NAILLEGEND

Callus Remover

Compliance & Technical Dossier

Professional High-pH Alkaline Gel (KOH/NaOH) + Companion Acidic Neutralizer | Corrosive — For Professional Use Only

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0. Dossier Overview & Legal Notice

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

What this dossier is

This is the **Compliance & Technical Dossier** for the NailLegend **Callus Remover** category. The primary product is a **professional high-pH alkaline callus-softening gel** (potassium-hydroxide / sodium-hydroxide system) used in salon/spa pedicure to soften hardened skin and calluses by alkaline keratin hydrolysis, supplied with its **companion acidic neutralizer**. 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 / OSHA HazCom)** and **EU (Regulation EC 1223/2009 and CLP Regulation EC 1272/2008)** 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.

Critical safety notice — corrosive product

The professional alkaline gel is a **strongly alkaline (high-pH) preparation** and is **not an ordinary low-hazard cosmetic**. At its working pH it can cause **skin and serious eye damage** on misuse. Three points are non-negotiable and run through this entire dossier:

1. **Contact time is limited** — the gel must be left on only for the stated time and must not exceed it.
2. **Neutralization is part of the product, not optional** — the acidic neutralizer must be applied after the gel to stop the reaction; skipping it is the most common cause of injury.
3. **It must never be mixed or co-stored with acidic products** (including its own neutralizer in the same container) — the two are kept separate at all times.

The **Safety Data Sheet (Section 3)** and the **pH & Alkali Concentration Data (Section 10)** are the most important documents in this dossier and should be read first.

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), CLP/GHS hazard classification and labelling, child-resistant packaging selection, 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 callus remover claiming **softens / removes calluses and hardened skin / smooths rough skin** is a **cosmetic**. Wording such as "*cures,*" "*treats,*" "*heals,*" or "*medical*" reclassifies the product as a **drug** and

triggers separate regulation. Keep claims cosmetic — "*softens and removes calluses / smooths rough, hardened skin,*" not "*cures / treats.*"

How to read the data

- **Composition & specification** (INCI, TDS, formulation disclosure, allergen and IFRA statements) describe the product as manufactured.
- **Safety & test sections** (SDS, preservative-efficacy, microbiological, stability, pH & alkali concentration) 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:** Callus Remover **Document:** INCI Ingredient List (representative — professional alkaline gel) | **Issue date:** 2026-06-22 | **Version:** 1.0

The list below is the representative INCI composition for the professional **high-pH alkaline callus-remover gel**. 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. The companion **acidic neutralizer** is a separate product with its own INCI list, summarised at the end. Ingredients in *italics* are line-dependent (fragranced / tinted variants).

INCI declaration — alkaline gel (descending order)

#	INCI name	Function
1	Aqua (Water)	Solvent / reaction medium
2	Potassium Hydroxide	Alkali — keratin-softening active / pH driver
3	*Sodium Hydroxide*	Alkali (alternative/co-active in some formulas)
4	Propylene Glycol	Humectant / solvent
5	Glycerin	Humectant / skin-conditioning
6	Carbomer	Thickener / rheology (alkali-stable grade)
7	Hydroxyethylcellulose	Thickener / cling (co-rheology)
8	Aloe Barbadensis Leaf Juice	Soothing / skin-conditioning
9	Disodium EDTA	Chelating agent / stabiliser
10	Phenoxyethanol	Preservative
11	Ethylhexylglycerin	Preservative booster / skin conditioning
12	*CI 42090 (Blue 1)*	Colourant (cool tint signalling "professional")
13	*Parfum (Fragrance)*	Fragrance (omitted in fragrance-free)
14	*Limonene, Linalool, Citronellol, Geraniol*	Fragrance allergens (declared at threshold — see Section 5)

Companion neutralizer — INCI summary (separate product)

#	INCI name	Function
1	Aqua (Water)	Solvent
2	Citric Acid	Acid — neutralises residual alkali
3	Lactic Acid	Acid / pH buffer
4	Glycerin	Humectant
5	Disodium EDTA	Chelating agent
6	Phenoxyethanol, Ethylhexylglycerin	Preservative system

