RISK ANALYSIS IN SOAPMAKING

*From raw-material **receipt** to the sale of the soap*

Identify failures - assess consequences - prevent - control - correct

Apisara technical and educational **guide** for artisans, professionals, trainers and **learn**ers.

Purpose. This **guide** provides a practical risk-analysis method covering the complete soapmaking flow: **receipt**, **storage**, **formulation**, **weighing**, alkaline solution, **manufacture**, **curing**, **control**, **packaging**, batch **release**, storage, sale, complaints and withdrawal/recall.

Important: the method draws on risk-**control** principles, Good Manufacturing Practices and tools inspired by FMEA/HACCP, but **it is neither a regulatory HACCP plan nor ISO 22716 certification**. It must be adapted to the company, product, country and applicable rules.

Apisara resources

In addition to the saponification calculator, technical **guide**s and reference sheets are available at apisara.org. Complementary educational articles are also published on Substack and Facebook.

Reading guide

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1. Why analyse risks?

A non-conformity does not arise only during saponification. It may be introduced when an oil is ordered or received, during **weighing**, after a fragrance-lot change, during labelling or even at dispatch. A process approach therefore aims to **prevent** an error from moving silently through the system until it reaches the **customer.**

- **Prevent** foreseeable errors rather than relying on final inspection.
- **Detect** deviations as early as possible.
- **Decide** in a documented way: accept, **quarantine**, reprocess when justified and permitted, reject or destroy.
- **Learn** from non-conformities to improve procedures, training and **control**s.

2. A chain of control, not a collection of checks

Control is a coherent sequence: **specification → receipt → identification → storage → manufacture** → control → **release → distribution → post-market monitoring.** If the identity of a raw material is uncertain, excellent final inspection cannot reconstruct lost traceability.

> **Fundamental principle:** a doubtful batch must not continue simply because no visible defect has been observed.

3. Practical vocabulary

Term	Practical definition
Hazard	Potential source of harm: chemical, physical, microbiological, regulatory or organisational.
Risk	Combination of consequence severity and the possibility of occurrence. This guide uses a simplified ranking method.
Non-conformity	Departure from a specification, procedure, approved dossier or applicable requirement.
Quarantine	Status preventing use or sale until a documented decision is made.
Release	Decision authorising use of a material or availability of a finished batch.
Corrective action	Action addressing the cause of a detected non-conformity to prevent recurrence.

4. Proposed scoring method

For training and internal management, Apisara proposes a simple three-factor **score**. It is not a universal regulatory requirement and may be adapted.

S - Severity

Score	Guide
1	Negligible impact; no expected effect on safety, compliance or function.
2	Minor defect, readily corrected before release.
3	Significant non-conformity; batch may be unusable or complaint likely.
4	Serious quality, compliance or user risk;

Score	Guide
	withdrawal may be required.
5	Potentially serious health/safety consequence or major non-conformity.

P - Probability of occurrence

Score	Guide
1	Very unlikely in the current system.
2	Rare.
3	Possible.
4	Frequent.
5	Very frequent or already recurrent.

D - Difficulty of detection before release/sale

Score	Guide
1	Almost always detected by a systematic control.
2	Good probability of detection.
3	Uncertain detection.
4	Difficult to detect before use.
5	Very difficult or impossible to detect with current controls.

> **Internal Risk Priority Number: RPN = S × P × D.** A higher value indicates a stronger need for prioritised **action**. A severity-5 hazard may nevertheless require immediate action even when its total RPN is not the highest.

> Illustrative internal thresholds: 1-20 = monitor; 21-40 = improve; 41-75 = **priority action**; >75 = urgent action. **These thresholds are educational and must be validated by the organisation.**

5. Receipt of oils, butters and fats

Failure: Wrong material delivered

Possible consequence: Incorrect formula, properties and alkali calculation

Prevention / control: Compare order, label, reference, lot and supplier documents

Decision / action: Quarantine; do not use until identity is certain

Failure: Lot or internal shelf-life data not recorded

Possible consequence: Incomplete traceability

Prevention / control: Record supplier, lot, date, quantity, condition and associated documents

Decision / action: Hold documentary acceptance until resolved

Failure: Oxidised oil / abnormal odour

Possible consequence: Instability, odour, accelerated rancidity

Prevention / control: Organoleptic check + supplier criteria; analysis where necessary

Decision / action: Quarantine, investigate, reject if out of specification

Failure: Damaged or contaminated pack

Possible consequence: Contamination or deterioration

Prevention / control: Systematic visual inspection

Decision / action: Isolate container; assess integrity and contamination

Failure: Unsuitable transport temperature

Possible consequence: Possible deterioration of sensitive materials

Prevention / control: Transport specifications appropriate to material

Decision / action: Document deviation and assess before acceptance

> Visual conformity alone does not always establish identity or quality. For critical materials, acceptance should rely on **specification**s and documentation appropriate to the risk.

