

NAILLEGEND

Cuticle Softener

Compliance & Technical Dossier

Gentle Softener · Professional Alkaline Remover | Liquid & Gel Forms

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0. Dossier Overview & Legal Notice

Issued by: NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cuticle Softener **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 **Cuticle Softener & Remover** category (gentle **softener** line and professional alkaline **remover** line; liquid and gel forms). 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.

Product nature (read first)

This category is a **water-based, alkaline** product applied to the cuticle (the keratin skin around the nail) to **soften or hydrolyse dead skin** so it can be pushed back or wiped away. The **softener** line works at a milder alkalinity (often with humectants and low-level AHA / urea, gentle, more forgiving on contact time). The **remover** line uses a higher alkalinity (potassium / sodium hydroxide) for fast keratin hydrolysis and is therefore a **time-limited contact** product. Alkalinity (pH), alkali concentration and contact time are the core safety variables for this category and are reported in Section 10.

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 cuticle softener / remover claiming **softens cuticles, conditions dead skin, makes the cuticle easier to push back or remove** is a **cosmetic**. Wording such as "*treats nail infection,*" "*cures,*" "*antifungal,*" or "*medical*" reclassifies the product as a **drug** and triggers separate regulation. Keep claims cosmetic — "*softens and helps remove cuticles,*" not "*treats / cures nail disease.*" Because the remover line is alkaline, an **irritation / time-limited use warning** is part of compliant labelling.

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, 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:** Cuticle Softener **Document:** INCI Ingredient List (representative — alkaline softener / remover base) | **Issue date:** 2026-06-22 | **Version:** 1.0

The list below is the representative INCI composition for the Cuticle Softener & Remover. 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 (gentle softener / professional alkaline remover / gel / fragranced variants).

INCI declaration (descending order)

#	INCI name	Function
1	Aqua (Water)	Solvent / base
2	Glycerin	Humectant / reduces alkali harshness
3	Propylene Glycol	Humectant / solvent
4	<i>Potassium Hydroxide</i>	Alkali — keratin softening / hydrolysis (remover line)
5	<i>Sodium Hydroxide</i>	Alkali / pH adjuster (remover line)
6	<i>Triethanolamine</i>	Milder alkali / pH adjuster (softener line)
7	<i>Urea</i>	Keratin softener / humectant (softener line)
8	<i>Lactic Acid</i>	Mild keratolytic — AHA / pH adjuster (softener line)
9	Panthenol	Soothing / conditioning
10	Allantoin	Soothing
11	Aloe Barbadensis Leaf Juice	Soothing / conditioning
12	<i>Xanthan Gum</i>	Thickener / rheology (gel form)
13	<i>Carbomer</i>	Thickener / rheology (gel form)
14	Tocopherol	Antioxidant / conditioning
15	Disodium EDTA	Chelating agent
16	Phenoxyethanol	Preservative
17	Ethylhexylglycerin	Preservative booster / skin conditioning
18	<i>Parfum (Fragrance)</i>	Fragrance (omitted in fragrance-free variant)
19	<i>CI 42090 / colourant</i>	Colourant (omitted in clear / professional variant)
20	<i>Limonene, Linalool, Citronellol, Geraniol</i>	Fragrance allergens (declared at threshold — see Section 5)

Notes for labelling

- **Ordering** is representative of standard production; the exact descending-order list is issued for the locked formula of each order.
- **Alkali content** (KOH / NaOH / TEA), free-alkali concentration and pH are reported in Section 10 and drive the **irritation / time-limited contact** warning required for the remover line.
- **EU fragrance allergens** present at or above the labelling threshold (0.001% leave-on basis) appear in the on-pack INCI list — see Section 5.
- **Preservative, colourant and any conditioning agent** 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:** Cuticle Softener **Document:** Technical Data Sheet (representative specification) | **Issue date:** 2026-06-22 | **Version:** 1.0

1. Product description

A water-based, **alkaline** manicure product applied to the cuticle to soften or hydrolyse dead skin so it can be pushed back or wiped away. Two lines are offered: a milder **softener** (gentle, more forgiving on contact time) and a stronger alkaline **remover** (faster acting, **time-limited contact**). Two forms: free-flowing **liquid** (dropper / brush application) and **gel** (thickened, stays in place for controlled contact, salon-preferred).