Notes for labelling

- **Ordering** is representative of standard production; the exact descending-order list is issued for the locked formula of each order.
- **Potassium/Sodium Hydroxide** drive the corrosive classification — see Sections 3 (SDS) and 10 (pH & alkali concentration). They also appear on-pack as INCI.
- **EU fragrance allergens** present at or above the labelling threshold (0.001% leave-on) appear in the on-pack INCI list — see Section 5.
- **The gel and the neutralizer are formulated, filled and packed separately** and must never be combined into one INCI list or one container.
- **Preservative and colourant** sit within the target-market permitted lists (EU Annex V / IV; US permitted colour additives).

2. Technical Data Sheet (TDS)

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

1. Product description

A professional **high-pH alkaline callus-remover gel** for salon/spa pedicure. The gel is applied to calluses and hardened skin on the heel/sole, left on for a **limited contact time** to soften the keratin by alkaline hydrolysis, then the softened skin is removed mechanically (callus shaver / file / powered tool). The gel is supplied with a **companion acidic neutralizer** that must be applied afterwards to stop the reaction and return the skin to a safe pH. **For professional use only.**

2. Physical & chemical specification (typical)

Property	Specification	Method
Appearance	Clear to slightly hazy viscous gel	Visual
Colour	Tinted blue/green (or to brief)	Visual
Odour	Characteristic of fragrance dosed / faint alkaline	Olfactory
pH (as is, 25 °C)	**12.0 – 13.0 (strongly alkaline)** — see Section 10	pH meter (ISO 4316)
Alkali content (as KOH equiv.)	Representative working level — see Section 10	Acid–base titration
Viscosity (25 °C)	5,000 – 15,000 mPa·s	Brookfield RVT, sp.4 @ 20 rpm
Relative density (25 °C)	1.01 – 1.06 g/cm³	Pycnometer
Net content	To order (e.g. 100 / 250 / 500 mL)	—
Neutralizer pH (as is, 25 °C)	2.5 – 4.0 (acidic)	pH meter (ISO 4316)

> The high pH is intentional and is the basis of the product's softening action; it is also the basis of its corrosive classification (see Sections 3 and 10).

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
Pseudomonas aeruginosa	Absent in 1 g	ISO 22717
Staphylococcus aureus	Absent in 1 g	ISO 22718
Escherichia coli	Absent in 1 g	ISO 21150
Candida albicans	Absent in 1 g	ISO 18416

The high-pH gel is self-inhibitory to most microorganisms; a preservative system is nevertheless included for the water phase. Typical results and preservation performance are reported in Sections 7 and 8.

4. Packaging & primary material

- **Alkaline gel:** alkali-compatible HDPE/PP bottle with **child-resistant closure (CRC — standard, not optional)**, hazard label and directions; dispensing cap/brush as specified.
- **Neutralizer:** separate bottle, clearly distinguished from the gel; **never co-filled or co-stored in the same primary container.**
- Secondary: carton / professional kit (gel + neutralizer) to brief, with hazard warnings carried on the outer pack.

5. Storage, shelf life & usage

Item	Value
Storage	Cool, dry place, away from direct sunlight; 5 – 30 °C; keep tightly closed (alkali absorbs CO_2)
Shelf life	24 months unopened; PAO 12M
Directions	Professional use only. Apply thin layer to calluses; **do not exceed the stated contact time**; remove softened skin; **apply neutralizer**; rinse and dry.
Warnings	**Corrosive. Causes skin/eye damage on misuse.** External use only. Avoid normal skin, broken skin, eyes and mucous membranes. Keep out of reach of children. In case of eye/skin contact, rinse with plenty of water and seek medical advice. Do not mix with acids. See Section 3 (SDS) for full hazard/precautionary statements.