6. Receipt of sodium hydroxide, potassium hydroxide and other critical materials

Failure: NaOH / KOH confusion

Risk: Major calculation and product error

Control: Clear identification, dedicated locations, cross-check before weighing

Failure: Purity differs from calculation assumption

Risk: Actual alkali excess or deficit

Control: Supplier specification / batch documentation where relevant; controlled purity parameter

Failure: Hygroscopic material poorly sealed

Risk: Absorption of water/CO2 changes effective composition

Control: Airtight storage, limited opening time, container monitoring

Failure: Damaged/incompatible packaging

Risk: Leak, exposure or contamination

Control: Inspection on receipt; secure storage according to SDS

Failure: Unreadable identification

Risk: Critical mix-up risk

Control: Immediate quarantine; never identify a hazardous chemical by appearance

7. Fragrances, essential oils, colourants and additives

Risk: Wrong fragrance reference

Typical cause: Similar bottles / poor storage

Prevention: Internal code + name + lot + identified location

Action: Hold manufactured batch if identity uncertain

Risk: Excess dose

Typical cause: Decimal error, unsuitable balance, transcription

Prevention: Approved limit + suitable balance + targeted double-check

Action: Isolate batch; assess before decision

Risk: Supplier composition/allergen data changed

Typical cause: Document version change

Prevention: Version control and revalidation after relevant change

Action: Suspend manufacture/labelling pending assessment

Risk: Colourant unsuitable for intended use

Typical cause: Choice based only on colour

Prevention: Use specification and supplier compliance evidence

Action: Replace; do not release without justification

Risk: Contaminated or damp additive

Typical cause: Poor storage

Prevention: Closed packaging and defined conditions

Action: Quarantine and investigate

8. Raw-material storage

- Clearly separate **quarantine / accepted / rejected** status.
- Protect sensitive oils from heat, light and oxygen according to **specification**s.
- Keep alkalis in compatible, closed, identified containers protected from moisture.
- Never allow anonymous secondary containers; identify every transfer container.
- Use appropriate stock rotation, such as FEFO where shelf life is relevant.
- Define cleaning, pest-**control** and contamination-**prevention** arrangements.

> **Classic organisational failure:** a good material loses its identity after opening or transfer. From that point onward, the problem is one of traceability as well as **formulation**.

9. Formulation and alkali calculation

Before weighing, the recipe should be an identified, approved version. A formula copied from an old notebook, message or screenshot without version **control** creates avoidable risk.

Failure: Wrong SAP value or wrong NaOH/KOH basis

Consequence: Incorrect alkali quantity

Prevention / detection: Controlled database; independent recalculation for every new formula

Failure: Gram / kilogram / ounce confusion

Consequence: Potentially massive error

Prevention / detection: Fixed unit on batch record; balance setting; cross-check

Failure: Percentages do not total 100%

Consequence: Incoherent formula

Prevention / detection: Automatic or independent sum check

Failure: Alkali purity ignored

Consequence: Difference between theoretical and actual quantity

Prevention / detection: Documented purity parameter where relevant

Failure: Superfat misunderstood

Consequence: Final composition differs from intention

Prevention / detection: Clearly defined calculation method

Failure: Oil changed without recalculation

Consequence: Alkali demand and soap profile change

Prevention / detection: Every substitution triggers formula review

10. Weighing and batch preparation

- Identify each material **before weighing** it.
- Verify balance capacity, resolution and status; use an appropriate metrological **control** procedure.
- Tare **before** each **weighing** and record the quantity actually weighed.
- For low-dose ingredients, use a balance with adequate resolution.
- Limit interruptions: calls, visitors and task switching increase omission/double-addition risk.
- Provide an 'added / checked' **field** on the batch record.

> **High-value barrier:** reserve independent double-checking for critical steps such as alkali identity, calculations, alkali **weighing** and restricted fragrance levels.

11. Preparing the alkaline solution

This step combines product risk and operator risk. The SDS, PPE, ventilation and local safety procedures remain essential.