2. Physical & chemical specification (typical)

Property	Specification	Method
Appearance	Clear to slightly hazy liquid / clear viscous gel	Visual
Odour	Characteristic of fragrance dosed / odourless (fragrance-free)	Olfactory
Colour	Clear / colourless (professional) or tinted to brief	Visual
pH (as is, 25 °C)	9.0 – 10.5 (softener); 11.0 – 12.5 (remover) — see Section 10	pH meter (ISO 4316)
Viscosity (25 °C)	1 – 50 mPa·s (liquid); 2,000 – 8,000 mPa·s (gel)	Brookfield RVT
Relative density (25 °C)	1.00 – 1.05 g/cm ³	Pycnometer
Free alkali (as KOH)	Reported by line — see Section 10	Titration
Net content	To order (e.g. 15 / 30 mL retail; 120 / 480 mL salon)	—

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 7 and 8. The high-pH remover line is largely self-preserving but is preserved and tested to the same limits.

4. Packaging & primary material

- **Liquid:** dropper bottle / brush-cap bottle for precise application. **Alkali-resistant** primary material and closure (standard, not optional).
- **Gel:** tube / pump bottle / brush-cap jar; **alkali-resistant** material.
- Secondary: carton / multi-pack / gift box (e.g. paired with cuticle pusher / cuticle oil) to brief.

5. Storage, shelf life & usage

Item	Value
Storage	Cool, dry place, away from direct sunlight; 5 – 30 °C
Shelf life	24 months unopened; PAO 12M
Directions	Apply a small amount to the cuticle, leave to act, then push back / wipe away and rinse hands. Remover line: do not exceed the stated contact time (see Section 10).
Warnings	External use only. Alkaline product — avoid eyes, broken or irritated skin. If stinging or whitening of the skin occurs, wipe off and rinse immediately. Keep away from children. Do not leave on longer than directed (remover).

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:** Cuticle Softener **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. Because this is an **alkaline** product, classification depends on the line — the softener line is mild, while the higher-pH remover line carries skin/eye irritation precautions. Batch- or formula-specific SDS is reissued where the agreed formula differs.

1. Identification — Product: Cuticle Softener / Cuticle Remover. Use: cosmetic, external nail / cuticle care. Supplier: NailLegend (naillegend.com). Contact: Lareina. Emergency: contact supplier during business hours.

2. Hazard identification — GHS classification: Softener line — generally not classified as hazardous. Remover line (high pH, KOH/NaOH) — Skin Irrit. 2 (H315) / Eye Irrit. 2 (H319), depending on free-alkali content and pH. Signal word: None (softener) / Warning (remover). Precautionary statements (remover line): P264, P280, P302+P352, P305+P351+P338, P337+P313. On-pack consumer warning covers time-limited contact and avoidance of eyes / broken skin.

3. Composition / information on ingredients — Mixture (cosmetic). Components of note: Potassium Hydroxide (CAS 1310-58-3), Sodium Hydroxide (CAS 1310-73-2), Triethanolamine (CAS 102-71-6), Urea (CAS 57-13-6), Phenoxyethanol (CAS 122-99-6) — present only in the relevant lines and within cosmetic use conditions. Full composition: see Section 1 (INCI).

4. First-aid measures — Eyes: rinse with water for several minutes; remove contact lenses; seek medical advice (alkaline). Skin: wipe off and rinse with plenty of water; if irritation persists, seek advice. Ingestion: rinse mouth, do not induce vomiting, seek advice. Inhalation: not a normal route of exposure.

5. Fire-fighting measures — Not flammable (water-based). Suitable extinguishing media: water spray, foam, CO₂, dry powder.

6. Accidental release — Wipe up; product is water-based and slippery — avoid slip hazard. Neutralise / dilute alkaline spill with plenty of water. Avoid bulk release to drains.

7. Handling & storage — Handle per good hygiene practice; avoid eye and prolonged skin contact (remover). Store cool, dry, out of direct sunlight in **alkali-resistant** packaging; keep closed until use.

8. Exposure controls / PPE — Consumer use: no PPE required; follow on-pack contact-time directions. Bulk handling (manufacturing): gloves and eye protection for high-pH concentrates; no specific occupational exposure limit assigned to the finished mixture.

9. Physical & chemical properties — Appearance, odour, pH, density and viscosity: see Section 2 (TDS). Alkaline (pH 9 – 12.5 by line). Flash point: not applicable (water-based). Solubility: miscible with water.

10. Stability & reactivity — Stable under recommended storage. Incompatibilities: strong acids (exothermic neutralisation); reactive with aluminium and some metals (alkaline) — select compatible

packaging. Hazardous decomposition products: none under normal use.

11. Toxicological information — Finished cosmetic confirmed safe for normal, directed use through the brand owner's CPSR. The alkaline remover line may be irritating to eyes, broken or sensitive skin; not for use on damaged skin and not to be left on beyond the stated contact time.

12. Ecological information — No significant adverse effects expected in normal consumer use. Avoid bulk discharge of concentrated alkaline product to the environment.

13. Disposal — Dispose of contents and container in accordance with local regulations.

14. Transport information — Finished cosmetic in retail packaging: not classified as dangerous goods for transport. UN number: none. (Bulk high-pH concentrate may require separate classification — assessed per shipment.)