3. Safety Data Sheet (SDS)

Issued by: NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Callus Remover **Document:** Safety Data Sheet — GHS 16-section (representative — alkaline gel) | **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, EU CLP Regulation (EC) 1272/2008, and EU REACH Annex II). **This SDS covers the professional high-pH alkaline callus-remover gel, which is classified as corrosive.** The companion acidic neutralizer is a separate, lower-hazard product with its own SDS. Classification reflects the representative formula; a batch- or formula-specific SDS is reissued where the agreed formula differs. **This is the most safety-critical document in the dossier — read it before handling the product.**

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1. Identification — Product: Callus Remover — professional alkaline gel (potassium/sodium hydroxide system). Use: professional cosmetic, salon callus softening; for trained professional use only. Supplier: NailLegend (naillegend.com). Contact: Lareina. Emergency: contact supplier during business hours; in an emergency call a local poison-control/emergency number.

2. Hazard identification — - **GHS classification: Skin Corrosion Category 1 — H314 (Causes severe skin burns and eye damage); Serious Eye Damage Category 1 — H318.** (Final category and any sub-category — 1A/1B/1C — are assigned by the brand owner's classifier against the locked formula, pH and any available data.) - **Signal word: Danger.** - **Pictogram: GHS05 (corrosion).** - **Hazard statements:** H314 Causes severe skin burns and eye damage. - **Precautionary statements:** P260 Do not breathe mist/spray; P264 Wash thoroughly after handling; P280 Wear protective gloves/eye protection; **P301+P330+P331** IF SWALLOWED: rinse mouth, do NOT induce vomiting; **P303+P361+P353** IF ON SKIN: remove contaminated clothing, rinse skin with water; **P305+P351+P338** IF IN EYES: rinse cautiously with water for several minutes, remove contact lenses; **P310** Immediately call a POISON CENTER/doctor; P405 Store locked up; P501 Dispose of contents/container per local regulations.

3. Composition / information on ingredients — Mixture (cosmetic). Hazard-relevant components: **Potassium Hydroxide (CAS 1310-58-3)** — Skin Corr. 1A, Acute Tox. 4 (oral); **Sodium Hydroxide (CAS 1310-73-2)** — Skin Corr. 1A (where used). Present at the working alkali level that drives the corrosive classification (see Section 10). Other components (humectants, thickeners, preservatives) are within cosmetic use limits. Full composition: see Section 1 (INCI).

4. First-aid measures — - **Eyes:** Immediately rinse with plenty of water for **at least 15 minutes**, holding eyelids open; remove contact lenses if present; **seek medical attention immediately** — alkali eye contact can cause serious damage. - **Skin:** Remove contaminated clothing; rinse affected skin with plenty of water; if the gel was left on beyond contact time or applied to normal/broken skin, **apply the acidic neutralizer as directed and rinse, then seek medical advice** if burning/irritation persists. - **Ingestion:** Do NOT induce vomiting; rinse mouth with water; give water to drink if conscious; **seek medical attention immediately.** - **Inhalation:** Not a normal route; if mist is generated, move to fresh air.

5. Fire-fighting measures — Not flammable (water-based). Suitable extinguishing media: water spray, foam, CO_2, dry powder. No special fire hazard; product is corrosive — protect responders from contact.

6. Accidental release — Wear gloves and eye protection. Contain and absorb with inert material; the spill is corrosive and slippery. Neutralise residue cautiously with a dilute acid (e.g. citric/acetic) where safe to do so, then rinse. Avoid bulk release to drains.

7. Handling & storage — **For professional handling only.** Avoid contact with skin, eyes and mucous membranes; do not exceed stated contact time on skin. **Store separately from acids and from the neutralizer; never mix with acidic products** (vigorous exothermic reaction). Keep tightly closed (alkali absorbs atmospheric CO_2, drifting pH). Store cool, dry, upright, with child-resistant closure engaged; keep out of reach of children.

8. Exposure controls / PPE — Professional/consumer salon use: **wear protective gloves and avoid eye contact**; technicians should have eyewash access. Bulk handling (manufacturing): chemical-resistant gloves, eye/face protection, apron; control mist; no specific OEL assigned to the finished mixture, but KOH/NaOH dusts/mists have occupational limits in some jurisdictions.