Failure: Water/liquid misweighed

Possible consequence: Wrong concentration and altered process behaviour

Prevention / action: Separate weighing; batch record; check before mixing

Failure: Alkali misweighed

Possible consequence: Potentially non-conforming product

Prevention / action: Double-check; stop and restart if actual quantity is uncertain

Failure: Unsuitable vessel

Possible consequence: Deformation, breakage, reaction or accident

Prevention / action: Dedicated compatible equipment under procedure/SDS

Failure: Solution not identified

Possible consequence: Mix-up between batches/concentrations

Prevention / action: Immediate label: batch, concentration/recipe, date, operator

Failure: Solution lost by splashing

Possible consequence: Actual quantity unknown

Prevention / action: Secure process; if significant unquantified loss occurs, do not proceed as though nothing happened

Failure: Unsafe dilution practice

Possible consequence: Heat generation / splashing

Prevention / action: Strictly follow the approved dissolution procedure and safety instructions

12. Mixing, emulsion, trace and saponification

Failure: Unsuitable process temperature

Signs / consequences: False trace, separation, acceleration

Control: Defined range for formula; record useful temperatures

Failure: Insufficient emulsion

Signs / consequences: Later separation

Control: Documented process criteria; observe before critical additions

Failure: Fragrance acceleration not anticipated

Signs / consequences: Seizing / incomplete filling

Control: Prior trials; adapted order of addition and temperature

Failure: Ingredient omitted

Signs / consequences: Formula differs from dossier

Control: Addition checklist; reconcile remaining quantities

Failure: Overheating

Signs / consequences: Cracks, overflow, altered additives

Control: Control insulation/temperature/mould; monitor

Failure: Cross-contamination

Signs / consequences: Colour, fragrance, allergen or foreign matter

Control: Validated cleaning and organised production campaigns

13. Moulding, unmoulding and cutting

- Identify the mould or rack with the **batch number** as soon as it is filled.
- **Prevent** unidentified soap from being moved into a shared area.
- Define unmoulding and cutting criteria to reduce deformation, breakage and mass variability.
- Use clean, suitable equipment; inspect wires, blades, moulds and surfaces.
- Record significant losses or anomalies to support batch reconciliation.

14. Curing: a production stage in its own right

Curing is not merely waiting time. Treat it as a **control**led process **stage**: location, duration, ventilation, humidity, relevant temperature, **identification** and contamination protection.

Failure: Batches mixed

Consequence: Traceability lost

Prevention: Identified racks/trays and physical separation

Failure: Cure shorter than internal standard

Consequence: Product differs from evaluated/expected state

Prevention: Defined minimum duration and calculated release date

Failure: Excess humidity / poor ventilation

Consequence: Uneven drying, surface changes

Prevention: Monitor room conditions where needed

Failure: Excess heat/light

Consequence: Accelerated ageing or oxidation

Prevention: Storage appropriate to materials/product

Failure: Unrecorded movements

Consequence: Uncertainty about status/quantity

Prevention: Controlled location or movement record

> **A batch under cure is not a released batch.** Physical availability must never be confused with authorisation to sell.

15. Finished-product control

Controls should be defined **before** production: what to measure, by which method, on how many units, against which limits, and what to do when results deviate.

Control: Appearance / homogeneity

What it may reveal: Separation, visual defect, foreign matter, major variation

Limitation: Does not by itself establish chemical safety

Control: Odour

What it may reveal: Oxidation, wrong fragrance, obvious contamination

Limitation: Subjective; requires reference and training

Control: Mass

What it may reveal: Cutting/drying/packing variability

Limitation: Interpret under applicable metrology rules

Control: Dimensions / internal hardness

What it may reveal: Process consistency

Limitation: Internal method must be standardised

Control: pH

What it may reveal: Can help characterise the product when method is defined

Limitation: Does not by itself prove absence of excess alkali or overall conformity

Control: Specific analyses

What it may reveal: Can address a defined risk

Limitation: Must be reliable, suitable and interpreted against specifications

> For cosmetics placed on the EU market, Regulation (EC) No 1223/2009 requires sampling and analysis to be performed in a reliable and reproducible manner. Product safety therefore cannot be reduced to one isolated craft test.

16. Batch-release decision

Release should be an identifiable decision made after review of the required evidence: complete batch record, acceptable **control**s, assessed deviations and appropriate regulatory status.