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.

16. Other information — Abbreviations: KOH potassium hydroxide; AHA alpha-hydroxy acid; 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. Formulation Disclosure Statement

Issued by: NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cuticle Softener **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 — including the target alkali concentration and pH, which are the core know-how of this category — 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
Aqueous base	Carrier, humectancy	Aqua, Glycerin, Propylene Glycol
Alkali / softening system (line-dependent)	Soften / hydrolyse cuticle keratin	Potassium Hydroxide, Sodium Hydroxide (remover); Triethanolamine, Urea, Lactic Acid (softener)
pH system	Set safe & effective alkalinity	KOH / NaOH / TEA
Soothing / conditioning	Reduce alkali harshness	Panthenol, Allantoin, Aloe, Tocopherol
Rheology	Viscosity, cling (gel)	Xanthan Gum, Carbomer
Preservation	Microbiological safety	Phenoxyethanol, Ethylhexylglycerin, Disodium EDTA
Sensory	Fragrance / colour	Parfum (or none), colourant (or none)

2. Restricted-ingredient confirmation

Ingredient (class)	Permitted basis	This product
Potassium / Sodium Hydroxide (alkali)	Permitted to adjust pH; finished-product pH and contact time controlled for safe cuticle use	Within controlled pH / free-alkali range — see Section 10
Triethanolamine (alkali)	Permitted cosmetic use; secondary-amine controls observed	Used as pH adjuster, softener line
Urea (keratin softener)	Standard cosmetic use level	≤ 10%
Lactic Acid (AHA, softener)	Within accepted cosmetic concentration	≤ 3% (as pH adjuster / mild keratolytic)
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%

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 target alkali concentration and pH), supplier identities, and process parameters.
- **Not disclosed:** proprietary process know-how unrelated to safety assessment.

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, that the alkalinity is controlled to a safe and effective level for the intended contact time, and that supporting analytical data (pH/alkali, preservative efficacy, microbiological, stability) is provided in this dossier.

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NailLegend · naillegend.com — Functional disclosure for safety-assessment support; exact percentages under NDA. Confidential — for the intended recipient only.

5. Fragrance Allergen Declaration

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

Basis: EU Regulation (EC) 1223/2009. As a leave-on-then-rinse cuticle product, allergens present at \geq **0.001% (10 ppm)** are named in the on-pack INCI list on the leave-on basis. The table below shows a representative light fragrance dosed at 0.2% (fragrance use is kept low in this category because alkaline conditions can affect scent and to limit skin exposure). Content is reconfirmed by the fragrance supplier for the specific fragrance of each order; a **fragrance-free / professional** 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 — light fragrance @ 0.2%)

#	Allergen (INCI)	CAS	Present	% in product	On-pack declaration
1	Linalool	78-70-6	Yes	0.0090	Required
2	Limonene	5989-27-5	Yes	0.0045	Required
3	Citronellol	106-22-9	Yes	0.0021	Required
4	Geraniol	106-24-1	Yes	0.0016	Required
5	Coumarin	91-64-5	Yes	0.0011	Required
6	Citral	5392-40-5	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: *Linalool, Limonene, Citronellol, Geraniol, 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 / professional** 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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6. IFRA Conformity Statement

Issued by: NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cuticle Softener **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 / professional** variant requires no IFRA statement.

1. Product use category

Item	Value
Product type	Cuticle Softener / Remover (applied to the cuticle, then pushed back / wiped / rinsed)
IFRA product category	Category 9 (rinse-off / brief skin contact, hand products) — confirmed with supplier for the use scenario
Fragrance dosage in finished product	0.2% (representative; to brief)
IFRA Standards edition	51st Amendment

2. Conformity statement

The fragrance compound used at **0.2%** in this Cuticle Softener / Remover 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 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:** Cuticle Softener **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. The high-pH remover line is largely self-preserving (alkalinity inhibits growth) but is still preserved and challenge-tested to the same criteria. A batch-specific challenge-test certificate is issued for production batches on request.

1. Test organisms (ISO 11930)

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

Incubation: 22.5 ± 2.5 °C. Reference product: representative production formula (Phenoxyethanol/Ethylhexylglycerin system; alkaline base).

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

Organism	T0 (cfu/g)	Day 7	Day 14	Day 28	Criterion A
<i>P. aeruginosa</i>	1.1×10 ⁶	> 3.0	> 3.0	No increase	≥3 (D7), ≥3 (D14), n.i. (D28)
<i>S. aureus</i>	1.0×10 ⁶	> 3.0	> 3.0	No increase	≥3 (D7), ≥3 (D14), n.i. (D28)
<i>E. coli</i>	1.2×10 ⁶	> 3.0	> 3.0	No increase	≥3 (D7), ≥3 (D14), n.i. (D28)
<i>C. albicans</i>	1.3×10 ⁵	≥ 1.0	≥ 1.0	No increase	≥1 (D7), ≥1 (D14), n.i. (D28)
<i>A. brasiliensis</i>	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 preservative system, supported by the alkaline base, 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:** Cuticle Softener **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.