9. Physical & chemical properties — Appearance, colour, viscosity, density: see Section 2 (TDS). **pH (as is): 12.0 – 13.0 (strongly alkaline)** — see Section 10. Flash point: not applicable (water-based). Solubility: miscible with water.

10. Stability & reactivity — Stable under recommended storage. **Reacts vigorously and exothermically with acids** — keep segregated from the neutralizer and all acidic products. Reacts with some metals (e.g. aluminium, zinc) — use alkali-compatible packaging only. Absorbs CO_2 from air. Hazardous decomposition products: none under normal use.

11. Toxicological information — **Corrosive to skin and eyes at the product pH.** Intended action is controlled softening of dead keratin under limited contact time followed by neutralization; misuse (overtime, application to normal/broken skin, eye contact) causes chemical burns. Not for use on damaged skin, mucous membranes, or by untrained users. Finished-product safety for the intended professional use is confirmed through the brand owner's CPSR.

12. Ecological information — High pH may be harmful to aquatic life in concentrated form; neutralise before disposal. No bioaccumulation expected. Avoid bulk discharge to the environment.

13. Disposal — Neutralise to near-neutral pH where safe, then dispose of contents and container in accordance with local regulations. Do not dispose of concentrated alkali to surface water.

14. Transport information — **The concentrated alkaline gel may meet the criteria for a corrosive substance.** Indicative: **UN 1760, Corrosive liquid, n.o.s. (contains potassium hydroxide), Class 8, PG II/III** depending on the finished concentration and pH. Final transport classification and any consumer-quantity / limited-quantity exemptions are confirmed by the shipper against the locked formula. The neutralizer is generally not dangerous goods.

15. Regulatory information — Cosmetic finished product placed under corrosive hazard rules. US: FDA cosmetic (MoCRA) + OSHA HazCom / GHS for the SDS and workplace label. EU: Regulation (EC) 1223/2009 (cosmetic) **and CLP Regulation (EC) 1272/2008** for physical-hazard labelling; child-resistant fastening and tactile warning of danger required for corrosive products per CLP. Ingredients comply with applicable cosmetic inventories for the declared markets.

16. Other information — Abbreviations: CRC child-resistant closure; OEL occupational exposure limit; PAO period after opening; PG packing group. **Unlike most cosmetics, an SDS and a CLP/GHS hazard label are central to lawful supply of this corrosive product** — this SDS is provided to support the brand owner's classification, labelling and logistics work and should accompany every shipment.

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4. Formulation Disclosure Statement

Issued by: NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Callus Remover **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 and the CLP/GHS hazard classification, while protecting NailLegend's specific know-how. Exact weight percentages of the locked formula — including the precise alkali level — are disclosed **confidentially to the named safety assessor / classifier under NDA**; this statement provides the functional framework and confirms each restricted ingredient sits within its permitted limit.

1. Functional composition framework — alkaline gel

Block	Function	Representative ingredients
Aqueous base	Reaction medium, humectancy	Aqua, Propylene Glycol, Glycerin
Alkali active	Keratin softening, high pH	**Potassium Hydroxide (and/or Sodium Hydroxide)**
Rheology	Viscosity, cling, controlled dwell	Carbomer (alkali-stable), Hydroxyethylcellulose
Soothing / conditioning	Mitigate harshness, skin feel	Aloe Barbadensis Leaf Juice, Glycerin
Stabiliser / chelant	System stability	Disodium EDTA
Preservation	Microbiological safety of water phase	Phenoxyethanol, Ethylhexylglycerin
Sensory	Tint / fragrance	CI colourant (or none), Parfum (or none)

2. Companion neutralizer — functional framework

Block	Function	Representative ingredients
Aqueous base	Carrier	Aqua, Glycerin
Acid active	Neutralise residual alkali, restore safe pH	Citric Acid, Lactic Acid
Preservation	Microbiological safety	Phenoxyethanol, Ethylhexylglycerin

