

Label & Claims Review before print

Product	Radiance Serum Niacinamide 10% · 30 ml
Brand	Atelier Nuée
Target market	France, then Belgium and Germany
Documents received	Carton + bottle artwork v3 (PDF), INCI list, perfumer's allergen declaration, IFRA certificate, list of planned claims
Reference	BF-REV-ETQ-0412
Reviewed by	Justine Teruel, formulator and regulatory consultant

Conclusion : Do not print as is. The label can go to print once the 3 blocking points below are fixed. The 4 'to fix' points must be handled before the product goes on sale.

3

blocking

4

to fix

2

to watch

11

compliant points

Blocking: prevents market placement or exposes to withdrawal. To fix: non-compliance to solve before sale. To watch: low risk or to document.

1. Findings and fixes

#	Item	Finding	Reference	Priority	Proposed fix
1	Carton claim	'Hypoallergenic' while the formula contains a fragrance with declarable Linalool and Limonene.	Reg. 655/2013; Commission technical document on claims (Annex III)	Blocking	Remove the claim. Possible alternative if a tolerance test exists: 'Tested under dermatological control'.
2	Responsible person	Only an email address appears on the back of the carton. No postal address.	Reg. 1223/2009, Art. 19(1)(a)	Blocking	Add the responsible person's name and full postal address (carton and bottle).
3	Fragrance allergens	Linalool (0.0021% in the finished product per the perfumer's declaration) missing from the INCI list.	Reg. 1223/2009, Annex III; 0.001% threshold for leave-on products	Blocking	Add 'Linalool' at the end of the INCI list, after 'Parfum'.
4	Efficacy claim	'Erases dark spots in 7 days': no study supplied, and 'erases' promises a total result.	Reg. 655/2013, evidential support and honesty criteria	To fix	'Helps reduce the appearance of dark spots'; keep 'in 7 days' only if a study shows it.
5	'Free from' claim	'Free from endocrine disruptors': denigrating claim, not accepted.	Commission technical document, fairness criterion	To fix	Remove. Highlight what the product contains rather than what it does not.
6	PAO	Open-jar symbol missing from the carton; shelf life above 30 months.	Reg. 1223/2009, Art. 19(1)(c)	To fix	Add the PAO symbol '6M' (duration to be confirmed by the in-use test).
7	Batch number	No area left for the batch number on the bottle.	Reg. 1223/2009, Art. 19(1)(e)	To fix	Keep a blank 25 × 8 mm area under the barcode for batch coding.
8	Languages	Label in French only; sales planned in Belgium and Germany.	Reg. 1223/2009, Art. 19(5) (language set by each State)	To watch	Provide FR / NL / DE for mandatory particulars, or one carton per country.
9	'Vegan'	Acceptable claim, but no supporting document received.	Reg. 655/2013, evidential support	To watch	Keep supplier statements (no animal-derived ingredient) in the PIF.

2. Claims: before / proposed

Before	Proposed	Why
Hypoallergenic	Tested under dermatological control	The fragrance contains declarable allergens: 'hypoallergenic' cannot be substantiated.
Erases dark spots in 7 days	Helps reduce the appearance of dark spots	Total result not shown; efficacy must be proven by a suitable study.
Free from endocrine disruptors	(removed)	Denigrates other products, not accepted.
Clean beauty	Short formula: 12 ingredients	'Clean' has no definition; a verifiable fact is stronger.

3. Mandatory particulars, face by face

Particular (Art. 19)	Carton	Bottle
Product name and function	Compliant	Compliant
Responsible person (name + address)	Blocking	Blocking
Nominal content (30 ml, e symbol)	Compliant	Compliant
PAO or date of minimum durability	To fix	Compliant
Precautions for use	Compliant	—
Batch number	—	To fix
Ingredient list (INCI)	Blocking	—

‘—’: not required on this face or moved to the carton, as Art. 19 allows when the bottle is too small.

4. INCI list checked

Aqua, Niacinamide, Glycerin, Propanediol, Pentylene Glycol, Sodium Hyaluronate, Panthenol, Xanthan Gum, Phenoxyethanol, Ethylhexylglycerin, Parfum, Limonene, **Linalool (to add)**

- Descending order respected above 1%.
- INCI names match the common glossary.
- Phenoxyethanol 0.9%: compliant (Annex V, 1% limit).
- Niacinamide 10%: no restriction; a 'may cause tingling' precaution is advised but not mandatory.

5. Action plan

1. Before print: fix points 1, 2 and 3 (claim, address, Linalool).
2. Before sale: points 4 to 7, then send the final artwork to the safety assessor for the CPSR.
3. Before Belgium and Germany: translate the mandatory particulars (point 8).
4. In the PIF: evidence for the 'vegan' claim and the tolerance test.

Already compliant

Content and e symbol, product name, function, precautions for use, INCI order and names, preservative level, carton/bottle consistency, legibility, 'short formula' claim, no medicinal claim, origin statement.

Scope of the review

This review covers the label and claims based on the documents received. It does not replace the safety assessment (CPSR), carried out and signed by a qualified assessor, nor the CPNP notification. One round of questions is included within 15 days of delivery.

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