- **Released:** the batch meets defined criteria.
- **Quarantine:** information is missing or a deviation remains under assessment.
- **Rejected:** the batch does not meet criteria and cannot be **release**d.
- **Reprocessing:** only where a justified, **control**led and legally acceptable procedure permits it; never use reprocessing to conceal an error.

17. Packaging and labelling

Failure: Wrong label on correct soap

Risk: Incorrect information / broken traceability

Recommended barrier: Batch-label reconciliation before start + in-process check

Failure: Obsolete ingredient list

Risk: Information non-conformity

Recommended barrier: Label linked to approved formula version

Failure: Missing/illegible batch number

Risk: Traceability and recall impaired

Recommended barrier: Legibility/permanence check

Failure: Unsupported claim

Risk: Regulatory / misleading-information risk

Recommended barrier: Pre-approval of claims and supporting evidence

Failure: Unsuitable packaging

Risk: Deterioration, moisture, odour or contamination

Recommended barrier: Compatibility and representative storage testing

Failure: Incorrect declared quantity

Risk: Commercial/metrology non-conformity

Recommended barrier: Appropriate quantity-control procedure

> For cosmetic products marketed in the European Union, labelling is governed in particular by Article 19 of Regulation (EC) No 1223/2009. Exact requirements depend on the product and situation; this **guide** does not replace a regulatory review.

18. Finished-product storage and dispatch

- Physically separate **unreleased** stock from saleable stock.
- Define **storage** conditions consistent with product stability.
- Preserve batch identity during order preparation.
- Record professional recipients where regulatory traceability requires it.
- Protect against moisture, heat, contamination, crushing and reference mix-ups.
- Use stock rotation consistent with the defined product life.

19. Placing on the market: documentary risk is real risk

A soap may be physically successful and still not be ready for sale. Requirements depend on the country and legal product category.

Example: European Union cosmetics framework

- A cosmetic product placed on the market must be safe under normal or reasonably foreseeable conditions of use.
- A **Responsible Person** must be designated.
- **Manufacture** must comply with Good Manufacturing Practice.
- A safety assessment and Cosmetic Product Safety Report are required **before** placing on the market.
- A **Product Information File (PIF)** must be maintained and retained as required.
- Prior electronic notification is required under the Regulation.
- Labelling and claims must comply with applicable requirements.

> **These** points are EU examples. For Madagascar, Brazil, the United States or any other market, verify the local framework and the exact legal category of the product.

20. Customer complaints: turn a signal into quality information

Stage	Question to document
Receipt	Who reports what, when, for which product and batch?
Triage	Is there a potential health risk or major non-conformity?
Investigation	Other complaints? What do batch records, materials, controls and retained samples show?
Decision	Customer information, monitoring, stock block, withdrawal or recall?
CAPA	What root cause and what corrective/preventive action?
Closure	Who approves the conclusion and what evidence is retained?

21. Withdrawal and recall: prepare before you need them

A small soap business should quickly answer three questions: **which batch? where is it? who received it?** A pre-written withdrawal/recall procedure reduces delay during an incident.

- Define who **decide**s and who contacts authorities when required.
- Rapidly identify quantities produced, in stock, sold and distributed.
- Immediately block remaining stock from the affected batch.
- Trace communications and returns.
- Assess whether other batches/products share the same cause.
- Document closure and corrective **action**s.

> Under the EU cosmetics framework, when a **Responsible Person** considers that a cosmetic product placed on the market is not compliant, corrective measures may include withdrawal or recall; where the product presents a risk to human health, competent authorities must also be informed as required.

22. Overall risk matrix - example

Stage	Failure	S	P	D	RPN	Priority action
Receipt	Oil misidentified	4	2	4	32	Quarantine + identity/documents
Storage	NaOH absorbs moisture	4	3	3	36	Airtight container + opening control
Calculation	Wrong SAP basis	5	2	4	40	Independent recalculation
Weighing	NaOH mass error	5	2	3	30	Critical double-check
Manufacture	Fragrance/additive omitted	2-4	2	2	8-16	Addition checklist
Curing	Batches mixed	4	2	4	32	Physical identification
Labelling	Wrong label	4	2	3	24	Reconciliation + cross-check
Sale	Unreleased batch dispatched	5	1	4	20	Physical/digital status block

Note: these scores are educational examples. Each organisation must score its own situations according to equipment, volumes, procedures, incident history and regulatory requirements.