3. Restricted / hazard-relevant ingredient confirmation

Ingredient (class)	Permitted / classification basis	This product
Potassium / Sodium Hydroxide (alkali)	Permitted in cosmetics as pH adjuster; at high level the finished product is **corrosive (Skin Corr. 1, H314)** and labelled per CLP/GHS	Used at the working level that gives pH 12.0–13.0 (see Section 10)
Phenoxyethanol (preservative)	EU Annex V / target-market list — ≤ 1.0%	Used at ≤ 1.0%
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 5 & 6
Disodium EDTA (chelant)	Standard cosmetic use	≤ 0.2%
Citric / Lactic acid (neutralizer)	Standard cosmetic use	Neutralizer only

4. What is and is not disclosed

- **Disclosed openly:** the functional framework, the corrosive nature of the alkaline gel, restricted-ingredient identities, and confirmation each is within its permitted limit.
- **Disclosed under NDA to the safety assessor / classifier only:** exact weight percentages of the locked formula (including precise alkali %), supplier identities, and process parameters.
- **Not disclosed:** proprietary process know-how unrelated to safety assessment or classification.

5. 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, that the alkaline gel is a corrosive preparation requiring CLP/GHS hazard labelling and child-resistant packaging, that the neutralizer is supplied as part of the system, and that supporting analytical data (pH/alkali, preservative efficacy, microbiological, stability) is provided in this dossier.

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5. Fragrance Allergen Declaration

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

> Basis: EU Regulation (EC) 1223/2009. As a **leave-on** product (the gel dwells on skin during use), allergens present at **≥ 0.001% (10 ppm)** must be named in the on-pack INCI list. The table below shows a representative fresh/cooling-type fragrance dosed at 0.3% in the alkaline gel. 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. Fragrance choice must be confirmed stable in the high-pH base.)

Allergen content (representative — fresh/cooling-type fragrance @ 0.3%)

#	Allergen (INCI)	CAS	Present	% in product	On-pack declaration
1	Limonene	5989-27-5	Yes	0.0120	Required
2	Linalool	78-70-6	Yes	0.0090	Required
3	Citronellol	106-22-9	Yes	0.0028	Required
4	Geraniol	106-24-1	Yes	0.0019	Required
5	Citral	5392-40-5	Yes	0.0012	Required
6	Coumarin	91-64-5	Yes	0.0010	Required (at threshold)
7	Other terpenes (trace)	—	Trace	< 0.0010	Not required (below threshold)
—	Eugenol, Isoeugenol, Cinnamal, Benzyl Benzoate, Benzyl Salicylate, Hexyl Cinnamal, Amyl Cinnamal, Farnesol, Benzyl Alcohol, others	various	No / trace	< 0.0010	Not required

On-pack declaration required for this fragrance: *Limonene, Linalool, Citronellol, Geraniol, Citral, Coumarin.*

Declaration

For the fragrance dosed in this product, the allergens marked "Required" 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, and the fragrance is confirmed compatible with the high-pH base.

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6. IFRA Conformity Statement

Issued by: NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Callus Remover **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	Callus Remover — professional alkaline gel (leave-on, applied to feet)
IFRA product category	Category 5A (body lotion / leave-on hand & body)
Fragrance dosage in finished product	0.3% (representative; to brief)
IFRA Standards edition	51st Amendment

2. Conformity statement

The fragrance compound used at **0.3%** in this callus-remover gel 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. The fragrance is additionally confirmed by the supplier to be stable in the high-pH (alkaline) base.

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 5.

4. Authorisation

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

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7. Preservative Efficacy (Challenge) Test

Issued by: NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Callus Remover **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 alkaline gel, issued by NailLegend in-house QC. The high pH of the product itself contributes substantial microbial inhibition; a preservative system supports the water phase. A batch-specific challenge-test certificate is issued for production batches on request.

