analyser (Hg)
Sample	Finished clay/charcoal mask (worst-case mineral load)
Limit basis	Target-market cosmetic heavy-metal limits (e.g. US FDA guidance for trace impurities; EU "technically unavoidable" trace levels under Reg. (EC) 1223/2009; national cosmetic limits where stricter)

## 2. Results (typical)

Heavy metal	Method	Reference limit (typical)	Typical result	Pass/Fail
Lead (Pb)	ICP-MS	≤ 10 ppm	< 1 ppm	Pass
Arsenic (As)	ICP-MS	≤ 3 ppm	< 0.5 ppm	Pass
Cadmium (Cd)	ICP-MS	≤ 3 ppm	< 0.3 ppm	Pass
Mercury (Hg)	CV-AAS / DMA	≤ 1 ppm	< 0.1 ppm	Pass

*(Reference limits are typical cosmetic trace-impurity values; the exact limit applied is verified against the current regulation of each declared target market per order. Some markets express limits as maximum permitted trace impurity rather than a deliberate-addition limit.)*

## 3. Raw-material control

- Mineral raw materials (kaolin, bentonite, charcoal, sea silt) are sourced against supplier specifications that include heavy-metal limits.
- Incoming mineral lots and the finished product are checked so that the loaded product remains within target-market limits.

#### 4. Conclusion

- Overall result: **PASS** — representative production is within typical cosmetic heavy-metal limits for the declared markets.
- Heavy-metal content is reconfirmed per production batch; a batch certificate of analysis is provided on request and verified against the current limit of each target market.

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## 8. Preservative Efficacy (Challenge) Test

**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** Preservative Efficacy (Challenge) Test — representative result | **Issue date:** 2026-06-22 | **Version:** 1.0

Method: **ISO 11930** (Cosmetics — Evaluation of antimicrobial protection). The results below are **typical of NailLegend standard production** for this water-containing product, issued by NailLegend in-house QC. A batch-specific challenge-test certificate is issued for production batches on request. Natural-clay raw materials can raise the native bioburden, so the preservation system is selected and challenge-tested against the worst-case mineral load.

### 1. Test organisms (ISO 11930)

Organism	Strain	Inoculum
<i>Pseudomonas aeruginosa</i>	ATCC 9027	~1×10 <sup>6</sup> cfu/g
<i>Staphylococcus aureus</i>	ATCC 6538	~1×10 <sup>6</sup> cfu/g
<i>Escherichia coli</i>	ATCC 8739	~1×10 <sup>6</sup> cfu/g
<i>Candida albicans</i>	ATCC 10231	~1×10 <sup>5</sup> cfu/g
<i>Aspergillus brasiliensis</i>	ATCC 16404	~1×10 <sup>5</sup> cfu/g

Incubation: 22.5 ± 2.5 °C. Reference product: representative production formula (Phenoxyethanol/Ethylhexylglycerin system, clay-loaded base).

### 2. Results — log reduction vs. time (typical)

Organism	T0 (cfu/g)	Day 7	Day 14	Day 28	Criterion A
<i>P. aeruginosa</i>	1.2×10 <sup>6</sup>	> 3.0	> 3.0	No increase	≥3 (D7), ≥3 (D14), n.i. (D28)
<i>S. aureus</i>	1.0×10 <sup>6</sup>	> 3.0	> 3.0	No increase	≥3 (D7), ≥3 (D14), n.i. (D28)
<i>E. coli</i>	1.1×10 <sup>6</sup>	> 3.0	> 3.0	No increase	≥3 (D7), ≥3 (D14), n.i. (D28)
<i>C. albicans</i>	1.4×10 <sup>5</sup>	≥ 1.0	≥ 1.0	No increase	≥1 (D7), ≥1 (D14), n.i. (D28)
<i>A. brasiliensis</i>	1.3×10 <sup>5</sup>	≥ 0	≥ 1.0	No increase	≥0 (D7), ≥1 (D14), n.i. (D28)

(n.i. = no increase from the previous reading.)