Reference batch (example): **CSR-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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9. Stability Test Report

Issued by: NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cuticle Softener **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-resistant dropper / brush bottle for liquid; tube / pump for gel). Particular attention is paid to **pH / free-alkali drift** and to **alkali-packaging compatibility**, which govern both efficacy and safety for this category. 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): **CSR-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-resistant brush/dropper bottle (liquid) / PP tube (gel).

2. Parameters & results (typical — remover line)

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	No significant change	No significant change	Pass
Odour	No off-note	Pass	Pass	Pass	Pass
pH	Target ± 0.5	11.8	11.6	11.6	Pass
Free alkali (as KOH)	Spec ± 10%	within	within	within	Pass
Viscosity (gel)	Spec ± 15%	4,500 mPa·s	within	within	Pass
Packaging compatibility (no corrosion / deformation)	No change	Pass	Pass	Pass	Pass
Microbial (end of study)	Section 8 limits	Pass	—	Pass	Pass

3. Conclusion

Based on accelerated and real-time data, the assigned shelf life is **24 months** unopened (PAO 12M). pH and free-alkali remain within range and the alkali-resistant packaging shows no corrosion or deformation. 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

Issued by: NailLegend · naillegend.com | **Contact:** Lareina | **Product:** Cuticle Softener **Document:** pH, Alkali Concentration & Contact-Time Data — representative | **Issue date:** 2026-06-22 | **Version:** 1.0

This is the **core safety data sheet** for the category. Cuticle softeners / removers work by alkaline softening or hydrolysis of cuticle keratin; **pH, free-alkali concentration and contact time** together drive both efficacy and the risk of skin irritation, and they underpin the on-pack warning. Values are **typical of NailLegend standard production**, issued by NailLegend in-house QC; batch-specific values are confirmed per production. Permitted conditions are verified against current target-market regulations for each order.

1. pH (by line)

Line	pH (as is, 25 °C)	Character	Method
Softener (gentle)	9.0 – 10.5	Mild alkalinity; softens, more forgiving on contact time	pH meter, ISO 4316
Remover (professional)	11.0 – 12.5	Stronger alkalinity; hydrolyses dead skin fast; time-limited contact	pH meter, ISO 4316

2. Alkali identity & concentration (typical)

Alkali	Role	CAS	Line	Free alkali (as KOH, typical)	Method
Potassium Hydroxide	Primary keratin hydrolysis	1310-58-3	Remover	~1.5 – 3.0%	Titration
Sodium Hydroxide	pH adjuster / alkali	1310-73-2	Remover	included in free-alkali total	Titration
Triethanolamine	Mild alkali / pH adjuster	102-71-6	Softener	lower, milder system	Titration / pH
Urea + Lactic Acid	Keratin softening (non-strong-alkali route)	57-13-6 / 50-21-5	Softener	n/a (mild route)	—

(Exact alkali source, free-alkali level and target pH are formula know-how, disclosed to the safety assessor under NDA and confirmed per order.)

3. Contact time (safe-use control – category-specific)

Line	Recommended contact time	On-pack instruction
Softener	Up to a few minutes; lower risk if slightly exceeded	"Leave to soften, then push back / wipe away."
Remover	Short, time-limited (typically under a few minutes)	"Do not leave on longer than directed. Wipe off and rinse. Avoid eyes and broken skin."

Contact time is a **safety-critical variable** for the remover line: over-exposure can cause stinging, whitening or irritation of the skin around the nail. The maximum contact time and warning wording are set with the brand owner for the locked formula.

4. Compliance flags

Market	Requirement	This product
US (FDA)	Cosmetic claims only ("softens / helps remove cuticles"); irritation / external-use warning for alkaline product	Cosmetic wording; alkaline-use warning on pack
EU (EC 1223/2009)	pH / alkalinity and warnings assessed in CPSR; on-pack precautions per CLP-style labelling for alkaline products	Within assessed conditions; warning + contact time on pack
Both	Contact-time and "avoid eyes / broken skin" warning are part of safe use	Stated on pack; do not exceed

5. Statement

Measured pH, free-alkali values and the contact-time control typical of standard production are recorded above. The brand owner's safety assessor uses these in the CPSR and to confirm labelling (including the alkaline-irritation and contact-time warnings) for each target market; batch-specific values are provided with shipment.

Issued by: **NailLegend – Quality Control (in-house)** · naillegend.com · 2026-06-22

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