1. Test organisms (ISO 11930)

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

Incubation: 22.5 ± 2.5 °C. Reference product: representative alkaline gel formula (high-pH base + Phenoxyethanol/Ethylhexylglycerin system).

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

Organism	T0 (cfu/g)	Day 7	Day 14	Day 28	Criterion A
P. aeruginosa	1.1×10^6	> 3.0	> 3.0	No increase	≥3 (D7), ≥3 (D14), n.i. (D28)
S. aureus	1.0×10^6	> 3.0	> 3.0	No increase	≥3 (D7), ≥3 (D14), n.i. (D28)
E. coli	1.2×10^6	> 3.0	> 3.0	No increase	≥3 (D7), ≥3 (D14), n.i. (D28)
C. albicans	1.3×10^5	≥ 1.0	≥ 1.0	No increase	≥1 (D7), ≥1 (D14), n.i. (D28)
A. brasiliensis	1.2×10^5	≥ 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 combination of the product's high pH and its preservative system provides adequate antimicrobial protection over the intended product life under the conditions tested. Performance is reconfirmed per production batch.

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8. Microbiological Test Report

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

> Finished-product microbiological data for this water-containing alkaline 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.
>
> Reference batch (example): **CR-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
Pseudomonas aeruginosa	ISO 22717	Absent / 1 g	Absent	Pass
Staphylococcus aureus	ISO 22718	Absent / 1 g	Absent	Pass
Escherichia coli	ISO 21150	Absent / 1 g	Absent	Pass
Candida albicans	ISO 18416	Absent / 1 g	Absent	Pass

Sample condition: appearance and odour normal; gel clear/tinted; no visible contamination. **Overall result: PASS** — representative production conforms to specification. The high product pH is itself self-inhibitory; each production batch is released against the same limits with a batch certificate.

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9. Stability Test Report

Issued by: NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Callus Remover **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 (alkali-compatible HDPE/PP bottle with child-resistant closure). For a high-pH alkaline gel the key stability risks are **pH drift from CO_2 absorption, thinning of the carbomer/cellulose rheology at extreme pH, colour fade and fragrance shift in the alkaline base, and packaging compatibility with the alkali.** Results are **typical of NailLegend standard production**, issued by NailLegend in-house QC. Batch-specific stability is monitored under the ongoing programme.

Reference batch (example): **CR-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: alkali-compatible HDPE/PP bottle with child-resistant closure; seal integrity included.

2. Parameters & results (typical)

Parameter	Acceptance	T0	Accel. 3 mo	Real-time 12 mo	Pass/Fail
Appearance (no separation/leak)	Conforms	Conforms	Conforms	Conforms	Pass
Colour	Within range	Pass	Slight fade — within range	No significant change	Pass
Odour	No off-note	Pass	Pass	Pass	Pass
pH	Target ± 0.5 (closed pack)	12.6	12.4	12.4	Pass
Alkali assay (as KOH equiv.)	≥ 90% of label	100%	97%	96%	Pass
Viscosity	Spec ± 15%	9,500 mPa·s	within	within	Pass
Closure / CRC function & seal	No leak; CRC operates	Pass	Pass	Pass	Pass
Packaging compatibility (no swell/stress)	Conforms	Conforms	Conforms	Conforms	Pass
Microbial (end of study)	Section 8 limits	Pass	—	Pass	Pass

3. Conclusion

Based on accelerated and real-time data, with the pack kept tightly closed to limit CO_2-driven pH drift, the assigned shelf life is **24 months** (PAO 12M). Real-time study to 24 months is ongoing and confirms stability to date. Overall result: **PASS (real-time ongoing).**

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10. pH & Alkali Concentration Data

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> Applies to the professional **high-pH alkaline gel**. pH and alkali concentration are the **defining parameters of this product**: they drive both efficacy (alkaline keratin hydrolysis) and hazard (skin/eye corrosivity), and they are the basis of the corrosive CLP/GHS classification, the child-resistant-packaging requirement, the limited contact time and the mandatory neutralization step. Values are **typical of NailLegend standard production**, issued by NailLegend in-house QC; batch-specific values are confirmed per production. **This section is read together with the SDS (Section 3) and is one of the two most important documents in the dossier.**