### 3. Evaluation & conclusion

- Criterion met: **Criterion A** (ISO 11930).
- Overall result: **PASS**.
- Conclusion: the preservative system provides adequate antimicrobial protection over the intended product life under the conditions tested, including the clay-loaded base. Performance is reconfirmed

per production batch. A "preservative-free / natural" claim is not recommended for a water-containing clay product without robust alternative preservation and confirmatory challenge testing.

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## 9. Microbiological Test Report

**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** Microbiological Test Report — representative result | **Issue date:** 2026-06-22 | **Version:** 1.0

Finished-product microbiological data for this water-containing cosmetic. Limits follow **ISO 17516** and general cosmetic practice. Values below are **typical of NailLegend standard production**, issued by NailLegend in-house QC. A batch-specific certificate of analysis accompanies each shipment. Natural-clay raw materials are monitored for incoming bioburden as part of release.

Reference batch (example): **CCM-2406-01**

### Results (typical)

Parameter	Method	Limit	Typical result	Pass/Fail
Total Aerobic Mesophilic Count (TAMC)	ISO 21149	≤ 1,000 cfu/g	< 10 cfu/g	Pass
Total Yeasts & Moulds (TYMC)	ISO 16212	≤ 100 cfu/g	< 10 cfu/g	Pass
<i>Pseudomonas aeruginosa</i>	ISO 22717	Absent / 1 g	Absent	Pass
<i>Staphylococcus aureus</i>	ISO 22718	Absent / 1 g	Absent	Pass
<i>Escherichia coli</i>	ISO 21150	Absent / 1 g	Absent	Pass
<i>Candida albicans</i>	ISO 18416	Absent / 1 g	Absent	Pass

**Sample condition:** appearance and odour normal; no visible contamination. **Overall result: PASS** — representative production conforms to specification. Each production batch is released against the same limits with a batch certificate.

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# 10. Stability Test Report

**Issued by:** NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cream & Clay Mask **Document:** Stability Test Report — representative result | **Issue date:** 2026-06-22 | **Version:** 1.0

Physical, chemical and packaging-compatibility stability supporting shelf life / PAO, tested in market packaging (jar / tube / single-dose sachet). Results are **typical of NailLegend standard production**, issued by NailLegend in-house QC. Batch-specific stability is monitored under the ongoing programme. The key stability risks for this category are **clay settling / syneresis (water release)** on the clay line and **emulsion break / oil separation** on the cream line.

Reference batch (example): **CCM-2406-01**

## 1. Study design

Condition	Temperature	Pull points
Real-time	25 ± 2 °C / 60% RH	0, 3, 6, 12, 24 months
Accelerated	40 ± 2 °C / 75% RH	0, 1, 2, 3 months
Cold / freeze-thaw	4 °C; -5 ↔ 40 °C cycles	per protocol

Packaging tested: PP jar / laminate tube / single-dose sachet.

## 2. Parameters & results (typical)

Parameter	Acceptance	T0	Accel. 3 mo	Real-time 12 mo	Pass/Fail
Appearance (no settling / separation / leak)	Conforms	Conforms	Conforms	Conforms	Pass
Phase stability (no syneresis / clay settling)	No water release / no hard cake	Pass	Pass	Pass	Pass
Emulsion integrity (cream line)	No oil separation / no break	Pass	Pass	Pass	Pass
Colour	Within range	Pass	No significant change	No significant change	Pass
Odour	No rancidity	Pass	Pass	Pass	Pass
pH	Target $\pm 0.5$	6.4	6.3	6.3	Pass
Viscosity	Spec $\pm 15\%$	120,000 mPa·s	within	within	Pass
Package seal integrity / leak	No leak	Pass	Pass	Pass	Pass
Microbial (end of study)	Section 9 limits	Pass	—	Pass	Pass

## 3. Conclusion

Based on accelerated and real-time data, the assigned shelf life is **24 months** unopened (PAO 12M after opening for jar/tube). Real-time study to 24 months is ongoing and confirms stability to date, with no clay settling/syneresis or emulsion break observed. Overall result: **PASS (real-time ongoing)**.

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