23. Practical form - raw-material receipt

Field	To complete
Date / supplier	....
Material / reference	....
Supplier batch	....
Quantity received	....
Packaging intact?	Yes / No - observations: ....
Label matches order?	Yes / No
Documents received / version	....
Checks performed	Appearance / odour / other: ....
Status	QUARANTINE / ACCEPTED / REJECTED
Decision by / date	....

24. Practical form - non-conformity

Field	To complete
Non-conformity No.	.....
Product / material / batch	.....
Factual description	....
Detected at	Receipt / manufacture / control / customer / other
Immediate action	Block / quarantine / stop / other: .....
Risk assessment	S = ... P = ... D = ... RPN = ...
Root cause	....
Decision	Justified acceptance / rejection / other

Field	To complete
	documented decision
Corrective action	....
Effectiveness check	....

25. Checklist before batch release

Control point	OK / N.A. / deviation
Correct formula and version	.....
All materials and batches traceable	.....
Weighings and critical steps recorded	.....
Manufacturing deviations documented and assessed	.....
Required cure duration/conditions achieved	.....
Finished-product controls acceptable	.....
Packaging compliant	.....
Label exactly matches product/version	.....
Batch number present and legible	.....
Required regulatory dossier available/up to date	.....
Quantities acceptably reconciled	.....
Final release decision signed/dated	.....

26. Twelve high-value barriers

- A **version-controlled formula** never changed verbally.
- A genuinely enforced **quarantine** status/area.
- Immediate **identification** of every secondary container.
- A balance suitable for each **weighing** range.
- Targeted double-checking of alkali and critical ingredients.
- A batch record completed at the time of the **action**, not reconstructed later.
- A **batch number** physically attached to the product throughout processing.
- A written non-conformity procedure.
- Clear separation between **curing** product and **release**d product.
- Label-product-batch reconciliation **before packaging**.
- A tested complaint and withdrawal/recall procedure.
- A culture in which an operator can stop the process when in doubt.

> **The best procedure is the one that prevents the error, or makes it visible before it becomes a product sold to a customer.**

27. Training approach: risk-analysis exercise

For training, select one real process step and ask the group to answer **these** questions in sequence:

- What can go wrong?
- Why could it happen?
- What would be the **consequence** for the user, product, compliance and traceability?
- How can it be **prevent**ed?
- If it happens anyway, how can it be **detect**ed?
- Who has authority to block the batch?
- What documentary evidence will remain?
- What should be changed to **prevent** recurrence?

> The purpose is not to create the longest possible table. It is to identify the few **failure**s that justify robust barriers and make those barriers practical in everyday work.

28. Summary: from supplier to customer

A **control**led soapmaking operation is not one in which no error ever occurs. It is an organisation able to **prevent foreseeable errors, detect deviations quickly, stop a doubtful batch from progressing, decide from evidence and learn from each non-conformity**.

Risk analysis connects **formulation** with business reality: suppliers, stock, people, equipment, documents, **manufacture**, **control**, regulation and customers. It turns quality into a system rather than a final inspection.

> **Receipt → identification → storage → formulation → weighing → manufacture → curing → control → release → packaging** → sale → **monitoring.**
>
> At every arrow, ask: **“What could make this product different from what we believe we are making, and what barrier will prevent that difference from reaching the customer?”**

29. References and reading framework

ISO 22716:2007 - Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices. Provides guidelines for production, **control**, **storage** and shipment of cosmetic products. ISO reports that the standard was last reviewed and confirmed in 2022 and remains current at the date of this version.

Regulation (EC) No 1223/2009 on cosmetic products. Relevant provisions include **Responsible Person** obligations and corrective measures, supply-chain **identification**, GMP, safety assessment, Product Information File, reliable/reproducible sampling and analysis, notification and labelling. The applicable consolidated text should always be checked for the target market and date.

FMEA principles. Used here as an educational method for ranking potential **failure**s. The S × P × D scoring system and thresholds in this document are Apisara internal teaching conventions, not universal legal requirements.

Note on HACCP. The logic of hazard-**prevention**-monitoring-corrective **action** is educationally useful, but cosmetic soap is not, merely by being soap, subject to a food HACCP plan. This **guide** must not be presented as a certified HACCP plan.

DISCLAIMER

> This **guide** is an educational resource. It does not replace laboratory analysis, an SDS, supplier **specification**s, a cosmetic safety assessment, GMP certification, legal or regulatory advice, or the obligations applicable to the product and country concerned.

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