1. pH (alkaline gel and neutralizer)

Product	pH (as is, 25 °C)	Method
Alkaline callus-remover gel	**12.0 – 13.0 (strongly alkaline)**	pH meter, ISO 4316
Companion neutralizer	2.5 – 4.0 (acidic)	pH meter, ISO 4316
Skin after neutralization & rinse (target)	~5.5 – 7.0 (near skin pH)	pH strip / meter, in-use check

2. Alkali identity & concentration (typical — alkaline gel)

Alkali	Role	CAS	Total conc. (typical)	Basis of measure	Method
Potassium Hydroxide	Primary keratin-softening alkali	1310-58-3	~2 – 4% (representative working level)	Free + combined alkali as KOH equiv.	Acid–base titration
Sodium Hydroxide	Co-/alternative alkali (some formulas)	1310-73-2	line-dependent	As KOH equiv.	Acid–base titration
Total alkalinity (as KOH)	Working alkali load	—	reported per batch	Titration to endpoint	Acid–base titration

(Exact alkali percentage is locked-formula know-how, disclosed under NDA to the brand owner's safety assessor / classifier — see Section 4. Representative ranges are shown to illustrate the order of magnitude.)

3. Corrosivity classification — basis

Driver	Reading	Consequence
Product pH	≥ 12.0 (with high alkaline reserve / buffering)	Treated as **corrosive to skin and eyes** under CLP/GHS extreme-pH rules
GHS classification	**Skin Corr. 1 — H314; Eye Dam. 1 — H318**	Pictogram **GHS05**, signal word **Danger** (see Section 3)
Alkaline reserve	High (the gel resists dilution-driven pH drop)	Reinforces corrosive classification beyond pH alone

Under CLP/GHS, a mixture with pH ≤ 2 or ≥ 11.5 is normally treated as corrosive to skin/eyes unless other data show otherwise; the high **alkaline reserve** of this product supports the corrosive classification. Final classification (and any 1A/1B/1C sub-category) is assigned by the brand owner's classifier against the locked formula.

4. Safe-use parameters (contact time & neutralization)

Parameter	Representative basis	On-pack / professional instruction
Maximum contact time	Short, formula-specific (typically a few minutes)	**Stated on pack; must not be exceeded** — overtime causes chemical burns
Neutralization	Acidic neutralizer applied after the gel	**Mandatory step — not optional**; stops the reaction and restores safe skin pH
Application site	Calluses / hardened skin only	**Avoid normal skin, broken skin, eyes, mucous membranes**
User	Trained professional	**For professional use only**; not for untrained / consumer use

5. Compliance flags

Market / area	Requirement	This product
US (OSHA HazCom / GHS)	SDS + workplace hazard label for a corrosive; cosmetic claims kept non-drug	SDS provided (Section 3); corrosive label elements; "softens/removes calluses" claims
EU (CLP 1272/2008)	Corrosive labelling (GHS05/Danger/H314), **child-resistant fastening + tactile danger warning**	Corrosive labelling supported; CRC packaging standard
EU / US packaging	Child-resistant closure for corrosive product	**CRC standard, not optional** (see Sections 2 & 9)
Transport	Possible dangerous-goods (Class 8) classification	Confirmed by shipper per concentration/pH (see SDS Section 14)
Professional vs retail	Labelling must match channel; professional-only warnings	Labelled "For professional use only"; contact-time & neutralization stated

6. Statement

Measured pH, alkalinity and the basis of corrosive classification typical of standard production are recorded above. The brand owner's safety assessor / classifier uses these in the CPSR, the CLP/GHS classification and labelling (corrosive elements, contact-time and neutralization instructions, child-resistant packaging) for each target market; batch-specific values are provided with shipment. **The alkaline gel and the acidic neutralizer are always kept separate and must never be mixed or co-stored.**

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